April, 2025

WERABE UNIVERSITY

RESEARCH PUBLICATION ETHICS AND DISSEMINATION DIRECTORATE

Institutional Research Ethics Review Committee (IRERC)

Standard Operating Procedure (SOP)

Version 01

Contact address
Werabe University
Werabe, Ethiopia
Email: RPEDD@wru.edu.et
Website: https://www.wru.edu.et/

Number of copies printed	01
Title of the SOP	Werabe University Institutional Research Ethics Review Committee Standard Operating Procedure (SOP)
Version No	01
Month/Year of Publication	April, 2025
Author/s	Musa Jemal (MSc in Human Nutrition) Seyfedin Luncha (MSc in Journalism and Communication) Ahmed Hussein (MSc in Animal Production) Matewos Kebede (PhD)
Editors	Dr. Eng., Towfik Jemal (PhD, Associate Professor, Werabe University President**)** Assistant Professor Anwar Ahmed (VPARTTCS)
Reviewers	Hassen Mosa (MSc in maternity Health Nursing) Abdurehman Usman (PhD candidate)

Preamble

Scientific inquiry constitutes a foundational pillar of societal advancement and human development. It is a collective, rigorous, and methodologically diverse endeavor dedicated to the generation, validation, and dissemination of knowledge through systematic observation, critical reflection, empirical investigation, and theoretical interpretation.

Irrespective of the methodological specifics of particular scientific disciplines or organizational conditions under which researches are conducted, science can progress through the researchers' commitment to ethical ideals and values, such as respect for human dignity, freedom, equality, honesty, truthfulness, and integrity.

Maintaining the integrity and credibility of research is the responsibility of all actors involved in research. These responsibilities rest not solely upon individual researchers, but extend to all entities engaged in the research ecosystem: academic institutions, funding bodies, regulatory authorities, publishers, and broader stakeholder communities.

At the core of Werabe University's scholarly mission lies an unwavering dedication to the principles of academic freedom and ethical responsibility. In pursuit of research excellence, the University affirms its institutional commitment to nurture the culture of honesty and transparency in all its institutional research activities. In an effort to maintain ethics in all types of research, WRU has developed and endorsed this Standard Operating Procedure (SOP) that governs the ethical review of research conducted in the fields of Human Health, Agriculture, Environment, Technology, Social Sciences, and other disciplines.

This document articulates the ethical principles, institutional expectations, and procedural standards that shall govern the planning, execution, and review of research activities at Werabe University, in alignment with both national regulatory frameworks and globally recognized norms of responsible research conduct.

Dr. Eng., Towfik Jemal (PhD, Associate Professor)
President of Werabe University
Chairperson of the University Senate

Background

Research is conducted for the benefit and welfare of the society. Health, environment, animal, plant and engineering research draw the attention of scientists and should be conducted according to research ethics principles (1). Although scientific and social value are the fundamental justification for undertaking research, researchers, sponsors, research ethics committees and health authorities have a moral obligation to ensure that all research is carried out in ways that uphold human rights, and respect, protect, and are fair to study participants and the communities in which the research is conducted (2).

In this rapidly advancing, complex, and sophisticated era of genetic studies, preventive, diagnostic, and therapeutic clinical trials, as well as collaborative research and human biological material transfer being commonplace, oversight and regulation is imperative to properly safeguard the rights, safety and welfare of human research subjects (1).

Institutional Research Ethical Review Committees (IRERCs), an independent committees established in an institution to conduct initial and continuing review of research projects, are part of efforts made to minimize or eliminate research wrongdoings while improving research quality, robust scientific research methodology, active engagement and respect for research participants and their communities as well as enhancing the protection of research subjects.

Werabe University (WRU) has been granting as well as reviewing ethical aspects of researches. In order to ensure researches are conducted in accordance with different ethical standards and for the benefit as well as welfare of its community, WRU had organized a committee to review researches ethical issues independently of the technical check. So far the committee is providing an incredible contribution for ethical assurance and giving clearance letter for requesting researchers.

Rationale

To regulate and provide oversight for research ethics, considering its increasing landscape, complexity, and SOP, the Ministry of Education in December 2021 finalized the comprehensive research ethics guideline that addresses the Animal, Plant, Environment and Engineering fields in addition to the human health ethics fields. The Health Science and Technology Policy in article 4.3.5 stresses the

need to "Organize an ethical committee to review the ethical aspects and procedures of research undertakings as required" as one strategy. In addition, article 4.3.6 emphasizes the need to ―encourage institutional peer review.

The updated MoEs National Research Ethics Review Technical Guideline also mandates that all "IRERC in Ethiopia have to be registered by the Secretariat, and the registration shall be issued when they provide list of trained professionals (IRERC members) along with standard operating procedures (SOPs)". Hence, as per the updated guideline registration of the IRERC, it is found important to authorize the members as well as the permits they provide. Therefore the current Standard Operating Procedure (SOP) aims to close this gap by providing a process guide for organizational and technical flows. Additionally, it will help to refine and continuously monitor capacities, and activities of Werabe University Institutional Research Ethics Review Committee (WRU-IRERC).

Organization of the SOP

There are a total of 28 separate SOPs generally classified into six parts specifically: i) Preparation and amendment procedures of the SOP; ii) IRERC constituting procedures: iii) Technical process showing application up to decision; iv) Communication and documentation process of the IRERC activities v) Monitoring and inspection parts. Each SOPs has their own purposes, scope responsibility, work flows, detailed instruction, glossary, annexes, references, and working forms.

Master table of contents

Master List of Forms

Table of Contents

1. PURPOSE

This Standard Operating Procedure (SOP) defines the process for writing, reviewing, distributing and amending SOPs within the Institutional Research Ethics Review Committee (IRERC) of Werabe University (WRU).

The SOPs will provide clear, unambiguous instructions so that the related activities in the ethics review committee are conducted in accordance with the national and international ethical operating guidelines for IRERC that review researches.

2. SCOPE

This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the scope WRU-IRERC and SOP team of Werabe University.

3. RESPONSIBILITY

3.1 Chairperson of IRERC

It is the responsibility of the Chairperson of IRERC to Review, approve the SOPs, appoint the SOP Team to formulate the SOPs by following the same procedures, format, and coding system when drafting or editing any SOP of the WRU. Moreover, the chairperson is responsible to signs and dates receipt of the approved SOPs.

3.2 Secretariat of IRERC:

- Co-ordinates activities of writing, reviewing, distributing and amending SOPs
- Maintains on file all current SOPs and the list of SOP
- Maintains an up-to-date distribution list for each SOP distributed
- Distributes the SOPs with a receipt to all users
- Ensures all ethics review committee members and involved administrative staff have access to the SOPs
- Ensures the ethics review committee member and involved staff are working according to current versions of SOPs

3.3 SOP team:

- Proposes required SOPs
- Selects the format and coding system
- Drafts the SOP in consultation with IRERC members and involved administrative staff
- Assesses the request for SOP revision in consultation with the Secretariat and Chairperson

3.4 IRERC members and involved administrative staff:

- Sign and date when they receive the approved SOPs
- Maintain a file of all SOPs received
- Return all out-of-date SOPs to SOP Administrator

4. FLOW CHART

No.	Activity	Responsibility
1	List all relevant SOPs	SOP Team
	↓	
2	Design a format and layout	SOP Team
	↓	
3	Write and approve a new/revised SOP	SOP Team and Chair person
	↓	
4	Implement, distribute and file all SOPs	Secretariat
	↓	
5	Review and revise of existing SOP	SOP Team / IRERC members/ administrative staff/chair person
	↓	
6	Manage and archive superseded SOPs	Office Assistant

5. DETAILED INSTRUCTIONS

5.1. List all relevant SOPs

- Write down step by step all IRERC procedures.

- Organize, divide and name each process.
- Make a list of SOPs with coding reference, effective and expiry dates.(Annex AF 01-001/01.0)

5.2. Format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format SOP/XXX/YY.W will be assigned to each SOP item by *Secretariat.* XXX is a three-digit number assigned specifically to the SOP. YY is a two-digit number identifying the version of the SOP, and W is a one digit number identifying the version of SOP with minor changes in the SOP. The number of version should be started from 01 and the W should be started with 0, for example, SOP001/01.1 is the SOP number 001 version 01 with one minor revision i.e. 01.1.

Each annex will be given unique code number with the format AF/BB-XXX/YY.W. AF is the abbreviation for Annex Form. BB is a two-digit number identifying the number of the annex, for example AF/01-001/01.0 means Annex Form number one of the SOP/001/01.0 Each SOP will be prepared according to the standard template. Please refer to Annex 2 –AF 02/-001/01.0

5.3. Write and approve a new/revised SOP

- If an SOP supersedes a previous version, indicate the previous SOP version and the main changes in the historical form (Annex 3 –AF/ 03-001/01.0).
- When the need for a new SOP has been identified and agreed on, a draft will be written by a designated member of the SOP team.
- The draft SOP will be discussed with IRERC members and all relevant administrative staff. The SOP should be agreed upon by the people involved in that particular task. The final version will be passed to the Chairperson for review and approval.

5.4. Implement, distribute and file all SOPs

- The approved SOPs will be implemented from the effective date.
- The approved SOPs will be distributed to the IRERC members and the relevant staff by the Secretariat according to the distribution list. (Annex 4 – AF 04-001/01.0).
- When revised version is distributed, the old version will be retrieved and destroyed.

- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the secretariat of the ethics committee and keep the file in the IRERC *office.*

5.5. Review and revise an existing SOP

- Any member of the ethics committee, secretariat or administrative staff who notices an in-consistency between two SOPs or has any suggestions on how to improve a procedure should use the form in Annex 5 – AF 005-001/01.0) to make a request.
- If the SOP Team agrees with the request, an appropriate team will be designated to proceed with the revision process. If the committee does not agree, the Chairperson will inform the person who made the request of the decision.
- Revision of the SOPs will be reviewed and approved in the same manner as new SOPs (section 5.3).
- The Secretariat is expected to review the SOPs at least every 2 years and record the dates of review on the SOP Master file.

5.6. Manage and archive superseded SOPs

- Superseded SOPs should be retained and clearly marked "superseded" and archived in the historical file by the secretariat**.**

6. GLOSSARY

Standard Operating Procedure (SOP)	Detailed, written instructions, in a certain format, describe all activities and action undertaken by an organization to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice.
IRERC members	Individuals serving as regular and alternate members on the institute's operation (i.e., IRERC membership). These Committee members are constituted in accordance with the IRERC membership requirements set forth in national and international ethical standards.

SOP Team	A selected committee of the institute members and administrative staff who oversee the creation, preparation, review and periodic revision of the university SOPs.
Master SOP files	An official collection of the institute SOP accessible to all staff, IRERC members, auditors and government inspectors as a paper copy with an official stamp on each page and the approval signatures. Photocopies made from these official paper versions of the SOP cannot be considered current or official.
SOP historical files	A collection of previous official versions of a SOP, table of contents, relevant information regarding changes and all preplanned deviations.

7. ANNEXES

ANNEX 1	AF 01-001/01.0	List of WRU SOPs
ANNEX 2	AF 02-001/01.0	Standard Operating Procedures Template
ANNEX 3	AF 03-001/01.0	Document History
ANNEX 4	AF 04-001/01.0	Log of SOP Recipients
ANNEX 5	AF 05-001/01.0	Request for Revision of an SOP

8. REFERENCES

1. WHO Operational Guidelines for Ethical Review Committee That Review Biomedical Research (Geneva 2000 www.who.int/tdr/publications/publications/ - accessed 11 February 2005)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

AF 01-001/01.0

No.	List of SOPs.	Code	Version	Effective date
1	Preparation of Standard Operating Procedures	WRU 001	01.0	15 April 2025
2	Preparation of Guidelines	WRU 002	01.0	15 April 2025
3	Constituting an IRERC	WRU 003	01.0	15 April 2025
4	Confidentiality / Conflict of Interest Agree-ments	WRU 004	01.0	15 April 2025
5	Training Personnel and IRERC Members	WRU 005	01.0	15 April 2025
6	Selection of Independent Consultants	WRU 006	01.0	15 April 2025
7	Management of Protocol Submission	WRU 007	01.0	15 April 2025
8	Use of Study Assessment Form	WRU 008	01.0	15 April 2025
9	Expedited Review	WRU 009	01.0	15 April 2025
10	Initial Review of Application Protocol	WRU 010	01.0	15 April 2025
11	Review of Resubmitted Protocol	WRU 011	01.0	15 April 2025
12	Review of Protocol Amendments	WRU 012	01.0	15 April 2025
13	Continuing Review of Study Protocol	WRU 013	01.0	15 April 2025
14	Review of Protocol Termination	WRU 014	01.0	15 April 2025

ANNEX 1

AF 01-001/01.0

No.	List of Sops.	Code	Version	Effective date
15	Review of Final Reports	WRU 015	01.0	15 April 2025
16	Emergency Meeting	WRU 016	01.0	15 April 2025
17	Response to Participants' Requests	WRU 017	01.0	15 April 2025
18	Monitoring and Evaluation of Serious Adverse Events (SAE) Reports	WRU 018	01.0	15 April 2025
19	Communication Records	WRU 019	01.0	5 January 2021
20	Site Monitoring Visit	WRU 020	01.0	5 January 2021
21	Non-Compliance/Violation Intervention	WRU 021	01.0	5 January 2021
22	Maintenance of Active Study Files	WRU 022	01.0	5 January 2021
23	Archive and Retrieval of Documents	WRU 023	01.0	5 January 2021
24	Maintaining Confidentiality of IRERC's Documents	WRU 024	01.0	5 January 2021
26	Audit and Inspection of the IRERC	WRU 026	01.0	5 January 2021
27	Glossary of Terms and Definition	WRU 027	01.0	5 January 2021
28	Preparation of Meeting, Agenda, Minutes and Action letters	WRU 028	01.0	5 January 2021
29	Review of New Medical Device Studies	WRU 029	01.0	5 January 2021

ANNEX 2

AF 02-001/01.0

Standard Operating Procedures Template

Name of Institution	
Title: *Title which is self-explanatory and is easily understood*	
SOP No: IRERC /00? /0?	Page: ? of ?

TITLE *Title which is self-explanatory and is easily understood*

Effective Date: Supersedes: Author: Date:……. *(Name).* Approved by: Date *(name)*

Table of contents

ANNEXES:

Main Text:

1. **PURPOSE** - summarizes and explains the objectives of the procedure.
2. **SCOPE** – states the range of activities that the SOP applies to.
3. **RESPONSIBILITY** – refers to person(s) assigned to perform the activities involved in the SOP
4. **FLOW CHART** – simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity
5. **DETAILED INSTRUCTIONS** – describe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.
6. **GLOSSARY** – clarifies uncommon or ambiguous words or phases by explanation.
7. **ANNEX** - documents that explain further or clarifies complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.
8. **REFERENCE** – lists sources of the information given in the SOP.

Annex 3

AF 03-001/01.0

Document History

The first draft 001 of the SOP History should be produced as the output of the first circulation of the document and the final version is the version after the approval by the Chairperson)

Author –	**Version**	**Date**	**Describe the main change**
name	01.1	*dd-Mmm-yy*	first draft
Name	01.2	*dd-Mmm-yy*	Second draft
name	01.3	*dd-Mmm-yy*	Third draft
name	01.X	*dd-Mmm-yy*	Final draft

Annex 4

AF 04-001/01.0

Log of SOP Recipients

No.	Name of Recipients	SOP#	No. of Copies	Signature	Date
1	Chairperson	SOP/001/01.0 SOP/002/01.0 SOP/003/01.0			
2	Member X	>>			

Annex 5

AF 05-001/01.0

Request for Revision of an SOP

Please complete this form whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP Code number:		
Title:		
Details of problems or deficiency in the SOP:		
Identified by:	Date (D/M/Y):	
Discussed with:		
SOP revision required:	☐ Yes	☐ No
If yes, to be carried out by whom?		
If no, why not?		
Date SOP re-finalized:		
Date SOP approved:		
Date SOP becomes effective:		

Table of Contents

1. PURPOSE

This procedure describes how to prepare a new guideline or update an existing one as well as the layout and format of each guideline.

2. SCOPE

This SOP applies to any IRERC guidelines and their amendment versions published and distributed by the WRU.

The IRERC of the WRU works according to internal rules that must be described in written SOPs. The SOPs are *confidential* but may be disclosed to authorities upon request. However, in order to maintain a transparent relationship with non-members of the IRERC, certain procedures will form guidelines for use by investigators, scientific experts and by the Institute personnel.

3. RESPONSIBILITY

It is the responsibility of the IRERC Secretariat or designated persons from the IRERC members to prepare or amend the guidelines as and when the need arises. The designated persons will manage the preparation/amendment of the guidelines with the assistance of the Secretariat/ Chairperson.

4. FLOW CHART

No.	Activity	Responsibility
1	Numbering of Guidelines	SOP Team
	↓	
2	Numbering of the Version	SOP Team
	↓	
3	Contents and Layout of A Guideline	SOP Team
	↓	
4	Approval of New and Updated Guidelines	IRERC Chairperson / Member
	↓	
5	Information for Personnel	IRERC Members / Secretariat
	↓	
6	Distribution of Guidelines	IRERC Secretariat/Chairperson

5. DETAILED INSTRUCTIONS

5.1 Numbering of the Guidelines

- Procedure SOP# IRERC 001 lists all procedures and guidelines used by the IRERC of the WRU.
- When a new guideline will be created, a subsequent number should be allocated at the end of the list of existing Guidelines.
- When a guideline is no longer used, its status is changed to "inactive". It is not allowed to reuse the guideline number of an inactive guideline.
- All guidelines are named and numbered in the following way : IRERC 001 to IRERC 099

5.2 Numbering of the Version

- Number guideline versions as follows:
  - Draft versions:

    *All draft versions are always indicated as "**version 01**" followed by the word "**draft**". For example : **Version 01, draft***

  - For minor changes on a final version: ***Version V.0, final*** to ***Version V.n, final***

    For example, the third update concerning minor issues on "version 02, final" will be indicated as "version 03 final".

  - For major changes on a final version:

    Version V.n, final to ***Version (V+1).0, final***

    For example, major changes on "version 2.3, final" will be indicated as "vision 1.02 final".

5.3 Contents and Layout of a Guideline

A new or updated guideline has four sections:

1. Cover Page
2. Table of Contents
3. Main text

4. References
5. Appendices

Sections 1 to 3 are mandatory. The *"Appendices"* section is not mandatory.

5.3.1 Cover Page

The cover page will have the following information:

- Logo of the IRERC, if any, Organization and related information (address, telephone number, fax number, email address).
- Title and number of the guideline date of implementation of the guideline
- Date of the previous issues. If not applicable, the date of pervious issue is indicated by "N/A" (= not applicable).
- Name (directory names and path included) of the corresponding computer document, if relevant.
- Name of the editors and address of the contact office.
- A copyright declaration.
- Refer to ANNEX (AF 01-205) for an example of a cover page.

5.3.2 Table of Contents

The table of contents lists all major headers and subheadings of the guideline, including the appendices and page numbers on which these appear in the guideline.

5.3.3 Main Text

- Introduction
- Summarize and explain the purpose of the guideline.
  - A short note on how the guideline was prepared.
  - A short note on how to use the guideline.
- Detailed description
  - Long guidelines should be split into shorter ones.

- ❖ Wherever possible and relevant references should be added
- ❖ Limitation of the guidelines may be mentioned

5.3.4 Appendices

- ❖ Replace long and complex descriptions.
- ❖ "Descriptions-by-example" are always recommended to avoid writing difficult and hard to understand texts.
- ❖ Glossary
- ❖ Full form of abbreviations

5.4 Approval of New and Updated Guidelines

- ❖ The IRERC members shall prepare a new guideline or update an existing guideline.
- ❖ The Chairperson of the IRERC and the RPED director should approve each new or updated guideline.
- ❖ The final version is the one to be implemented.

5.5 Information for Personnel

- ❖ All members of the IRERC must read and understand a new or updated guideline.
- ❖ Each member will sign a form indicating that they have read and understood each new or updated guideline.
- ❖ *Refer to ANNEX 2 (FF 02-025) for an example.*
- ❖ If the guideline is for investigators/students/institute personnel then they should be given a copy of the guideline after taking their signature.

5.6. Distribution of Guidelines

- ➢ Guidelines are not confidential and may be disclosed for use by investigators, scientific experts and IRERC members.
  - ❖ A Log of Guideline Distribution should be maintained for inventory records (ANNEX 3, AF 03-025).

6. GLOSSARY

Guideline	Any suggestion, rules, etc., intended as a guide for specific practice

7. ANNEXES

ANNEX 1	AF 01-002/01.	Cover page of a Guideline (2 pages)
ANNEX 2	AF 02-002/01.0	List of Signatures
ANNEX 3	AF 03-002/01.0	Log of Guideline Distribution

8. REFERENCES

8.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

8.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

AF 01-002/01.0

Cover page of a Guideline

Guideline for

IRER……
……

Version No…….

Institutional Research Ethics Review committee of Werabe University

Address:

ANNEX 1

AF 01-002/01.0

Information on the Back of the Cover Page

Number of Copies Printed

Title of the Guideline

Version No.

Month/Year of Publication

Author/s:

Editor/s:

ANNEX 2
AF 02-002/01.0

LIST OF SIGNATURES

Title of the Guideline: ……..

Number of the Guideline: GL …….

The following listed persons with their signatures have read this guideline.

No.	Full Name of IRERC members	Signature	Date

ANNEX 3

AF 03-002/01.0

Log of Guideline Distribution

#	Name of Recipients	Affiliation	Guideline#	No. of Copies	Date

Table of Contents

1. PURPOSE

Werabe University Institutional Research Ethics Review Committee (WRU-IRERC) is established on April 2025 E.C in order to provide independent guidance, advice, and decision (in the form of "approval/ IRERC recommendation/stipulation/ disapproval") on research protocols involving human subjects, animal, plant, soil, technologic device and environment. The IRERC is composed of both scientist and non-scientist members. It is independent in its reflection, advice, and decision.

This Standard Operating Procedures (SOP) describe the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of the WRU- IRERC. The TOR is further supported by other SOP's of Werabe University.

2. SCOPE

The SOP applies to all activities under the IRERC of WRU

3. Responsibility

IRERCs should provide independent, competent and timely review of the ethics of proposed studies. In their composition, procedures and decision-making IRERCs need to have independence from political, institutional, professional and market influences. They need similarly to demonstrate competence and efficiency in their work. IRERCs are responsible for carrying out the review of proposed research before the commencement of the research. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision.

IRERCs are responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers and having due regard for the requirements of relevant regulatory agencies and applicable laws.

Generally, it is the responsibility of the IRERC members, secretariat, and chairperson to read, understand and respect the rules set by the IRERC of the WRU.

4. FLOW CHART

No.	Activity	Responsibility
1	Ethical basis / Guidelines	IRERC Members, Secretariat
	↓	
2	Composition of the IRERC	IRERC Members and Secretariat

	↓	
3	Membership Requirements	IRERC Members and Secretariat
	↓	
4	Resignation, Disqualification, Replacement of Members	IRERC Members and Secretariat
	↓	
5	Independent Consultants	IRERC chairperson
	↓	
6	Conditions of Appointment	IRERC Members and Secretariat
	↓	
7	Officers	IRERC Chairperson and Vice-Chairperson
	↓	
8	Secretariat	IRERC Secretary
	↓	
9	Quorum Requirements	IRERC Members and Secretariat
	↓	
10	Dissolving of the IRERC	IRERC Members and Secretariat

5. Detailed Instructions

5.1. Ethical basis

- The IRERC recognizes that the protocols may also be approved by national and/or local ethics committees prior to their implementation in specific localities.
- In evaluating protocols and ethical issues, the IRERC is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.
- The IRERC also seeks to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research it has approved.
- The IRERC is guided in its reflection, advice, and decision by the ethical principles expressed in the *Declaration of Helsinki (1964 and subsequent revisions).*
- It makes further reference to the *Werabe University Institutional Research Ethics Review Guideline, National and International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS), the *Belmont Report*, the European *Convention on Human Rights and Biomedicine, United Nations Social and Environmental standards,*

World Organization for Animal Health (WOAH) standards on animal welfare along with others.

- The IRERC establishes its own standard operating procedures based on the *Operational Guidelines for Ethics Committees that Review Biomedical Research* (WHO), the WHO & ICH Guidelines for Good Clinical Practice (ICH-GCP), other ethical standards in Social sciences, Animal and plant researches, science and technology, and other disciplines, and local regulations.
- The IRERC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations.

5.2. Composition of the IRERC of WRU

- The IRERC is composed of ***at least 5 voting members***
- The members shall include at least one member whose primary concern is in medical sciences, and at least one member from animal science, plant science, social science, and at least a member from community outside the institute.
- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the University.
- Professional qualifications may include medical science (such as physician, epidemiology/public health specialty, pharmacy/paramedic etc.), veterinary medicine, plant sciences, natural sciences, social sciences, law, engineering, and other disciplines.
- The IRERC cannot consist entirely of men or entirely of women.
- The IRERC should have one community representative
- The IRERC should have representatives from the older and younger generations.

5.3. Membership requirements

- The Vice President for Academic Research Technology Transfer and Community Service (VPARTTCS) / Research Publication Ethics and Dissemination Director (RPEDD) of Werabe University is responsible for making the appointment of committee members
- Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IRERC work.
- Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.

- The IRERC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision, refer to SOP# WRU004/01.0 - Confidentiality / Conflict of Interest Agreement.
- Members will be required to sign a confidentiality agreement at the start of their term.
- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IRERC in the course of its work.
- Members are appointed for a period of 3 years
- Their appointments may be renewed by the WRU VPARTTCS or RPEDD for up to two consecutive terms.
- The Ethics Committee will include some rotation after a period of three-year for up to two consecutive terms, but it will also strive to ensure continuity within the IRERC.
- The Chairperson should be selected by the IRERC members through a process of nominations followed by secret ballot voting; the VPARTTCS or RPEDD assign a committee to process this nomination and the committee is obliged to inform the appointing authority (the VPARTTCS or RPEDD).
- Should the Chairperson decide to step down as Chairperson of the IRERC, he/she should inform the Committee in writing at least one month in advance; the committee is obliged to inform the appointing authority.

5.4. Resignation, Disqualification, and Replacement of Members

Membership may be terminated voluntarily. The member should write a resignation letter to the appointing authority through the IRERC Chairperson giving at least a one-month notice.

- The Chairperson may resign by sending his/her resignation letter to the appointing authority after informing the committee at its next meeting.
- Membership should be terminated by the appointing authority on the advice of the IRERC if a member is going to be away for more than one year.
- Membership could be terminated by the appointing authority upon advice of the IRERC if the member has been absent from four consecutive meetings without offering an explanation.
- Whenever a member is absent for three consecutive meetings without valid reasons, the IRERC will be notified of his/her absence and requested for replacement.

- Members may resign their positions by submitting a letter of resignation to the Chairperson.
- Members that have resigned or have been disqualified may be replaced by appointing authorities.
- Membership should be terminated by the appointing authority for misconduct that tarnishes the credibility of the IRERC as determined by the IRERC.
- Membership should be terminated if a member is convicted of a criminal offence.

5.5 Independent Consultants

- The IRERC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.
- Independent Consultants are appointed by the Chairperson of the IRERC.
- Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, social science, law, ethics, religion. Independent Consultants are appointed for the duration of the period sought (see SOP# WRU 006/01.0)

5.6 Conditions of Appointment

- Members and Independent Consultants are appointed to the IRERC under the following conditions:
  - Willingness to publicize his/her full name, profession, and affiliation;
  - All financial accountability, reimbursement for work and expenses, if any, within or related to the IRERC should be IRERC ordered and made available to the public upon request;
  - All IRERC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

5.7 Officers

The following officers through their respective responsibilities contribute to the good functioning of the IRERC:

Chairperson	Responsible to chair the meetings and IRERC with the VPART-TCS or RPEDD, report the meeting outcomes, have the authority to sign official IRERC documents such as approval certificates, and invite independent consultants to provide special expertise to the IRERC on proposed research protocol.
Vice-Chairperson	Responsible to chair the meetings in the absence of the Chairperson and act as vice-chair during meetings with the Chairperson
Secretary	Responsible for the administrative aspect of the IRERC

- The officers are elected by the IRERC members for **three-year terms**. They may be re-elected but not for more than two consecutive terms. Should they resign or be disqualified, the IRERC members elect a replacement until the completion of the normal term.
- Supporting staffs are responsible to office assistance activities

5.8 Secretariat

- The Secretariat is composed of the IRERC secretary and the administrative supporting staff.
- The supporting staffs are staff members of the Werabe University appointed by the University.
- The Secretariat shall have the following functions:
  - Organizing an effective and efficient tracking procedure for each proposal IRERC received (see SOP#WRU/007/01.0, #WRU/023/01.0).
  - Preparation, maintenance and distribution of study files (see SOP#WRU022/01.0)
  - Organizing IRERC meetings regularly (SOP#WRU028/01.0).
  - Preparation and maintenance of meeting agenda and minutes (see SOP# WRU028/01.0)
  - Maintaining the IRERC documentation and Archive (See SOP# WRU010/01.0 and WRU023/01.0)
  - Communicating with the IRERC members and applicants (SOP# WRU019/01.0)

- ❖ Arrangement of training for personnel and IRERC members (see SOP#WRU005/01.0)
- ❖ Organizing the preparation, review, revision and distribution of SOPs and guidelines (see SOP# WRU001/01.0 and WRU025/01.0)
- ❖ Providing the necessary administrative support for IRERC related activities to the Chairperson of the Committee (e.g. communicating a decision to the applicant - SOP# WRU 007/01.0 – WRU 021/01.0)
- ❖ Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

5.9 Roles and responsibilities of IRERC members

- ➢ Participate in the IRERC meeting
- ➢ Review, discuss and consider research proposals submitted for evaluation
- ➢ Monitor serious adverse event reports and IRERC commend appropriate action(s) (SOP# WRU 018/01.0)
- ➢ Review the progress reports and monitor ongoing studies as appropriate
- ➢ Evaluate final reports and outcomes
- ➢ Maintain confidentiality of the documents and deliberations of IRERC meetings (SOP# WRU 024/01.0)
- ➢ Declare any conflict of interest
- ➢ Participate in continuing education activities in biomedical ethics and biomedical research

5.10 Quorum Requirements

- ➢ A minimum of 50% plus one of the members must be present at a meeting in order to issue a valid advice and/or decision.

5.11 Dissolving of the IRERC

- ➢ At any point in time, should the Werabe University cease to exist, the IRERC is automatically dissolved.

- The IRERC may also be dissolved at any time by the VPARTTCS or RPEDD following written notification to each of the members.

6. GLOSSARY

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IRERC's information and documents
IRERC	Institutional Research Ethics Review Committee (IRERC) is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.
Scientists	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed

7. ANNEXES

8. REFERENCES

8.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

8.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

TABLE OF CONTENTS

1. PURPOSE

The purpose of this section is to provide a form of Confidentiality / Conflict of Interest Agreement and identify who should read, understand, accept, keep in mind, sign and date the form. The procedures provide details when and where to sign as well as how the signed document should be kept.

2. SCOPE

This SOP covers the Agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the Institutional Research Ethics Review Committee (IRERC).

3. RESPONSIBILITY

It is the responsibility of all newly-appointed IRERC members to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning their ethical review tasks with the IRERC Chairperson to protect the rights of study participants.

4. FLOW CHART

No.	Activity	Responsibility
1	Read the text carefully and thoroughly	IRERC members / guest attendees
	↓	
2	Ask questions, if any	IRERC members / guest attendees
	↓	
3	Sign to indicate consent	IRERC members / guest attendees
	↓	
4	Keep the Agreement in mind.	IRERC members / guest attendees

5. DETAILED INSTRUCTIONS

Read the text carefully and thoroughly.

- Newly appointed members obtain two copies of the Agreement Form AF 01-004/01.0.
- Read through the text of the form very carefully.
- The members fill in their names and their office on the blanks.

Ask questions, if any.

- Direct questions to the Secretariat/chairperson, if any part or sentences is not clear.

- Let the officer explain or clarify the contents of the document.

Sign with consent.

- Sign and date both copies at the document.
- Give the forms back to a chairperson to sign and date.
- The members keep a copy as their records.

Keep the Agreement in mind.

- The compliance office keeps a copy of the signed agreement as the institute's records.
- Keep the copies in a confidentiality/conflict of interest agreement file.
- Store the file in a secure cabinet with limited key holders.

6. GLOSSARY

Confidentiality	The non-occurrence of unauthorized disclosure of information.
Confidentiality Agreement	Sometimes called Secrecy or Nondisclosure agreements. An agreement designed to protect job secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Conflict of Interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

There are three key elements in this definition: financial interest; official duties; professional interest.

A conflict of interest occurs when:

- ❖ An individual's private interest differs from his or her professional obligations to the institute.
- ❖ Professional actions or decisions occur that an independent observer might reasonably question.
- ❖ A conflict depends upon situation and not on the character or actions of the individual.
- ❖ Potential conflicts of interest must be disclosed and managed as per policy.

7. ANNEXES

ANNEX 1	AF01-004//01.0	Confidentiality / Conflict of Interest Agreement Form for IRERC members
ANNEX 2	AF 02-004//01.0	Confidentiality Agreement for Guest Attendees to IRERC Meetings
ANNEX 3	AF 03-004//01.0	Confidentiality Agreement for Non-members Requesting Copy (ies) of IRERC Documents

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

AF 01-004/01.0

Confidentiality / Conflict Of Interest Agreement Form for IRERC

In recognition of the fact that I *(member's name, and his /her affiliation)* herein referred to as the "Undersigned" have been appointed as a member of the University IRERC and have been asked to assess research studies in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines.

Whereas, the appointment of the undersigned as a member of the University IRERC is based on individual merits and not as an advocate or representative of a home province/ territory/community nor as the delegate of any organization or private interest.

The fundamental duty of an IRERC member is to independently review both scientific and ethical aspects of research protocols involving human participants and make a determination and the best possible objective recommendations, based on the merits of the submissions under review.

The University IRERC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of the University IRERC is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the University IRERC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary job secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential in-

formation provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRERC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the IRERC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of research participants.

It is the policy of the University IRERC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IRERC.

The Undersigned will immediately disclose to the Chairperson of the University IRERC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the IRERC, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IRERC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the IRERC member (s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IRERC review or approval except to provide information requested by the committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

ANNEX 1

AF 01-004/01.0

Agreement on Confidentiality and Conflict of Interest for IRERC members

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the University IRERC. A copy will be given to you for your records.

In the course of my activities as a member of the IRERC, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for reviewing and voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____	_____
Undersigned Signature	Date
_____	_____
IRERC Chairperson	Date

ANNEX 2

AF 02-004/01.0

Confidentiality Agreement Form for Guest Attendees to IRERC Meetings

I,……., understand that I am allowed to attend the IRERC meeting as a guest or an observer. In the course of the meeting of the IRERC, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as Confidential.

Indicate the details (date and number) of the IRERC Meeting attended:

……

……

……

_____	_____
Signature of the Guest or Observer	Date
_____	_____
Chairperson of IRERC	Date

ANNEX 3

AF 03-004/01.0

Confidentiality Agreement Form for Non Members Requesting Copies of IRERC's Documents

I,……..,..,., as a non-member of IRERC, understand that the copy (ies) given to me by the IRERC is (are) confidential. I shall use the information only for the indicated purpose as described to the IRERC and shall not duplicate, give or distribute these documents to any person(s) without permission from the IRERC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following IRERC documents:

……

……

…….

_____ _____

Signature of the recipient Date

_____ _____

Chairperson of IRERC Date

TABLE OF CONTENTS

1. PURPOSE

The purpose of this section is to inform the Institutional Research Ethics Review Committee (IRERC) personnel and members why training is necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

Werabe University (WRU) should recognize the importance of training and continuing professional development, therefore the institution will allocate an annual budget for specific training and study visits for IRERC personnel and members. New IRERC members are required to undergo a training program prior to joining the committee.

2. SCOPE

The SOP applies to all personnel of the WRU-IRERC.

3. RESPONSIBILITY

It is the responsibility of the WRU-IRERC members to have them educated and trained periodically.

4. FLOW CHART

No.	Activity	Responsibility
1	Topics for training	IRERC Chairperson/staff
	↓	
2	How to get trained	IRERC Chairperson/staff
	↓	
3	Keeping the training record.	IRERC members /staff

5. DETAILED INSTRUCTIONS

5.1. Topics for training

IRERC members should maintain competence by ensuring currency of their knowledge of:

- Good Clinical Practice (GCP)
- Declaration of Helsinki
- Ethical Issues
- Relevant laws

- Developments in relevant sciences, technical and environmental, health and safety aspects
- Relevant requirements of health, safety and environmental laws and regulations and related documents
- Audit procedures.
- Other standard regulation deemed necessary

An interchange of ideas, information and experiences with overseas institutions and organizations related to research ethics is also being carried out. International cooperation is also necessary to discuss ways of tackling harmful information distribution and joint efforts to tackle such distribution patterns. Efforts are being made to collect information on overseas trends and to attend international specialist meetings organized for the exchange of experience and information.

5.2. How to get trained

- Get information about training courses, workshops, conferences, etc. which is periodically announced on websites, bulletin boards and various media channels.
- Select the ones you need.
- Register to attend.
- Keep the receipt.

5.3. Keeping the training records

- Fill in the form AF 01-005 to record the training/workshop/conference activities in chronological order.
- Make a copy of the form.
- Keep the original form as your record.
- Give the copy to the administrative staff to keep in the IRERC file.

6. GLOSSARY

Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Meeting	Deliberations between at least two (2) persons where such deliberations de-

	termine or result in the joint conduct or disposition of business.
Workshop	A group of people engaged in study or work on a creative project or subject

ANNEXES

ANNEX 1 AF 01- 005/01.0: Training Record Form

REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

AF 01-005/01.0

Training Record Form

First name:	Last name:
Staff / Membership since:	Status:
Education Background:	
Work Experience:	

Training Experience					
s#	**Courses / Work-shops / Conferences / Meetings Attend-ed**	**Organized by:**	**Where?**	**Duration**	**Source of Funding**
1					
2					
3					
4					
5					
6					
7					
8					
9					

Table of contents

1. PURPOSE

The purpose of this SOP is describing the process of selecting independent consultants based on their expertise. If the protocol is found to be beyond the expertise of the existing IRERC members, an independent consultant will be invited to review the specified research.

If the Chairperson or the IRERC determines that a study will involve procedures or information that is not within the area of expertise of the IRERC members, the Chairperson or the IRERC may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to those available in the IRERC.

2. SCOPE

This SOP section provides procedures for engaging the expertise of a professional as a consultant to the IRERC.

3. RESPONSIBILITY

The nomination of the name of one or more special consultant in their field of expertise could be carried out by the Chairperson/ IRERC member/s and after endorsement by chairperson and IRERC members; finally it will be approved by the chairperson.

4. FLOW CHART

4.1. Activities and responsible bodies

No.	Activity	Responsibility
1	Selection of Independent Consultants	IRERC Chairperson
	↓	
2	Consultation Services	Consultant
	↓	
3	Termination of the Services	Consultant / IRERC Chairperson

5. DETAILED INSTRUCTIONS

5.1. Selection of Independent Consultants

- Identify the experts by the IRERC member and Chairperson.

- Nominate the consultants.
- Conduct a qualification review of the prospective consultant.
- Make decision based on expertise, availability and independence criteria.
- Get approval from the IRERC.
- Contact the consultant.
- The consultant provides:
  - ❖ A curriculum vitae
  - ❖ Any special training certificate which directly related with his/her expertise.
  - ❖ A signed Professional Services Agreement (AF 01-006, see ANNEX 1of this SOP).
  - ❖ A signed Confidentiality/Conflict of Interest Agreement (AF 01- 004/01.0, ANNEX 1 of the SOP# 004)
- Keep the documents in a consultant's file.
- Create a roster of consultants and the areas of their expertise.

5.2. Consultation Services

- IRERC provides study protocol documents to the appropriate consultant for review.
- The consultant must complete a consultative report (Annex 3 of this document AF 02-006/01.0) to be reviewed by the IRERC at the time the study is reviewed.
- The consultant may attend the IRERC meeting, present the report and participate in the discussion but ***cannot vote*****.**
- The report becomes a permanent part of the study file.

5.3. Termination of the Services

- Consultation services may be terminated by either the consultants themselves or by the IRERC Chairperson.

- Upon termination of the consultant's services, a member of the Secretariat ensures that all the qualifying documentation and the reason for discontinuation of the services are filed with the administrative documents.

6. GLOSSARY

Independent consultant	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.

7. ANNEXES

ANNEX 1 AF 01-006/01.0 Professional Services Agreement Form

ANNEX 2 AF 01-004/01.0 Confidentiality/Conflict of Interest Agreement Form

ANNEX 3 AF 02-006/01.0 Consultant Report Form

8. REFERENCE

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

AF 01-006/01.0

Confidentiality Agreement Form for an Independent Consultant

I, _____

(Name and Designation) as a non-member of Institutional research ethics Review Comiittee (IRERC) understand that the copy / copies given to me by the IRERC is/are confidential. I shall use the information only for the indicated purpose as described by the IRERC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IRERC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

_____ _____ _____ _____

Signature of the Consultant Date Signature of the chair Date

ANNEX 2
AF 01-004/01.0

Confidentiality/Conflict of Interest Agreement Form

I understand that it is the policy of the IRERC that no reviewer may participate in the review, comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by the IRERC.

I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the IRERC to me.

In the event that I develop any conflict of interest in relation to the particular proposal during the review process, I will declare it to IRERC and refrain from reviewing it.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature of IC Date

_____ _____

Chairperson's Signature Date

ANNEX 3
AF 02-006/01.0

Consultant Report Form

IRERC Protocol/proposal Number: _____

Protocol/proposal Title: _____

_____

_____

Comments on the protocol/proposal:

_____

_____

_____

Comments on the Informed Consent Document:

_____

_____

_____

Comments on any other issues/ aspects:

Remarks:

☐Recommend approval

☐Recommend approval after incorporation of changes suggested

☐Recommend disapproval (Please state Reasons)

_____

☐Any other (Please specify with reasons)

_____

_____

Name of the Consultant _____

Signature with Date: _____

Table of Contents

1. Purpose

WRU annually or specially funded all health research, as well as agricultural, environmental, Social Science, Natural science research, and other researches containing ethical concerns, as evidenced by technical reviewers will be sent to WRU-IRERC for independent ethical review. Additionally, WRU-IRERC will evaluate any other external researches whenever requests are submitted. This standard operating procedure is designed to describe how the WRU-IRERC secretariat manages protocol submissions to the WRU-IRERC

2. Scope

Protocol submissions include:

- Submission for Initial Review
- Resubmission of Protocols with Corrections
- Protocol Amendment
- Continuing Review of Approved Protocols
- Protocol Termination

3. Responsibility

It is the responsibility of the WRU-IRERC secretariat to receive record, **distribute for review and get the submission packages** approved by the WRU-IRERC, as well as to deliver the review results to the protocol applicants.

4. Flow chart

No.	Activity	Responsibility
1	Receive Submitted Packages ↓	WRU-IRERC Secretariat
2	Check for submission items: ❑ Initial Review Application ❑ Resubmission of Protocols with Corrections ❑ Protocol Amendment ❑ Continuing Review of Approved Protocols ❑ Protocol Termination ↓	WRU-IRERC Secretariat
3	Complete the submission process	WRU-IRERC Secretariat

↓

4 Store the received packages WRU-IRERC Secretariat

5. Detailed instructions

5.1 Receive submitted packages

5.1 Initial Review Application

- Go to 5.2.

5.1.2 Resubmission of Protocols with Corrections

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.2

5.1.3 Protocol Amendment

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.3

5.1.4 Continuing Review of Approved Protocols

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.4

5.1.5 Protocol Termination

- Retrieve the previous receipt form from the Secretariat's records.
- Go to step 5.2.1.5

5.2 Check for submission items

5.2.1 Get relevant forms:

5.2.1.1 Initial Review Application

- ❖ a checklist for contents of a submitted package, form AF 01-007 (see ANNEX 1),
- ❖ a document receipt form, AF 02-007,(see ANNEX 2) and
- ❖ An application form for initial review, (see ANNEX 1 of AF 01-009).
- ❖ Go to step 5.2.2.
- ❖ For e-submission, go to 5.2.3 (Filled AF 01-009 should be attached).

5.2.1.2 Resubmission of Protocols with corrections

- ❖ a checklist form (AF 01-007, see ANNEX 1),
- ❖ a document receipt form (AF 02-007, see ANNEX 2) and
- ❖ a review form (AF 01-011 in ANNEX 1 of SOP WRU 011)
- ❖ Go to step 5.2.2

5.2.1.3 Protocol Amendments

- ❖ a checklist for contents of a submitted package, form AF 01-007 (see ANNEX 1),
- ❖ a document receipt form, AF 02-007, (see ANNEX 2) and
- ❖ a re-review report form, AF 01-011, (ANNEX 1 of SOP WRU/ AF 011)
- ❖ Go to step 5.2.2

5.2.1.4 Annual Continuing Reviews of Approved Protocols

- ❖ a checklist for contents of a submitted package, form AF 01-007 (see ANNEX 1),
- ❖ a document receipt form, AF 02-007, (see ANNEX 2) and
- ❖ a re-review report form, AF 01-011, (ANNEX 1 of SOP WRU/AF 011)

- Go to step 5.2.2

5.2.1.5 Protocol Termination

- a checklist for contents of a submitted package, form AF 01-007 (see ANNEX 1),
- a document receipt form, AF 02-007, (see ANNEX 2) and
- a re-review report form (AF 01-011 in ANNEX 1 of SOP WRU/AF 011)
- Go to step 5.2.2

5.2.2 Fill in the forms:

- Give the form AF 02-007 and the form AF 01-009 to the applicants to fill up the relevant information.

5.2.3 Verify Contents of Submitted Package

- Use the checklist for contents of a submitted package, form AF 01-007, (ANNEX 1).
- Check the applicable documents to ensure that all required forms and materials are contained within the submitted package.
- Verify contents of the protocol submitted package to include
  - Original Application Form for Initial Review
  - Summary Sheet or Memorandum of the study Protocol
  - Study Protocol and Protocol-Related Documents
- Check completeness of necessary information in the Application Form for Initial Review.
- Check the Summary Sheet or Memorandum of the study protocol for inclusion of the followings:

- Title of the Protocol
- Principal Investigator
- Sponsor
- Abstract
- Type of Protocol (screening, survey, clinical trial and phase)
- Objectives
- Anticipated Outcome
- Inclusion/Exclusion Criteria
- Withdrawal or discontinuation Criteria
- Modes of Treatment Studied
- Methodology (synopsis of study design)
- Analysis (methods)
- Activity plan / Timeline
- IND Number (if applicable)
- Schedule and Duration of Treatment
- Efficacy or Evaluation Criteria (Response/Outcome)
- Safety Parameters Criteria (Toxicity)

❖ Check the submitted **Protocol and Related Documents** for the following contents

- Subjects' information sheets
- Informed Consent Form

- Case Record Form (CRF)
- Study budget and budget justification
- Agreement of the study
- Curriculum Vitae (CV) of investigators
- Investigators' Brochure (if applicable)

❖ See if changes made to the documents be underlined or highlighted.

5.2.4. Verify electronic documents (where applicable)

❖ Place the electronic computer documents (protocol summary, protocol and protocol-related documents) on the WRU-IRERC server or the Local Area Network at the time of submission for initial protocol review or protocol amendment packages in the following drive and folder:

C:\studies\protocols\new\ (short name of title)

❖ Verify that the electronic version and the contents of the documents match the copy submitted by comparing a hard copy of the electronic document with the submitted one.

❖ Check that all pages of the documents have been included and that the submitted protocol and protocol-related documents do not have missing pages.

❖ Certify the printed hard copy in the same manner as the submitted document(s) with the dated signature.

❖ Stamp and assign a running number to the received protocols, applying the system of 7 digits with running number of the year in the first three boxes, then slash sign and the last two digit of the year, followed by a dash sign and the month.

For example, 001/21-01 means protocol number one submitted in January, 2021

❖ Count for correct numbers of copies.

- ❖ Store the hard copy of the electronic document with the submitted documents.
- ❖ Use the assigned running number of the protocol as the labeled name.
- ❖ Identify clearly as the hard copy of the electronic document.

5.2.5 Create a Protocol Specific File

- ❖ Get the "**Protocol Submission"** file.
- ❖ Record the name and the number of the submitted protocol.
- ❖ Record the receiving date and the name of the receiver.

5.3 Complete the submission process

- ❖ Get the Form AF 02-007 and AF 01-009 back from the applicants.
- ❖ Check for completeness of information.
- ❖ Notify the applicants if a package is incomplete.
- ❖ State clearly the items missing in the package.
- ❖ Fill up the related parts and the missing documents.
- ❖ Stamp the receiving date on the form and the first page of the documents.
- ❖ Initial the receiver's name on the receiving documents.
- ❖ Make a photocopy of the completed Form AF 02-007.
- ❖ Return the original copy of the AF 02-007 to the applicants for their records.
- ❖ Attach the filled checklist (AF 01-007) with the copy of the form AF 02-007 with a staple.
- ❖ Keep the copy of the document receipt form in the "***Protocol Receipt***" file.
- ❖ Attach an Initial Review Application Form (AF 01-009 see ANNEX 1) to the Research Protocol packages.

- ❖ Keep the copy of the submitted documents with original signatures in the "Submission" file.

5.4 Store the received packages

- ❖ Bind the packages together appropriately.
- ❖ Store the dated and initial original protocol packages on the WRU-IRERC submission shelf for review in FIFO sequence.

6. Glossary

FIFO	First In First Out sequence

7. ANNEX

ANNEX 1	AF 01-007	Contents of a Submitted Package (Checklist)
ANNEX 2	AF 02-007	Document Receipt Form

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
Form AF 01-007/01.0

Contents of a Submitted Package

Protocol Number……

☐ **Initial Review Submitted Package**

- ❑ Protocol Summary Sheet or Memorandum
- ❑ Original Initial Review Application Form
- ❑ Protocol and Protocol-Related Documents
  - ☐ Information for subjects
  - ☐ informed consent form
  - ☐ Case report forms (CRF)
  - ☐ study budget
  - ☐ Investigator's brochure
  - ☐ others……

☐ **Resubmission for Re-review Submitted Package**

- ❑ Resubmission or "Correction" Memorandum
- ❑ Revised Protocol Summary Sheet (if submitted initially)
- ❑ Original Initial Review Application Form
- ❑ Protocol and Protocol-Related Documents
  - ☐ Information for subjects
  - ☐ informed consent form
  - ☐ Case report forms (CRF)
  - ☐ study budget

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the document or the software package used to prepare the documents.

☐ **Protocol Amendment Submitted Package**

- ❑ Request for Amendment Memorandum
- ❑ Original Amendment Submission Form
- ❑ Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

☐ **Annual Continuing Review Package**

- ❑ Request for Annual Continuing Review Memorandum
- ❑ Original Continuing Review Application Form
- ❑ Current Informed Consent Document (last approved by the WRU-IRERC)

☐ **Protocol Termination Package**

- ❑ Request for Termination Memorandum
- ❑ Original Continuing Review Application Form (Termination Submissions are contained on this form).

ANNEX 2
AF 02-007/01.0

Document Receipt Form

		Received number:	☐☐☐/☐☐-☐☐
Protocol Number:		**Submitted date:**	
Type of Submission:	☐ Initial Review ☐ Resubmission for re-review ☐ Protocol Amendments ☐ **Progress Report (quarterly)**	☐ Continuing Review of Approved Protocols ☐ Protocol Termination	
Protocol Title:			
Principal Investigator:			
Telephone number:		**Fax :**	
E-mail:		**Preferred Contact**	☐ Phone ☐ Fax ☐ e-mail
Institute:			
Delivery route:	☐ Post ☐ E-submission ☐ in Person		
Documents submitted:	☐ Complete ☐ incomplete, will submit on……...		
Documents to be submitted later :	☐ information for subjects ☐ informed consent form ☐ case report forms (CRF) ☐ study budget ☐ investigator's brochure ☐ Others……	Check what documents are received later on. ☐ information for subjects ☐ informed consent form ☐ case report forms (CRF) ☐ study budget ☐ investigator's brochure ☐ others……	
Received by:		**Date received:**	
Signature:			

Note: *Please bring this receipt with you when contacting the WRU-IRERC.*

Table of Contents

1. Purpose

This SOP describes how WRU-IRERC members use the assessment forms when reviewing the study protocols initially submitted for approval. The Assessment Form is designed to standardize the review process and to facilitate reporting, recommendation and comments given to each individual protocol.

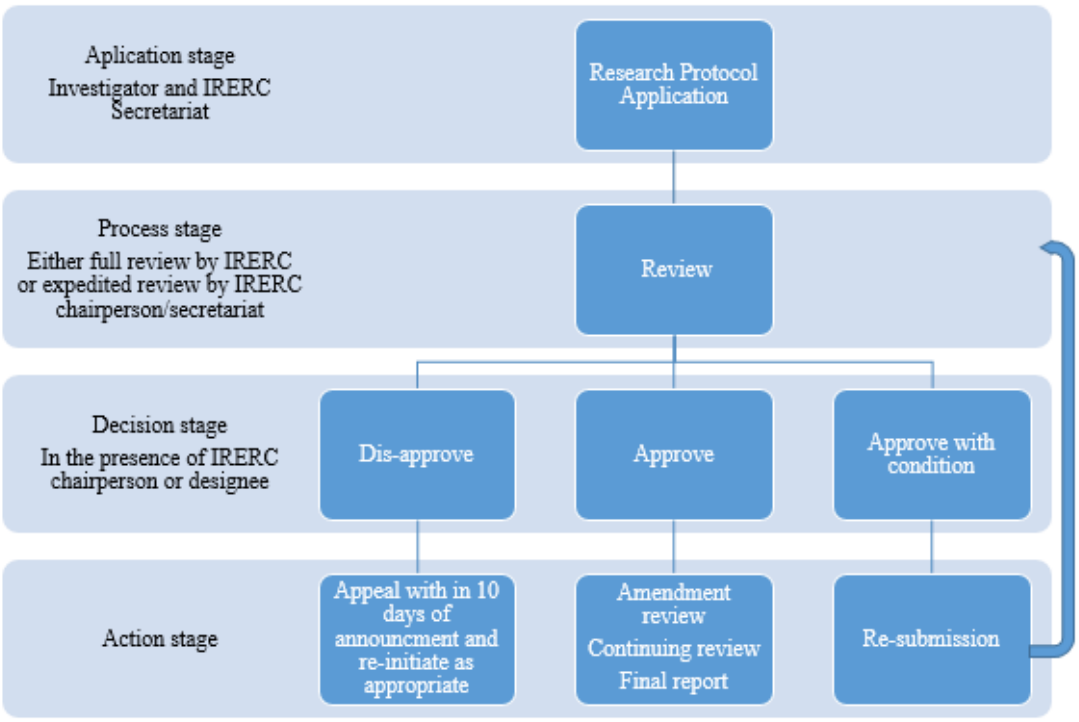
2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval from WRU-IRERC. The specific questions in the Assessment Form must be adequately addressed in the protocol itself and/or protocol-related documents under review.

Relevant points made during discussion and deliberation about a specific protocol should be recorded on the form. Additionally, the decision reached by the committee and the reasons for its decision is recorded on the Application Assessment Form.

3. Responsibility

It is the responsibility of the reviewers to fill the assessment form along with decision and comments they might have after reviewing each study protocol. WRU-IRERC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision. The Chairperson or delegated body must sign and date to approve the decision in the form.



IRERC research protocol submission, review, decision, and action process

4. Flow chart

No.	Activity	Responsibility
1	Summarize the protocol in an Assessment Form	WRU-IRERC Secretariat
	↓	
2	Review the Study Protocol	WRU-IRERC members / Reviewers
	↓	
3	Examine qualification of Investigators and study sites	WRU-IRERC members / Reviewers
	↓	
4	Review study participation	WRU-IRERC members / Reviewers
	↓	
5	Examine community involvement and impact (if applicable)	WRU-IRERC members / Reviewers
	↓	
6	Make a decision	WRU-IRERC
	↓	
7	Gather Assessment Reports	WRU-IRERC Secretariat
8	Record the IRERC's Decision	WRU-IRERC Secretariat

5. Detailed instructions

5.1 Summarize the protocol in an Application Assessment Form.

5.1.1 General Protocol Information

- Record general information about the protocol in the form (ANNEX 1) such as:
  - Title of the protocol
  - Protocol number and date
  - Principal Investigators, license & contact number
  - Co-investigators & contact number
  - Funding agency & contact number
  - Study types
  - Duration of the study
  - Status of the protocol – New / Revised / Amended
  - Review status – Regular / Expedited / Emergency
  - Reviewer's name
  - Objective and description of the Study

5.2. Review the study protocol.

- Need for human participants and plant, animal and environmental related ethical concern for study
- Objectives of the study
- Review of literature
- Sample size
- Methodology and data management

- ❖ Inclusion/exclusion criteria
- ❖ Control arms (placebo, if any)
- ❖ Withdrawal or discontinuation criteria

5.3. Examine the qualification of investigators and of study sites.

- ❖ Consider whether study and training background of the participating investigators relate to the study.
- ❖ Examine disclosure or declaration of potential conflicts of interest
- ❖ Can facilities and infrastructure at study sites accommodate the study?
- ❖ If the IRERC believes that the principal investigators (PIs) are without sufficient subject matter expertise, he/she shall be advised to consult a professional with the right expertise as necessary

5.4. Review study participation.

- ❖ Voluntary, non-coercive recruitment/participation
- ❖ Procedures for obtaining informed consent
- ❖ Contents of the patient information sheet
- ❖ Contents and language of the informed consent document
- ❖ Translation of the informed consent document in the local language used – plain and easy to understand by general public
- ❖ Contact persons with address and phone numbers
- ❖ Privacy and confidentiality
- ❖ Risks – physical / mental / social
- ❖ Benefits – to participants and to others
- ❖ Compensation – Reasonable / unreasonable
- ❖ Involvement of vulnerable participants

- ❖ Provisions for medical/psychosocial support
- ❖ Treatment for study related injuries
- ❖ Material transfer agreement (if applicable)
- ❖ Transport, use, storage and proper disposal of biological materials

5.5 Examine community involvement and impact (if applicable).

- ❖ Community consultation
- ❖ Involvement of local researchers and institutions in the protocol design, analysis and publication of the results
- ❖ Contribution to development of local capacity for research and treatment
- ❖ Benefit to local communities
- ❖ Availability of study results

Social science research ethical conditions

Ethical concerns like deception, scientific advocacy, cross-cultural dimension, and social injustice should be assessed in social science researches.

Review ethical concerns of animal and plant participants

Respect for dignity and their genetic resources, principle of replacement, the principle of proportionality (risk-benefit analysis), maintaining biological diversity, minimization, and replacement in Animal and plant studies should be the focus of the ethical review in addition to the general ethical principles.

Review ethical concerns in environmental studies

Environmental ethics issues such as: Anthropocentrism (human value), Zoo-centrism, Bio and Eco-centrism, and principle of replacement should be strictly reviewed.

Review of science and technology study related ethical issues

Science and technology researches should be reviewed for ethical conditions through the lenses of universal ethical standards and special standards that arise from science and

technology researches and outputs. These concerns include ensuring that the purpose of the technology/data-driven solutions are ethically justified; there are mechanisms to identify and mitigate unintended consequences; algorithms/ models produce fair outcomes across diverse populations; issues of AI or automated systems are being used and clearly explained; weather e-wastes will be responsibly managed.

5.6 The reviewer makes a recommendation.

- Get the assessment report form see ANNEX AF 02-008
- Record the recommendation by marking in the desired block any of the following: "*Approved, Approved on Conditions, or Not Approved.*"
- Include comments, suggestion and reason for Approved on conditions and disapproval.
- Check the completeness and correctness of the assessment form.
- Sign and date the decision form.
- Give or send the complete forms to WRU-IRERC Secretariat.

5.7 Gather the assessment reports.

- Collect the assessment forms and the review result from each reviewer.
- Organize the forms in order.
- Summarize the comments, suggestions, and opinions of each study in the meeting agenda.
- Follow SOP Preparation of meeting agenda and minutes.

5.8 Record IRERC's decision.

- Get the IRERC decision form. See Annex AF 03-008
- Complete the information. (by the Secretariat)
- List participating members and their votes.

- Summarize the guidance, advice and decision reached by the WRU-IRERC members.
- Sign and date the document. (by the Chairperson of WRU-IRERC or by Delegated person, where applicable).
- Make a copy of the completed decision form.
- Keep the original copy in the file labeled "WRU-IRERC's decision".
- Keep the copy of the decision form with the study protocol
- Return the file and the protocol to the appropriate shelves.

6. Glossary

Study Assessment Form	An official record that documents the protocol review process.
Document	Document may be of any forms, eg., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

7. ANNEX

ANNEX 1	AF 01-008	Study Assessment Form (5 pages)
ANNEX 2	AF 02-008	Assessment Report Form
ANNEX 3	AF 03-008	IRERC's Decision

8. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Ethical Guidelines for Biomedical research on Human Subjects, 2000.

ANNEX 1
Form AF 01-008/01.0

Study Assessment Form

Protocol Number :		Date (D/M/Y):	
Protocol Title :			
Principal Investigator (s):		License: No:	
Institute:		Contact No.	
Co – investigator(s):		Contact No.	
Total No. of Participants:		No.of Study site:	
Funding Agency:		Contact No.	
Duration of the Study:		Status:	☐ New ☐ Revised ☐ Amended
Reviewer's name :		Contact No.	
Study design :	☐ Case studies (case report , case series ☐ ☐ Cross-sectional (Descriptive , comparative) ☐ Observational (cohort, case control) Interventional (clinical trial, field trial, quasi experimental) ☐ Others, specify…….		
Review Status:	☐ Regular ☐ Expedited ☐ Exempted ☐ Emergency		

Description of the Study in brief: Mark whatever applied to the study.

☐ Randomized	☐ Stratified Randomized	☐ Open-labeled
☐ Double blinded	☐ Placebo controlled	☐ Treatment controlled
☐ Cross-over	☐ Parallel	☐ Interim Analysis
☐ Use of Tissue samples	☐ Use of Blood samples	☐ Use of genetic materials
☐ Multicenter study	☐ Screening	☐ Descriptive

Brief the study design and the statistic used:
Study Objectives:
……
……
……

ANNEX 1
Form AF 01-008/01.0

Mark and comment on whatever items applicable to the study.

1. Protocol Number	**Review Status** ☐ New ☐ Re – Submitted ☐ Amended ☐ Renewal
2. Protocol Title:	
3. Name of PI/s	License No. _____ (If Applicable)
4. Name of the PI/s Institution	**Tel/Fax.** _____
5 Name of Co-investigators	Tel/Fax _____

1.	Background Information and Data ☐ Sufficient ☐ Insufficient	Comment:
2.	Objectives of the Study ☐ Clear ☐ Unclear	What should be improved?
3.	Need for Human Participants ☐ Yes ☐ No ☐ N/A	Comment:
4.	Need for Animal, plant, or environmental ethical concerns ☐ Yes ☐ No ☐ N/A	Comment:
5.	Methodology: ☐ Clear ☐ Unclear	What should be improved?
6.	Risks and Benefits Assessment ☐ Acceptable ☐ Unacceptable	Comment:

7.	Inclusion Criteria ☐ Appropriate ☐ Inappropriate	Comment:
8.	Exclusion Criteria ☐ Appropriate ☐ Inappropriate	Comment:
9.	Withdrawal Criteria ☐ Appropriate ☐ Inappropriate	Comment:
10.	Involvement of Vulnerable Participants ☐ Yes ☐ No ☐ N/A	Comment:
11.	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No ☐ N/A	Comment:
12.	Sufficient number of participants? ☐ Yes ☐ No ☐ N/A	Comment:
13.	Control Arms (placebo, if any) ☐ Yes ☐ No ☐ N/A	Comment:
14.	Are Qualification and experience of the Participating Investigators appropriate? ☐ Yes ☐ No	Comment:
15.	Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
16.	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate ☐ N/A	Comment:
17.	Community Consultation ☐ Yes ☐ No ☐ N/A	Comment:

18.	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and Publication of Results ☐ Yes ☐ No ☐ N/A	Comment:
19.	Contribution to Development of Local Capacity for Research and Treatment ☐ Yes ☐ No	Comment:
20.	Benefit to Local Communities ☐ Yes ☐ No	Comment:
21.	Availability of similar Study / Results ☐ Yes ☐ No	Comment:
22.	Are blood/tissue samples sent abroad? ☐ Yes ☐ No ☐ N/A	Comment:
23.	Does the study involve sample storage? If 'No', go to # 27 ☐ Yes ☐ No	Comment:
24.	Is the duration of specimen storage specified? ☐ Yes ☐ No	Comment:
25.	Separate consent for specimen storage sought ☐ Yes ☐ No	Comment:
26.	Planned practice for storage, coding and further utilization of stored specimens ☐ Appropriate ☐ Inappropriate	Comment:
27.	Institutional support/permit confirming adequate samples storage commitment for long term storage sought ☐ Yes ☐ No	Comment:

28.	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	Comment:
29.	Contents of the Informed Consent Document ☐ Clear ☐ Unclear	Comment:
30.	Language of the Informed Consent Document ☐ Clear ☐ Unclear	Comment:
31.	Contact Persons for Participants ☐ Yes ☐ No	Comment:
32.	Privacy & Confidentiality ☐ Yes ☐ No	Comment:
33.	Inducement for Participation ☐ Unlikely ☐ Likely	Comment:
34.	Provision for Medical / Psychosocial Support ☐ Appropriate ☐ Inappropriate ☐ N/A	Comment:
35.	Provision for Treatment of Study-Related Injuries ☐ Appropriate ☐ Inappropriate ☐ N/A	Comment:
36.	Provision for Compensation ☐ Appropriate ☐ Inappropriate ☐ N/A	Comment:
For Social science studies		
Does the study use:		
37.	Deception ☐ Appropriate ☐ Inappropriate ☐ N/A	Comment:
38.	scientific advocacy	Comment:

	☐ Appropriate ☐ Inappropriate ☐ N/A	
39.	cross-cultural dimension ☐ Appropriate ☐ Inappropriate ☐ N/A	Comment:
40.	Prone for social injustice ☐ Yes ☐ No ☐ N/A	Comment:
For studies involving animal and plants		
Does the study followed Ethical Principles appropriately?		
41.	Respect for animals' dignity and their genetic resources ☐ Yes ☐ No ☐ N/A	Comment:
42.	Replacement ☐ Yes ☐ No ☐ N/A	Comment:
43.	Minimization ☐ Yes ☐ No ☐ N/A	Comment:
44.	Proportionality (risk-benefit analysis) ☐ Yes ☐ No ☐ N/A	Comment:
45.	Maintaining biological diversity ☐ Yes ☐ No ☐ N/A	Comment:
For environmental studies		
Do the research considers ethical concerns appropriately?		
46.	Anthropocentrism (human value) ☐ Yes ☐ No ☐ N/A	Comment:
47.	zoo-centrism ☐ Yes ☐ No ☐ N/A	Comment:

48.	Bio and Eco-centrism ☐ Yes ☐ No ☐ N/A	Comment:
49.	Principle of replacement ☐ Yes ☐ No ☐ N/A	Comment:
50.	Has a thorough environmental impact assessment has been conducted, including for the potential effects on biodiversity, ecosystems, and food chains? ☐ Yes ☐ No ☐ N/A	Comment:
51.	Do the researchers have a reasonable plan to monitor and manage unintended ecological consequences? ☐ Yes ☐ No ☐ N/A	Comment:
52.	Do the project activities risk ecosystem disruption? ☐ Yes ☐ No ☐ N/A	Comment:
For studies concerned with science and technology		
53.	Is the purpose of the technology/data-driven solution ethically justified? ☐ Yes ☐ No ☐ N/A	Comment:
54.	Are there mechanisms to identify and mitigate unintended consequences? ☐ Yes ☐ No ☐ N/A	Comment:
55.	Does the algorithm produce fair outcomes across diverse populations? ☐ Yes ☐ No ☐ N/A	Comment:
56.	Is the model's performance equitable across all demographic groups?	Comment:

	☐ Yes ☐ No ☐ N/A	
57.	Are users aware when AI or automated systems are being used? ☐ Yes ☐ No ☐ N/A	Comment:
58.	Is e-waste responsibly managed? ☐ Yes ☐ No ☐ N/A	Comment:
59.	Do users have meaningful control over how they interact with the technology? ☐ Yes ☐ No ☐ N/A	Comment:
60.	Can users opt-out or override automated decisions? ☐ Yes ☐ No ☐ N/A	Comment:
61.	Is informed consent built into the system design? ☐ Yes ☐ No ☐ N/A	Comment:
62.	Are there any other ethical risks that are associated with this study not mentioned above? ☐ Yes ☐ No ☐ N/A	Comment:

ANNEX 2
Form AF 02-008

Assessment Report

Review Date (D/M/Y):…… Protocol number…….

Protocol Title :		
Elements Reviewed (AF 01-008)	☐ Attached ☐ Not attached	
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
Recommendation :	☐ Approved ☐ Approved on Conditions ☐ Not Approved	
Comment:		
Signature :		Date:

ANNEX 3
Form AF 03-008

WRU-IRERC Decision

Meeting No.: ……../…….. Date (D/M/Y):……
Protocol number…… Assigned No.:……..

Protocol Title :		
Principal Investigators:		
Institute:		
Elements Reviewed (AF 01-008) :	☐ Attached	☐ Not attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review:	
Decision of the meeting:	☐ Approved ☐ Approved on Conditions ☐ Not Approved	

No.	Voting WRU-IRERC members	Decision		
		AP	AC	DA

Note: *AP - Approved; AC– Approved on Conditions; DA – Not Approved*

Signature:

…… **……..…**
Chairperson **Secretary**
Date:…… **Date:……**

Table of Contents

1. PURPOSE

This standard operating procedure describes how WRU-IRERC manages to review an initially submitted protocol.

2. SCOPE

This SOP applies to the review process of the study protocol package submitted for the first time.

3. RESPONSIBILITY

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments to the WRU-IRERC in the Assessment Form and return to the Secretariat Office on the date due.

The WRU-IRERC Secretariat is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version of the received packages. In addition, the secretariat should create a protocol specific file, distribute the packages and get them reviewed by WRU-IRERC and deliver the review results to the applicants.

4. FLOW CHART

No.	Activity	Responsibility
1	Send the protocol to the assigned member/reviewer	WRU-IRERC Secretariat
	↓	
2	Receive the distributed protocol package	WRU-IRERC Members/Reviewer
	↓	
3	Verify the contents of the package	WRU-IRERC Members/Reviewers
	↓	
4	Review the protocol	WRU-IRERC Members / Reviewers
	↓	
5	Discuss in WRU-IRERC's meeting	WRU-IRERC Members / Reviewers / Secretariat / Chairperson
	↓	
6	Preliminary Communication of the Decision	WRU-IRERC Secretariat/ Chairperson
	↓	
7	Final Communication of the Decision	WRU-IRERC Secretariat / Chairperson
	↓	
8	Storage of the Documents	WRU-IRERC Chairperson/ Secretariat

5. DETAILED INSTRUCTIONS

Appointment of primary reviewers

- The Chairperson or/and Secretary will appoint two or more primary reviewers for each study on the basis of expertise in the related field and experience. They should include one professional and one non-professional person as applicable. More than two may be appointed if necessary.

Distribute the protocol package

- The Secretariat will fill in the required details in the cover letter to the WRU-IRERC Members requesting initial review.
- The Secretariat will send a packet *(three hard and soft copy)* to the WRU-IRERC members.
  - Letter to WRU-IRERC Members requesting Initial Review
  - Study assessment form
  - Study Submission Application Form
  - Protocol and related documents
  - Confidentiality agreement and conflict of interest forms if the reviewer is an independent consultant

Receive the distributed protocol packages

- Check the distributed packages.
- Acknowledge receipt upon receiving the packages to the secretariat.
- Secretariat to print and file the relevant communication

Verify the contents of the package

- Look for an Assessment Form.
- Look for the due date for the review.
- Check the meeting date to see if he/she is available to attend the meeting.

- Notify WRU-IRERC secretariat if there are documents missing, conflict of interest or the specified date cannot be met.

Review the Protocol

5.5.1 Initial Review Application Form

- Check the form for completeness of the information and signatures of the principal investigator, WRU-IRERC Chairperson and Secretariat.
- Check and attach the Initial Review Application Form to the Research Protocol.

5.5.2 Assessment Form

- Use the Assessment Form to guide the review and deliberation process.

  Note: The completed Assessment Form is the official record of the decision reached by WRU-IRERC for the specific protocol.

- Consider the following criteria when performing the review:
  - minimize risks to participants;
  - risks must be reasonable in relation to anticipated benefits;
  - participants are selected equitably;
  - informed consent is adequate, easy to understand and properly documented;
  - the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
  - there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate; and
  - Appropriate safeguards are included to protect vulnerable participants.
- Make comments where appropriate.
- Sign and date the reviewer's name.

IRERC meeting

- The primary reviewer presents a brief oral or written summary of the study design and his/her comments.
- The Chairperson or designee entertains discussion on each document under consideration (e.g., protocol, informed consent, investigators and site qualifications, advertisements).
- Recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes as 'with modifications made by WRU-IRERC and will be communicated to the investigator.
- The Chairperson or designee calls for a separate vote on each element in review. The Committee votes to either:
    - Approve the study to start as presented with no modifications
    - Require modifications to items noted at the convened meeting and follow-up by the Chairperson, after receipt of the requested modifications. = *Approved on Conditions.*
    - Not approve the study, stating the reason for disapproval = *Not Approved*
- If the study is approved, the principal investigator should submit renewal application annually.
    - The Secretariat sends an action letter along with the approved documents to the investigator.
    - The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- Put a seal/stamp and expiry date on every page of each participant information sheet and informed consent form approved by WRU-IRERC.
- If the Committee votes not to approve the study, the Secretariat notifies within 10 working days the investigator in writing about the decision and the reason for not approving the study.

- If the investigator wishes to appeal to the decision, he/she may do so by contacting WRU-IRERC Secretariat. The appeal process is stated in the action letter to the investigator.

➢ If the Committee requires modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to WRU-IRERC.

Preliminary Communication of the Decision

5.7.1 Verbal Communication of the Decision

- The Chairperson notifies the Secretariat of the Committee decision and the reasons for the decision during the meeting.

5.7.2 Written Communication of the Decision

- The Secretariat, in turn forwards the Committee decision to the principal investigator (eg., via e- mail) and files "sent" or "received" e-mail messages in the protocol file within one working day whenever possible, but no later than 10 working days after the review has taken place.

Final Communication of the Decision

5.8.1 Signature of Approval

❖ Obtain and complete the appropriate forms, after a decision has been reached by WRU-IRERC.

❖ Get signature from the Chairperson.

❖ Date the form.

5.8.2 The Assessment Form

❖ Complete the Assessment Form.

❖ Get signature of the Chairperson.

❖ Maintain the completed Assessment Form and the minutes of the meeting relevant to the protocol review.

- Process the above tasks *within 5 working days after the meeting.*

5.8.3 The Application Review Form

- Let the Chairperson/delegate approve the original version of the form within 10 working days.
- Sign and date the form by the chairperson/Secretariat.
- Assign WRU-IRERC number at the bottom boxes on the last page of the Form (AF 01-009) by filling in the boxes with numbers in sequential order, "☐☐☐/☐☐-☐☐"; the approval sequence in the first three boxes, the current month after the slash and the current year after the dash sign.

5.8.4 The Action Letter

- Prepare an Action Letter to inform the investigator or the project manager about the Committee's decision
- State clearly the actions that need to be taken by the investigator.
- For the decision disapproval, a notifying letter to the investigator or the project manager should state the followings:

  "If you wish to appeal to this decision, please contact the WRU-IRERC Secretariat and submit your appeal in writing, addressed to WRU-IRERC Chairperson with justification as to why the appeal should be granted"

- Verify the correctness of the wordings and spelling.
- Notify the application about the action letter within 10 working days.

Storage of the Documents

- Keep a copy of the Action Letter in the Correspondence file.
- Place the original documents of the Application Review and the Assessment Forms in sequence of approval number in the Approved file.
- Store the file on an appropriate shelf in the designated cabinet and consider digital data storage.

6. GLOSSARY

Initial Review	The first time review of that protocol made by two or three individual reviewers (WRU-IRERC members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.
Phase I studies	Initial introduction of an investigational new drug (IND) in-to humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to ex-plore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials per-formed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relation-ship of the drug and to provide an adequate basis for physi-cian labeling.
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.
Stipulation	Specify as terms of or condition for an agreement, contract, etc. state, put forward for a necessary condition.

7. ANNEX

ANNEX 1 AF 01-009: Application Form for Initial Review (2 pages)

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996

ANNEX 1

Form AF 01-009/01.0
Page 1 of 3

APPLICATION FORM for INITIAL REVIEW

Protocol Title:	
Protocol number:	Total Participants to be included:

STUDY TYPE: (Mark "✓ " whichever apply to the study)

☐ Case studies (case report , case series
☐ Cross-sectional (Descriptive , comparative)
☐ Observational (cohort, case control)

☐ Interventional (clinical trial , field trial, quasi experimental) Phase I, Phase II Phase III , Phase IV

Others, specify…….

STUDY POPULATION: ☐ Healthy ☐ Patient ☐ Vulnerable groups

CHARACTERISTICS of PARTICIPANTS:
Age Range: ☐ <1 month ☐ 1 month- 12 years ☐ >12-17 years ☐ 18yrs & above
Impaired ☐ None ☐ Physically ☐ Cognitively ☐ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:
☐ None ☐ Male ☐ Female ☐ Children ☐ Other (specify)

SPECIAL RESOURCE REQUIREMENTS (check all that apply):
☐ Intensive Care ☐ Isolation unit ☐ Surgery
☐ Pediatric Intensive Care ☐ Transfusion ☐ CAT/MRI scan
☐ Gene therapy ☐ Controlled substances (Narcotics/Psychotropic)
☐ Prosthetics ☐ Gynecological service ☐ Others, specify…….
☐ Organ transplantation, specify…… …….

IONIZING RADIATION USE (X-rays, radioisotopes, etc):
☐ None ☐ Medically indicated only

INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):
☐ None ☐ IND ☐ IDE

PROCEDURE USE: ☐ Invasive ☐ Non-invasive

MULTI-SITE COLLABORATION: ☐ YES ☐ NO

FINANCIAL DISCLOSURE: ☐ YES ☐ NO

PRINCIPAL INVESTIGATORS' INSTITUTE CONTACT

Name:……

Address:……

Telephone:……

Fax:……

E-mail:……...

Form AF 01-009
Page 3 of 3

INVESTIGATORS:

Full Name	Academic Qualification	Responsibility	Institution	Telephone / email.
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

	TYPE OF REVIEW:	
☐	☐ Initial Review ☐ Resubmission Review ☐ Amendment Review ☐ Expedited Review ☐ Exempt review	☐ Emergency Review ☐ Continuing Review ☐ Report Review ☐ Protocol Termination
	Principal Investigators signature_____Date: …….. Secretariat, WRU-IRERC signature_____Date: ……	
	APPLICATION NUMBER : ☐☐☐/☐☐-☐☐	

Table of Contents

1. PURPOSE

The purpose of this SOP is to provide criteria for determination of which study protocols can be reviewed through expedited process as well as instructions on management, review and approval of the expedited review

2. SCOPE

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes of currently approved studies.

3. RESPONSIBILITY

It is the responsibility of the WRU-IRERC Secretary in consultation with the Chairperson/Vice Chair to define of which study protocols should be reviewed and approved through expedited review.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the submitted documents.	WRU-IRERC Secretariat
	↓	
2	Determine protocols for expedited review.	WRU-IRERC Secretary in consultation with the Chairperson/Vice Chair
	↓	
3	Expedite process.	WRU-IRERC Members / Chairperson
	↓	
4	Communicate with the WRU-IRERC and the Investigator.	WRU-IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Receive the submitted documents.

- ❖ Receive the application documents submitted by investigators.
- ❖ Get contents of submitted package (checklist) form, to check items received.
- ❖ Stamp the receiving date on the letter and the documents.
- ❖ Sign the receiver's name on the receiving documents.

❖ Hand the received documents to the WRU-IRERC secretariat.

5.2 Determine protocols for expedited review.

❖ WRU-IRERC Secretary in consultation with the Chairperson/Vice Chair determines whether a study is qualified for expedited review according to the following criteria:

5.2.1 Modification /amendment of protocol

- ***Administrative revisions***, such as correction of types
- Addition or deletion of ***non-procedural items***, such as the addition of study personnel names, laboratories, etc.
- ***Non-significant risk*** research activity
- The research activity includes only ***minor changes*** from previously approved protocol.

5.2.2 Proposals involve interviewing of a ***non-confidential nature*** (not of a private eg. relate to sexual preference *etc*.), ***not likely to harm*** the status or interests of the individual and ***not likely to offend*** the sensibilities of the people involved.

5.2.3 Those that involve ***collection of small amounts of blood samples*** (and not too frequent) e.g. by finger, heel or ear stick.

5.2.4 Those that involve collection of biological specimens for research purposes by ***non-invasive means*** (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

5.2.5 Collection of data for research purposes through ***non-invasive procedures*** (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However

procedures involving the ***use of x-rays or microwaves are NOT recommended for expedited review***.

5.2.6 Research involving data, documents or specimens that have been already collected or will be ***collected for ongoing medical treatment*** or diagnosis.

5.2.7 Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and ***no additional risks*** have been ***identified***.

- If the protocol satisfied any of the criteria for **expedited** review, the secretariat will send the protocol to Chairperson.

5.3 Expedited Process

- Chairperson nominates 2 or more WRU-IRERC members to review the protocol.
- The selected members are normally those who reviewed and recommended the previous version of that protocol, if it is not submitted for the first time.
- The secretariat sends the protocol to the selected members.
- Carry out the expedited review on the complete proposal (study protocol with all the attached documents as mentioned in the guidelines for submission of proposals -
- The review may be made either by circulation of comments, telephone discussion or meeting.
- If consensus can not be reached, the chairperson will refer the proposal back to WRU-IRERC for a full review
- The expedited review should not take longer than 1 month
- Inform WRU-IRERC of the proposals approved by expedited review at its regular meetings.
- If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review.

5.4 Communicate with IRERC and the investigator.

- The reviewers forward their comments to the Secretariat.

- ❖ Full Board notification of items approved through expedited review by the Chairperson or the designee is accomplished by providing notification and source documentation of the items in the meeting agenda / notes.
- ❖ The Secretariat communicates the decision to the investigator.

6. GLOSSARY

Administrative Documents	Documents include official minutes of committee meetings as described in Standard Operating Procedures, both historical and Master Files
Expedited approval	WRU-IRERC approval granted only by the Chairman or a designated board member (not the full Board) for minor changes to current WRU-IRERC approved research activities and for research which involves no more than minimal risk.
Expedited review	A review process by two or more designated WRU-IRERC members who then report the decision to the full Board meeting. An expedited review is a *speedy* one for minor *changes to the approved protocol* and for *research proposal* with *minimal risk in nature*.

7. ANNEX

Annex 1 - AF 01-008 Study Assessment Form

Annex 2 - AF 02-008 Assessment report form

Annex 3 - AF 03-008 IRERC decision form

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Code of Federal Regulation (CFR) 21.

Table of Contents

1. PURPOSE

The purpose of this procedure is to provide instructions for review and approval of medical device studies submitted to the IRERC.

2. SCOPE

This SOP applies to the submission and the review processes of protocols involving the study of new medical devices in human participants.

3. RESPONSIBILITY

During the review of medical device studies, the IRERC may make some different decision than those made during the review of drug studies. The IRERC must determine if the proposed investigation has Significant Risk (SR) or Non-significant Risk (NSR), and then the IRERC should decide if the investigation is approved or not. In determining SR or NSR, the IRERC must review all information submitted by the sponsor.

The IRERC should consider the nature of the harm that may result from the use of the device. If a device being investigated might cause significant harm to any one of the participants, the study will be considered SR. In deciding if a device presents significant or non-significant risks, the IRERC should consider the device's total risks, not those compared with the risks of alternative devices or procedures. If the device is used in conjunction with a procedure involving risk, the IRERC should consider the risks of the procedure in conjunction with the risks of the device. The IRERC may also consult with the regulatory agency to form its opinion.

The IRERC may agree or disagree with the sponsor's initial NSR assessment. If the IRERC agrees with the sponsor's initial NSR assessment and approves the study, the study may begin without submission of an IDE (Investigational Device Exemption) application to the regulatory agency. If the IRERC disagrees, the sponsor must notify the regulatory agency that an SR determination has been made. The study can be conducted as an SR investigation following regulatory approval of an IDE application.

4. FLOW CHART

No.	Activity	Responsibility
1	Submission of documents	Applicant/PI
	↓	
2	Activities before a Committe meeting	IRERC Chairperson / Secretary
	↓	
3	Activities during a Committe meeting	IRERC members / Secretary /
	↓	Chairperson
4	Activities after the meeting	IRERC Chairperson/Secretary
	↓	
5	Notify the investigators	IRERC Chairperson
	↓	
6	Storage of the documents	IRERC Secretary

5. DETAILED INSTRUCTIONS

5.1 Submission of documents

- Receive a new medical device study.
- Check the submitted package for completeness.
- Document the checking procedure by completing a checklist form (AF 01-007/01.0, Contents of a submitted package).

At a minimum, the IRERC must receive the following documents prior to review/approval of a medical device study:

- Proposed investigational plan

- ❖ Informed consent / assent form
- ❖ Description of the device
- ❖ Description of participant selection criteria
- ❖ Monitoring procedures
- ❖ Reports of prior investigations conducted with the device
- ❖ Investigator's Curriculum Vitae
- ❖ Investigator's professional license (s)
- ❖ Risk assessment data / information
- ❖ Statistics used in making the risk determination.
- ❖ Application for Review (AF 01-009/01.0)
- ❖ Document Received Form (AF 02-007/01.0)
- ❖ Copies of all labeling for investigational use only

- ➢ The sponsor should inform the IRERC whether other IRERCs have reviewed the proposed study and what determination was made.
- ➢ The sponsor should inform the IRERC of the Agency's assessment of the device's risk if such an assessment has been made.
- ➢ If the Sponsor believes the study is *NSR*, supporting information must be submitted.
- ➢ Contact the applicant to submit additional information or documents, if the application is complete.

5.2 Before the IRERC meeting

- Assign reviewers to review the study, according to the assessment form (see SOP# Annex AF 01-008).
- Prepare the documents for distribution to each IRERC member.
- Send the documents to each IRERC member.
- Place the new medical device study on the meeting agenda.

5.3 During the IRERC meeting

- Reviewers present a brief oral or written summary of the study design.
- The Chairperson leads discussion about each document under consideration (e.g. protocol, informed consent, investigators and site qualifications, advertisements).
- Decide the degree of risk.
- Consider whether or not the study should be approved.
- The Chairperson calls for a separate vote on each element in review. The IRERC votes to either:
  - Approve the study to start as presented with no modifications
  - Approve the study to start with minor modifications to item(s) noted at the convened meeting and to be followed-up by the Secretariat and Chairperson, after receiving the requested modifications
  - Require major modifications and/or request further information to be resubmitted and subjected to review in the next IRERC meeting.
  - Disapprove the study and state the reason.

- ❖ Record the vote of risk assessment in the decision form (AF 02-008/01.0) and the meeting minutes (AF 02-020/01.0).
- ❖ Note the recommendations for changes to the protocol and/or informed consent recommended by IRERC members in the minutes as with modifications made by IRERC and will be communicated to the investigator.
- ❖ Determine the frequency of Continuing Review for the approved study.

5.4. After the meeting

5.4.1 Prepare meeting minutes

- ➢ Follow the procedure in SOP# WRU 020.

5.4.2 Notify the investigators

- ➢ The Secretariat sends an action letter along with the approved documents to the investigator. The letter contains at a minimum, a listing of each document approved, the date set by the IRERC for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
- ➢ If the committee votes not to approve the study, the Chairperson or Secretariat immediately notifies the investigator in writing of the decision and the reason for disapproving the study. If the investigator wishes to appeal this decision, he or she may do so by contacting the VPARCSTT or RPED of WRU. This process is stated in the action letter provided to the investigator.
- ➢ If the IRERC votes to require modifications to any of the documents, the Secretariat generates and sends a written request of the specific changes to the in-

vestigator asking him or her to make the necessary changes and resubmit the documents to the IRERC.

5.4.3 Storage of the documents

- Prepare an appropriate label.
- Store the document packages in the shelf for active files.

6. GLOSSARY

Medical Device	Any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kits for in vitro diagnosis of disease and other conditions (for example, pregnancy).
Investigational Medical Device	A medical device which is the object of clinical research to determine its safety or effectiveness.
Investigational Device Exemption (IDE)	Investigational Device Exemption allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Pre-market Approval (PMA) application or a Pre-market Notification submission to the regulatory agency. Clinical studies are most often conducted to support a PMA. Only a small percentage of studies require clinical data to support the application. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE **before** the study is initiated.

	An IDE is approved by an institutional Research Ethics Review Committee (IRERC). If the study involves a significant risk device, the IDE must also be approved by the regulatory agency. An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements that would apply to devices in commercial distribution. Sponsors need not submit a PMA (Pre-Market Approval) or Pre-market Notification, registers their establishment, or lists the device while the device is under investigation. Sponsors of IDE's are also exempt from the Quality System (QS) Regulation except for the requirements for design control.
New Study	A study protocol including the informed consent, investigator qualifications, and advertisements presented to the WRU IRERC for approval for the first time. This includes re-application for those studies denied approval by WRU IRERC.
Non-significant Risk Device (NSR)	An investigational device that does not pose a significant risk. A list of examples is found in ANNEX 1.
Risk	The probability of harm or discomfort to study participants. Acceptable risk differs depending on the conditions for which the product is being tested. A product for sore throat, for example, will be expected to have a low incidence of side effects. However, unpleasant side effects may be an acceptable risk when testing a promising treatment for a life-threatening illness.

Significant Risk Device (SR)	An investigational device that: ➢ Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the participant, ➢ Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the participant, ➢ Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the participant, or ➢ Otherwise presents a potential for serious risk to the health, safety, or welfare of the participant. A list of examples is found in annex 2.

7. ANNEX

ANNEX 1 AF 01-026/01.0 Examples of Non-significant Risk Device Studies

ANNEX 2 AF 02-026/01.0 Examples of Significant Risk Device Studies

8. REFERENCES

1. Code of Federal Regulation (CFR) 21, Volume 8, Part 812, April 2003, Food and Drug Administration, U.S. Government Printing Office via GPO Access

ANNEX 1
AF 01-026/01.0

NON-SIGNIFICANT RISK DEVICE STUDIES

EXAMPLES:

- Bio-stimulation Lasers for treatment of pain
- Caries Removal Solution
- Daily Wear Contact Lenses and Associated Cleaners and Solutions
- Dental Filling Materials, Cushions or Pads made from traditional materials and designs
- Denture Repair Kits and Re-aligners
- Gynecologic Laparoscope and Accessories at power levels established prior to May 28, 1976 (excluding use in female sterilization)
- Externally worn Monitor for Insulin Reactions
- Jaundice Monitor for Infants
- Magnetic Resonance Imaging (MRI) Devices within specified physical parame-ters
- Menstrual Pads
- Menstrual Tampons of "old" materials (used prior to May 28, 1976)
- Non-implantable Male Reproductive Aids
- Ob/Gyn Diagnostic Ultrasound (within specified parameters)
- Transcutaneous Electric Nerve Stimulation (TENS) Devices for treatment of pain
- Wound Dressings, excluding absorbable hemostatic devices and dressings

ANNEX 2
AF 02-026/01.0

SIGNIFICANT RISK DEVICE STUDIES

General Medical Use

Catheters:

- Cardiology – diagnostic, treatment, transluminal coronary angioplasty, intra-aortic balloon with control system
- Gastroenterology and Urology – biliary and urologic
- General Hospital – long-term percutaneous, implanted, subcutaneous and intravascular
- Neurology – cerebrovascular, occlusion balloon
- Collagen Implant Material for use in ear, nose and throat, orthopedics and plastic surgery
- Lasers for use in Ob/Gyn, cardiology, gastro-enterology, urology, pulmonary, ophthalmology and neurology
- Tissue Adhesives for use in neurology, gastro-enterology, ophthalmology, general and plastic surgery, and cardiology

Anesthesiology

- Respiratory Ventilators
- Electro-anesthesia Apparatus
- Gas Machines for Anesthesia or Analgesia
- High Frequency Jet Ventilators greater than 150 BPM

Cardiovascular

- Arterial Embolization Device
- Artificial Heart, permanent implant and short term use

- Cardiac Bypass Systems: oxygenator, cardiopulmonary blood pump, ventricular assist devices
- Cardiac Pacemaker/Pulse Generator: implantable, external transcutaneous, anti-tachycardia, esophageal
- Cardiovascular/Intravascular Filters
- Coronary Artery Retroperfusion System
- DC-Defibrillators
- Implantable Cardioverters
- Laser Coronary Angioplasty Device
- Pacemaker Programmer
- Percutaneous Conduction Tissue Ablation Electrode
- Replacement Heart Valve
- Vascular and Arterial Graft Prostheses

Dental

- Endosseous Implant

Ear, Nose and Throat

- Cochlear Implant
- Total Ossicular Prosthesis Replacement
- Gastroenterology and Urology
- Anastomosis Device
- Endoscope and/or Accessories
- Extracorporeal Hyperthermia System
- Extrocorporeal Photophersis System
- Extracorporeal Shock-Wave Lithotriptor

- Kidney Perfusion System
- Mechanical/Hydraulic Impotence and Incontinence Devices
- Implantable Penile Prosthesis
- Peritoneal Shunt

General and Plastic Surgery

- Absorbable Hemostatic Agents
- Artificial Skin
- Injectable Silicone
- Implantable Prostheses: chin, nose, cheek, ear
- Sutures

General Hospital

- Infusion Pumps: Implantable and closed-loop, depending on infused drug
- Implantable Vascular Access Devices

Neurology

- Hydrocephalus Shunts
- Implanted Intracerebral / Subcortical Stimulator
- Implanted Intracranial Pressure Monitor
- Impalnted Spinal Cord and Nerve Stimulators and Electrodes

Obstetrics and Gynecology

- Cervical Dilator
- Chorionic Villus Sampling Catheter, phase II (pregnancy continued to term)
- Contraceptive Devices: tubal occlusion, cervical cap, diaphragm, intrauterine device (IUD) and introducer, and sponge

Ophthalmic

- Extended Wear Contacts Lens

- Intraocular Lens (investigations subject to 21 CFR 813)
- Eye Valve Implant
- Retinal Reattachment Systems: sulfur hexafluoride, silicone oil, tacks, per-fluoropropane

Orthopedics

- Implantable Prostheses: ligament, tendon, hip, knee, finger
- Bone Growth Stimulator
- Calcium Tri-Phosphate/Hydroxyapatite Ceramics
- Xenografts

Radiology

- Hyperthermia Systems and Applicators

Table of Contents

1. PURPOSE

This procedure describes how resubmitted study protocols are managed, re-reviewed and approved by the WRU-IRERC.

2. SCOPE

This SOP applies to study protocols that have been reviewed earlier with recommendations from WRU-IRERC for some corrections in the initial review process.

3. RESPONSIBILITY

It is the responsibility of the WRU-IRERC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for re-vision has been resubmitted to the WRU-IRERC for reconsideration.

A re-submitted protocol may be reviewed and approved by either the Chairperson or some WRU-IRERC members/reviewers, or full WRU-IRERC. How the protocol will be reviewed should have been determined by the WRU-IRERC at the time of the initial review. This information can be found on the Decision Section of the Assessment Form.

4. FLOW CHART

No.	Activity	Responsibility
1	Send the resubmitted protocol to the assigned member/reviewer	WRU-IRERC Secretariat
	↓	
2	Review the revised protocol	WRU-IRERC Members / Reviewers
	↓	
3	IRERC Meeting	WRU-IRERC Members
	↓	
4	Communicate the IRERC decision	WRU-IRERC Secretariat / Chairperson
	↓	
5	Document the decision	WRU-IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Receive protocol resubmitted package.

- Check the distributed packages for:
  - Memorandum addressing the corrections,
  - Initial Review Application Form
  - Revised version of protocol and related documents such as the informed consent document, data collection or case report forms, diary sheets, etc are included as part of the package.
  - *Changes made to the documents should be underlined or highlighted.*
- Sign and date an acknowledgement form upon receiving the packages.
- Return the receipt form back to the delivery person WRU-IRERC secretariat.

5.2 Review the revised protocol.

- Refer to the meeting minutes as guidance for the review.
- Consider whether the recommendation of the WRU-IRERC has been followed.
- Make further comments where appropriate.
- Sign and date the reviewer's name.
- Notify the Secretariat.

5.3 WRU-IRERC meeting

- The Secretariat receives the review report and informs the Chairperson.
- If no WRU-IRERC meeting is necessary, then go to step 5.4.
- If the WRU-IRERC previously decided to see the new revision, then proceed with the following steps:
  - The primary reviewer presents a brief oral or written summary of the study design and his/her comments to the WRU-IRERC members.
  - The Chairperson entertains discussion on the protocol revision.
  - Further recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes as 'with modifications made by WRU-IRERC ' and will be communicated to the investigator.
  - The Chairperson calls for a vote on the revision to either:
    - Approve the study to start as presented with no modifications = *Approved*
    - Require modifications to items noted at the convened meeting and follow-up by the Chairperson, after receipt of the requested modifications = *Approved on Conditions*
    - *Not Approved*

5.4 Document the WRU-IRERC decision.

- ❖ Place the original completed documents along with the completed re-review report, the Assessment Form and the Initial Review Application Form as well as the others in the protocol package.
- ❖ Prepare an approval letter.
- ❖ Send an approval letter to the principal investigator.
- ❖ Get the Chairperson's signature.

5.5 Communicate the decision.

5.5.1. Verbal Communication of the Decision

- ➢ The Chairperson notifies the secretariat immediately after the meeting about the decision and the reasons for the decision

5.5.2. Written Communication of the Decision

- ➢ The Secretariat notifies the principal investigator about the decision of the WRU-IRERC not later than 10 working days through an e- mail or telephone and files the "sent" and "received" e-mail messages in the protocol file.
- ➢ The Secretariat then prepares the Approval/Action Letter and gets the Chairperson's signature.
  - ❖ If the study is approved, the Committee determines the frequency of Continuing Review for each study site.
    - The Secretariat sends an Action Letter to the investigator notifying the WRU-IRERC decision and schedule of continuing review.
    - The letter contains, at a minimum, a listing of each document approved, the date set by the Committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
  - ❖ Put a seal/stamp and expiry date on every page of each participant information sheet and informed consent form approved by WRU-IRERC If the Committee requires modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator to make the necessary changes and resubmit the documents to the WRU-IRERC.

6. GLOSSARY

Document	All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or video tape.

Completed Assessment Form	An official record of the review decision along with comments and dated signature of the reviewer.

7. ANNEX

ANNEX 1 AF 01-011 Re-review Report Form

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
Form AF 01-011

Review of Resubmitted Protocol

Protocol No.:		Application No.: ☐☐☐ / ☐☐ - ☐☐
Protocol Title:		
Total Participants :		☐ 2nd Review ☐ 3rd Review ☐ 4th Review
Principal Investigator:		Tel.:
Initial Review Date:		Last Review Date:
NRERC Decision recorded in the meeting minute :	☐ Approved with minor changes or recommendation ☐ Major changes or recommendation need to be reconsidered	
Opinion of the reviewer: ✧ Revision or Modification according to the recommendation ✧ What need to be further revised :	☐ Yes ☐ No : Explain:……... ……... ……	

SIGNATURES:

_____ Date:……
Protocol Reviewer

APPROVAL:

_____ Date: ……..
Chairperson, WRU-IRERC

COMPLETION:

_____ Date:……
Secretary, WRU-IRERC

Table of Contents

1. PURPOSE

The purpose of this procedure is to describe how protocol amendments are managed and reviewed by the WRU-IRERC.

2. SCOPE

This SOP applies to previously approved study protocols but later being amended and submitted for approval by the WRU-IRERC. Amendments made to protocols may not be implemented until reviewed and approved by the WRU-IRERC.

3. RESPONSIBILITY

It is the responsibility of the Werabe University IRERC Secretariat to manage protocol amendments. Investigators may amend the contents of protocols from time to time. Protocol amendments may be submitted for either "expedited" review by the Chairperson / Secretariat/members / reviewers or full WRU-IRERC review.

4. FLOW CHART

No.	Activity	Responsibility
1	Manage the Amendment Package	WRU-IRERC Secretariat
	↓	
2	Notify the Chairperson of the WRU-IRERC	WRU-IRERC Secretariat
	↓	
3	Determine whether Expedited or Full Review	Secretary in consultation with the Chairperson/Vice Chair
	↓	
4	Expedited Review	Chairperson/members/ reviewers
	↓	
5	Full Committee Review	Chairperson/members/ reviewers
	↓	
6	Amendment Review Process	WRU-IRERC Secretariat / members / Chairperson
	↓	
7	Notify the Principal Investigator	WRU-IRERC Secretariat
	↓	
8	Store Documents	WRU-IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Manage the Amendment Package.

- The amendment package is prepared by the PI.
- Upon receipt of the amendment package, the Secretariat of the WRU-IRERC should follow the receiving procedure in SOP (Management of Protocol Submission) and SOP - Procedure for Maintaining Confidentiality of WRU-IRERC Documents.
  - **Request for Amendment Memorandum** of the Protocol by the Principal Investigator on an existing and previously approved protocol. The memorandum should:
    - State/describe the amendment
    - Provide the reason for the amendment
    - State any untoward effects with original protocol
    - State expected untoward effects because of the amendment
  - **Original Amendment Submission Form**
    - Check for completeness and for the presence of the required signatures (Principal Investigator or Medical Advisor of the Institute, if applicable). See ANNEX on page 9.
  - **Protocol and Related Documents**
    - The amended version of the protocol and related documents should be provided.
    - The changes or modifications should be underlined or highlighted.

5.2 Notify the Chairperson of the WRU-IRERC

- Upon receipt of the amendment package, the Secretariat should inform the Chairperson of the Werabe University IRERC verbally, by e-mail, or in writing.
- Keep "Sent" and "Received" mail related to the notification of the Chairperson in the protocol file under the Correspondence section.
- Send the request for amendment memorandum and the protocol and related documents to the Chairperson within one working day of receipt by the Secretariat.
- Follow Werabe University IRERC SOP in preparing and distributing the documents.
- After review of the materials, the Secretary/Administrator in consultation with the Chairperson/Vice Chair will determine whether the protocol requires expedited or full review.

5.3 Determine whether expedited or full review.

- Protocol amendment which increase risk to study participants, as judged by the Chairperson, such as a change in study design, which may include but is not limited to:
  - additional work
  - any changes in inclusion/exclusion criteria

- ❖ change in method
- ❖ significant change in the number of subjects (Increase: if there are <20 subjects enrolled, change of 5 is significant; if there are >20 subjects enrolled, a change of 20% is significant – Decrease: if the decrease in the number of subjects alters the fundamental characteristics of the study, it is significant)

- ➢ If the Secretary/Administrator in consultation with the Chairperson/Vice Chair decides the protocol requires full WRU-IRERC approval, the Chairperson will indicate this decision on the Checklist, sign and date the form.
- ➢ The Secretariat places the protocol amendment request on the agenda for the next convened meeting.
- ➢ The following documents are distributed to each Werabe University IRERC member:
  - The amendment's revision documents to clearly identify each change.
  - requested changes to the consent form, if applicable
- ➢ If an amendment is received just prior to the WRU-IRERC meeting, the Chairperson may decide to review the amendment in full WRU-IRERC, even though the amendment may be expedited.

5.4 Expedited Review

- ➢ Refer to SOP for expedited review procedure.

5.5 Full Review by the WRU-IRERC

- ➢ Refer to SOP for full IRERC Review.

5.6 Protocol Amendment Review Process

5.6.1 Review amended protocols

- ➢ Use the process outlined in the Application Assessment Form (see WRU-IRERC SOP) to review amended protocols and protocol-related documents.

Note: recommendations for changes to the protocol and/or informed consent requested by WRU-IRERC Members in the minutes as "with modifications made by WRU-IRERC and will be communicated to the investigator.

- ➢ The Chairperson or designee calls for a vote on the proposed amendment to:
  - ❖ Approve the protocol amendment as is with no modification of the informed consent
  - ❖ Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with follow-up by the Chairperson

- ❖ Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full WRU-IRERC review
- ❖ Suspend the study, until further information is obtained
- ❖ Not suspend the study as currently approved, but request further information regarding the amendment and the effects of the amendments on the approved study
- ❖ Not approve the amendment request, stating the reason – but allow the study to continue as previously approved

- ➢ If the WRU-IRERC approves the protocol amendment, the Secretariat staff communicates this decision to the investigator within 10 working days.
- ➢ If the WRU-IRERC does not approve the protocol amendment, the Secretariat notifies the investigator in writing of the decision and the reason for not approving the amendment within 10 working days.
- ➢ If the WRU-IRERC votes to require modifications to any of the documents, or the protocol amendment, the Secretariat sends a written request about the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to WRU-IRERC The Secretariat completes a decision form after the WRU-IRERC has reached its decision..
- ➢ Keep the forms, minutes of the meeting relevant to the discussion and the decision reached by the WRU-IRERC as the official records of the amendment review process.

5.6.2 Verbal Communication of the Decision

The Secretariat notifies the Principal Investigator verbally after the Werabe University IRERC meeting and in writing as soon as possible, but no later than 10 working days following the review.

5.6.3 Preliminary Written Communication of the Decision

The Chairperson must send an electronic version or fax a copy of the Amendment Submission Form with his/her signature and date of approval to the Secretariat no later than one working day or whenever possible, but no later than 3 working days after the review has taken place.

5.6.4 Completion of the Amendment Submission Form

- ➢ The Chairperson must sign and date the original version of this form and return this to the Secretariat no later than 5 working days after the review.
- ➢ Addition of Amendment to the Protocol Number
  The Secretariat assigns a letter to the protocol number that corresponds to the number of the amendment.
- ➢ Record the amended protocol number on the form.
- ➢ The Secretariat signs and dates the original version of the form.

5.7 Notify the Principal Investigator.

- Send a signed and dated Amendment Submission Form to the Principal Investigator (P.I.) for their records no later than 10 working days.
- The P.I. should then provide a "clean" copy (*underlining and highlighting removed*) of the protocol and related documents as well as the "clean" electronic version (where applicable) to the Secretariat of the WRU-IRERC not later than 10 working days.

5.8 Store documents.

- Place the original completed documents, the "clean" version of the protocol and related documents in the protocol file with the other documents pertaining to the amendment.

6. GLOSSARY

Amendment protocol package	A package of the amended parts and related documents of the protocol, previously approved by the WRU-IRERC. In the course of the study, the PI may decide to make changes in the protocol.
Expedited approval	WRU-IRERC approval granted only by the Chairperson of the WRU-IRERC or a designated WRU-IRERC member (not the full WRU-IRERC for minor changes to current WRU-IRERC approved research activities and for research which involves no more than minimal risk, as stated in the SOP# AF 009.

7. ANNEX

ANNEX 1 AF 01-012 Protocol Amendment Submission Form

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
3. Code of Federal Regulation (CFR), 21 §56.110, The United States of America, 1998

ANNEX 1
AF 01-012/01.0

Protocol Amendment Submission Form

PROTOCOL NUMBER:	SUBMITTED DATE:
PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	
INSTITUTE:	Telephone:
APPROVED DATE:	NO. OF AMENDMENT (S):
REASON FOR THE AMENDMENT:	

TYPE OF AMENDMENT REQUESTED:

- ☐ EXPEDITED (Minor changes)
- ☐ FULL REVIEW BY WRU-IRERC (More than minor changes or that amendment "materially affects risks to subjects")

SIGNATURES:

Date:……..
Principal Investigator

COMMENTS: ☐ EXPEDITED (Minor changes) ☐ FULL REVIEWED

APPROVALS

_____ Date: ……...
Chairperson, WRU-IRERC

COMPLETION

_____ Date: ……..
Secretary, WRU-IRERC

PROTOCOL NUMBER: WRU-IRERC ☐☐☐/☐☐-☐☐

Table of Contents

1. PURPOSE

This procedure describes how continuing reviews of previously approved protocols are managed by the IRERC.

The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants. Continuing review of the study may not be conducted through an expedited review procedure, unless 1) the study was eligible for, and initially reviewed by, an expedited review procedure; or 2) the study has changed such that the only activities remaining are eligible for expedited review.

2. SCOPE

This SOP applies to conducting any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the WRU-IRERC may choose to review or monitor the protocols more frequently.

3. RESPONSIBILITY

It is the responsibility of the WRU-IRERC Secretariat to remind the WRU-IRERC and the principal investigators regarding study protocols that should be continuously reviewed. The WRU-IRERC is responsible for determining the date of continuing review.

The WRU-IRERC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of change of participants. The protocol informed consent documents and assent documents are examined to ensure that the information remains accurate.

The WRU-IRERC has the same options for decision making on a continuing review package as for an initial review package. The decision is made as *approved; approval on conditions, or Not Approved.*

4. FLOW CHART

No.	Activity	Responsibility
1	Determine the date of continuing review	WRU-IRERC
	↓	
2	Notify the study team	WRU-IRERC chairperson/ Secretariat
	↓	
3	Manage continuing review package upon re-	WRU-IRERC chairperson/ Secretariat

	ceipt	
	↓	
4	Notify the members of the WRU-IRERC	WRU-IRERC chairperson/ Secretariat
	↓	
5	Prepare meeting agenda	WRU-IRERC Secretariat and Chair-person
	↓	
6	Protocol review process	WRU-IRERC Secretariat, Members and Chairperson
	↓	
7	Store original documents	WRU-IRERC chairperson/ Secretariat
	↓	
8	Distribute documents to the study team	Secretariat

5. DETAILED INSTRUCTIONS

5,1 Determine the date of continuing review.

- Look through the document archives for the due date of continuing reviews.
- Plan for continuing review meeting at least two months ahead and as close as possible to the due date or the anniversary of the effectivity date (date of original approval) of the protocol.
- Consult the Chairperson for scheduling the IRERC meeting date.

5.2 Notify the principal investigator or the study team

- Inform the Study Team at least **two months in advance** of the due date for the continuing review by fax, post, e-mail or other appropriate means.
- Fax, mail or e-mail also a Continuing Review Application Form (see ANNEX 1) to the Study Team to fill up.
- Keep the informed notice in the correspondence file.
- Allow the Study Team sufficient time to collate the information and to prepare a report package required for the continuing review.

5.3 Manage continuing review package upon receipt.

- Receive a package of continuing review for each protocol prepared and submitted by the Study Team.
- Upon receipt of the package, the Secretariat of the WRU-IRERC should perform the following:

5.3.1 Initial and date the submission package

- See SOP for procedures on receipt of submitted packages.

5.3.2 Verify the contents of the package.

- Make sure that the contents of the package include:

- **Continuing Review Application Form**
  - Check for complete information and for the presence of the required signatures (IRERC Chairperson, if applicable, Research Director and Medical and Scientific Director of the University).
  - See ANNEX for the Continuing Review Application Form
- **Continuing Review Memorandum** with progress report
  - Summarize the progress of the protocol since the time of the last review.
  - Include information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants.
- **Current Informed Consent Document**
  - Both printed and electronic copies in the Local Area Network (where applicable) in the following drive:

❖ Verify electronic Informed Consent Document (where applicable).

- Check if the electronic copy for matches the hard copy submitted by the study team.
- Store the hard copy with the submitted documents.
- Clearly identify the document as the hard copy of the electronic informed consent document.
- Ensure that the version of the informed consent document is the most recently approved informed consent document.

5.3.3 Photocopy the package.

❖ Make sufficient copies (for both members and reviewers) of the original continuing review package in accordance with WRU-IRERC – Procedures for Maintaining Confidentiality of WRU-IRERC Documents.

5.3.4 Store the continuing review package.

❖ Store the original package in the protocol specific file.

5.4 Notify the Members of the WRU-IRERC.

➢ Distribute the protocol progress report and the informed consent document to the WRU-IRERC.

5.5 Prepare meeting agenda.

❖ See SOP# AF 028 for procedures on the preparation of meeting agenda.
❖ Place the review on the agenda for the meeting of the WRU-IRERC which coincides with the anniversary of the protocol effective date (original approval date).

- ❖ Distribute the materials to the WRU-IRERC members by electronic mail (e-mail), fax or by post, according to SOP# AF 024 (Procedures for Maintaining Confidentiality of WRU-IRERC Documents) at least one and a half to two weeks in advance of the scheduled meeting.
- ❖ Keep copies of "sent" e-mail, fax cover memos and/or letter accompanying posted materials in the Correspondence Section of the protocol specific file.
- ❖ Record and keep the WRU-IRERC members' response upon receipt of the agenda in the member correspondence file.

5.6 Protocol Review Process

5.6.1 Continuing Review Application Form

- Use the Continuing Review Application Form (see ANNEX 1 AF01-013) to guide the review and deliberation process.
- Sign and date the Continuing Review Application Form by the Chairperson/designee of the WRU-IRERC after a decision has been reached.
- The completed Continuing Review Applications Form is the official record of the decision reached by the IRERC for the protocol.
- Maintain and keep the form and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

5.6.2 Preliminary Communication of the Decision

- Verbal Communication of the Decision
  - The Chairperson notifies the secretariat verbally of the decision and the reasons for the decision as soon as possible after the meeting.
- Preliminary Written Communication of the Decision
  - The Chairperson must send an electronic version of the completed Continuing Review Application Form to the Secretariat within one working day whenever possible, but no later than 5 working days after the review has taken place.
  - The Secretariat, in turn, forwards this to the study team (by e-mail). "Sent" or "Received" e-mails are filed in the protocol file under "Correspondence".

5.6.3 Final Documentation and Communication of the Decision

- Complete the printed version of the Continuing Review Application/ Assessment Form by the Chairperson of the WRU-IRERC:
  - Sign and date the printed version of the form containing the decision and return this to the Secretariat.
  - Complete the process within 10 working days of the WRU-IRERC meeting.
- Complete the original version of the Continuing Review Application Form by the Chairperson:

- Sign and date the original version of the form.
- The Secretariat must sign and date the form.

5.7 Store original documents.

- Place the original completed documents with the other documents in the Continuing Review Package in the protocol file.

5.8 Distribute documents to the Study Team.

- Distribute copy version of the completed Continuing Review Application/Assessment Form to the Principal Investigator within 10 working days.

6. GLOSSARY

Approved Protocols Protocols that have been *approved* by the WRU-IRERC may proceed.

Protocols that have been *approved with conditions* by the WRU-IRERC may not proceed until the conditions set by the WRU-IRERC in the decision have been met. Protocols should be amended and submitted to the WRU-IRERC within two months for re-review.

7. ANNEX

ANNEX 1 AF 01-013: Continuing Review Application Form (2 pages)

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
AF 01-013
Page 1 of 2

Continuing Review Application Form

PROTOCOL No:-	ASSIGNED No.: ☐☐☐ / ☐☐-☐☐
PROTOCOL TITLE:-	
INSTITUTE MEDICAL ADVISOR:	

ACTION REQUESTED:
- ❑ Renew - New participant accrual to continue
- ❑ Renew - Enrolled participant follow up only
- ❑ Terminate - Protocol discontinued

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?
- ❑ NO
- ❑ YES (Describe briefly in attached narrative)

SUMMARY OF PROTOCOL PARTICIPANTS:
- _____ Accrual ceiling set by NRERC
- _____ New participants accrued since last review
- _____ Total participants accrued since protocol began

ACCRUAL EXCLUSIONS
- ❑ NONE
- ❑ MALE
- ❑ FEMALE
- ❑ OTHER (specify: _____)

IMPAIRED PARTICIPANTS
- ❑ None
- ❑ Physically
- ❑ Cognitively
- ❑ Both

HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?

- ❑ NO
- ❑ YES (Explain changes in attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?

- ❑ NO
- ❑ YES (Explain changes in attached narrative)

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE NRERC'S EVALUATION OF THE RISK/BENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PRO-TOCOL?

- ❑ NO
- ❑ YES (Discuss in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW?
- ❑ NO
- ❑ YES (Discuss in the attached narrative)

HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST NRERC APPROVAL?
- ❑ NO
- ❑ YES (Discuss in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE
☐ NONE ☐ IND ☐ IDE

IONIZING RADIATION USE (X-rays, radioisotopes, etc)
- ❑ None
- ❑ Medically indicated only

HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?
- ❑ NO
- ❑ YES (Identify all changes in the attached narrative)

HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
- ❑ NO
- ❑ YES (Identify all changes and provide an explanation of changes in the attached narrative)

ANNEX 1
AF 01-013
Page 2 of 2

CHANGE IN MEDICAL ADVISOR / INVESTIGATOR? ❑ NONE ❑ DELETE:…….. ❑ ADD: ……	HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST? ❑ NO ❑ YES (Append a statement of disclosure)

SIGNATURES:

_____Date: …….
WRU-IRERC Chairperson (if applicable)

_____ Date: …….
WRU-IRERC Secretary

_____ **WRU-IRERC**

Comment/Decision:

APPROVALS

_____ Date:……
Chairperson, WRU-IRERC Committee,

COMPLETION

_____ Date:……
Secretary, WRU-IRERC

Table of Contents

1. PURPOSE

The purpose of this SOP is to provide instructions on the review and follow-up, if appropriate, of Final Reports for any study previously approved by the WRU-IRERC

2. SCOPE

This SOP applies to the review and follow-up of the Final Report which is an obligatory review of each investigator's activities presented as a written report of studies completed to the WRU-IRERC.

Although WRU-IRERC provides a Study Report Form (ANNEX 1 AF 01-014) to the investigator, any mechanism (letter format, form provided by the Sponsor, etc.) may be used, provided that the information submitted is sufficient.

3. RESPONSIBILITY

It is the responsibility of the WRU-IRERC chairperson/secretariat to review the report for completeness before making copies for the Committee meeting.

4. FLOW CHART

No.	Activity	Responsibility
1	Activities before a WRU-IRERC meeting	WRU-IRECR chairperson/Secretariat
	↓	
2	Activities during the WRU-IRERC meeting	WRU-IRERC Secretariat / Members / Chairperson
	↓	
3	Activities after the WRU-IRERC meeting	WRU-IRERC chairperson/ Secretariat

5. DETAILED INSTRUCTIONS

5.1 Before each meeting

- See SOP (Management of Protocol Submission) for receiving and checking the report packages.
- The Secretariat reviews the submitted report and briefs to the Chairperson.
- Make a sufficient number of copies.

5.2 During the meeting

- Each member reviews a copy of the Final Report.
- The Chairman or designee entertains any discussion of the study.
- If appropriate to the discussions, WRU-IRERC member may call for consensus on whether to request further information or to take other action with the investigator.
- Summarize what action should be taken.

5.3 After the WRU-IRERC meeting

- Notify the investigator of the decision within 10 working days.
- Accept and file the Final Report, if no action is taken.
- Note the decision in the meeting minutes
- Consider the study as closed.
- Get a copy of the final report signed by the Chairperson or the designee.
- Send an acknowledged letter to the investigator within 10 working days.
- Archive the entire study protocol and the report.

6. GLOSSARY

---

7. ANNEX

ANNEX 1 AF 01-014 Study Report Form

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
AF 01-014

Study Report Form

Protocol No.:	Assigned No.: ☐☐☐ / ☐☐-☐☐
Protocol Title :	
Principal Investigator:	
Phone number:	E-MAIL ADDRESS :
Sponsor's Name	
Address:	
Phone :	E-MAIL :
Study site(s):	
Total Number of study participants :	NO. OF STUDY ARMS:
Number of participants who received the test articles:	
Study materials:	
Treatment form:	
Study dose(s):	
Duration of the study	
Objectives:	
Results: (Use extra blank paper, if more space is required.)	

Signature of P.I.:	Date:

Table of Contents

1. PURPOSE

To provide instructions for taking action and maintaining records that identify investigators/institutes who fail to follow the procedures written in the approved protocol or to comply with national / international guidelines for the conduct of human research, including those who fail to respond to the university IRERC's requests.

2. SCOPE

This SOP applies to all WRU-IRERC approved research protocols involving human subjects, animals, plant and the environment.

3. RESPONSIBILITY

The designated member of the Secretariat is responsible for collecting and recording the non-compliance list (AF 01-015).

4. FLOW CHART

No.	Activity	Responsibility
1	Noting protocol deviation / non-compliance / violation.	IRERC members and Chairperson
	↓	
2	Committee discussion and decision	IRERC members and Chairperson
	↓	
3	Notify the investigator	IRERC Secretariat, and Chairperson
	↓	
4	Keep records and follow up	IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1. Whenever protocol deviation / non-compliance / violation has been observed:

- Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the IRERC meeting.
- Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IRERC's request for information/action.

***Note*:** The Committee may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

5.2 The IRERC's Decision

- The chairperson notifies the investigator of the IRERC's action in writing, when the Board
  - suspends or
  - terminates approval of a current study or
  - refuses subsequent applications from an investigator cited for non-compliance.

5.3 Notify the investigator

- The IRERC Secretariat members record the IRERC's decision.
- Draft and type a notification letter.
- Get the Chairperson to sign and date the letter.
- Make **four copies** of the notification letter.
- Send the original copy of the notification to the investigator.
- Send a copy of the notification to the relevant national authorities and institutes.
- Send the third copy to the sponsor or the sponsor's representative of the study.

5.4 Keep records and follow up

- Keep the last copy of the notification letter in the "non-compliance" file.
- Store the file in the shelf with an appropriate label.
- Follow up the action after a reasonable time.

6. GLOSSARY

Deviation / Non-compliance / Violation	The IRERC monitors whether investigators do not perform the study in compliance with the approved protocol, ICH GCP, FMHACA regulations and/or fail to respond to the IRERC's request for information/action.

7. ANNEX

ANNEX 1 AF 01-015 Deviation /Non-Compliance/Violation Record

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
Form AF 01-015

Deviation / Non-Compliance / Violation Record

Application Number: ☐☐☐ / ☐☐ - ☐☐	Date:……
Study Title:	
Investigator	Contact No.:
Institution:	Contact No.:
Sponsor:	Contact No.:

☐ Deviation from protocol ○ Major ○ Minor	☐ Non-Compliance ☐ Violation
Description:	
IRERC's Decision:	
Actions taken:	Outcome:

Found by:…… Date:……	Reported by:…… Date:……

Table of Contents

1. PURPOSE

Since the university IRERC considers protection of the rights and welfare of the human subjects participating, biodiversity and environment in a research approved by the IRERC as its primary responsibility, Informed Consent documents reviewed by the IRERC may routinely contain the statement, "Questions regarding the rights of a research participant may be addressed to the IRERC Chairperson with the university's *address and/or phone number.* On some occasions the first contact a participant may have would be the IRERC Secretariat.

This procedure provides guidelines for dealing with and accommodating requests by participants regarding their rights as a participant in any approved research study.

2. SCOPE

This SOP applies to all requests concerning the rights and well-being of the research participants participating in studies approved by the WRU-IRERC.

3. RESPONSIBILITY

The Institute's policy designates the Chairperson of the IRERC as the person responsible for communicating with participants regarding their rights as study participants. Delegation of this responsibility to another IRERC member is acceptable as long as the delegation is documented (in writing). Delegation to non- IRERC members is not permitted.

It is the responsibility of all Staff and IRERC members acting on behalf of the university IRERC to facilitate participant requests within the scope of their responsibilities.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive the request	IRERC Members and Secretariat
	↓	
2	Take action	IRERC Members and Chairperson
	↓	
3	File the request document	IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Receive the request.

- The IRERC staff or member receives the inquiry or requests from research participants.
- Record the request and information in the request record form (Form ANNEX 1 AF 01-016 see)
- Communicate with the IRERC about study participant rights for instruction.
- Refer the inquiry to the IRERC Chairperson in writing.
- University staff may provide assistance in contacting the Chairperson, but will not provide comments/opinions about the inquiry.
- The Chairperson shall
  - Document the communication for the IRERC study file,
  - Request follow-up information,
  - Provide advice as required,
  - Inform the other IRERC members about the inquiry,
  - Follow-up at the next IRERC meeting. or
  - Delegate these tasks to IRERC Secretariat or members.

5.2 Take Action

- Investigate the fact.
- Record information and any action or follow-up taken in the form AF 01-016.
- Sign and date the form.
- Report to the IRERC about the action taken and the outcomes.

5.3 File the request document

- Keep the record form in the "response" file.
- Keep a copy in the study file.

- Store the file in the appropriately labeled shelf.

6. GLOSSARY

Participants' rights	Recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world. … It is essential … that Human Rights should be protected by the rule of law.

7. ANNEX

ANNEX 1 FF 01-016 Request Record Form

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
Form AF 01-016

Request Record Form

Date Received:	
Received by :	
Request from :	❑ Telephone call No……... ❑ Fax No……..…. ❑ Mailed letter / Date…… ……. ❑ E-mail / Date…… ❑ Walk-in / Date / Time…….. ❑ Other, specify …….
Participant's Name:	
Contact Address: Phone:	
Title of the Partici-pating Study	
Starting date of par-ticipation :	
What are requested?	
Action taken: Outcome:	

Table of Contents

1. PURPOSE

This procedure describes how the university IRERC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the IRERC, Data Safety Monitoring Board (DSMB) (if applicable), Scientific Director, sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. SCOPE

This SOP applies to any study approved by the university IRERC that is being recommended for termination before its scheduled completion.

3. RESPONSIBILITY

It is the responsibility of the IRERC Chairperson to terminate any study that the IRERC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The Secretariat is responsible for management of the termination process.

4. FLOW CHART

No.	Activity	Responsibility
1	Receive recommendation for study termination	Investigator and IRERC Secretariat
	↓	
2	Review and Discuss the Termination Package	IRERC members, Secretariat and Chairperson
	↓	
3	Notify the Principal Investigator	IRERC Secretariat
	↓	
4	Store the Protocol Documents	IRERC Secretariat
	↓	
5	Inactivate the Protocol Document	IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Receive recommendation for study termination.

- Receive recommendation and comments from DSMB, IRERC members, Scientific Director, Sponsor or other authorized bodies for study protocol termination.
- Inform the principal investigator or the study office to prepare and submit a protocol termination package.
- Receive the study protocol termination package prepared and submitted by the principal investigator or the study office.
- Verify the contents of the package for inclusion of:
  - Request for Termination Memorandum (AF 01-017, see ANNEX 1 of this SOP.)
    - The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.
  - Original Continuing Review Application Form (AF 01-013), see ANNEX 1 of SOP# FE 013.
    - Termination is indicated under “Action Request”.
    - Completeness of the information, including accrual data since the time of the last continuing review.
    - Presence of the required signatures (Principal Investigator).
- Initial and date the package upon receipt.

5.2 Review and discuss the Termination Package.

- Notify the Chairperson regarding the recommendation for study protocol termination.
- Send a copy of the termination package to the Chairperson within one working day upon receipt.
- The Chairperson reviews the results, reasons and accrual data.
- The Chairperson calls for an emergency meeting to discuss about the recommendation.

- The Chairperson signs and dates the Continuing Review Application Form in acknowledgment and approval of the termination.
- The Chairperson returns the form back to the Secretariat within 5 working days of receipt of the package.
- The Secretariat reviews, signs, and dates the Continuing Review Application Form indicating that the termination process is complete.

5.3 Notify the Principal Investigator.

- Make a copy of completed Continuing Review Application Form
- Send the copy to the principal investigator for their records within 7 working days.

5.4 Store the protocol documents.

- Keep the original version of the request memorandum for termination & the original version of the Continuing Review Application Form in the Protocol file.
- Send the file to archive.
- Store the protocol documents indefinitely.

5.5 Inactivate the protocol documents.

- Place the study protocol into the ***inactive*** protocol folder in the computer records under the following directory: F:\studyfiles\inactive protocols

6. GLOSSARY

7. ANNEX

ANNEX 1	FF 01-017	Termination Memorandum

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
AF 01-017/01.0

Study Termination Memorandum

PROTOCOL NUMBER:		ASSIGNED No.: ☐☐☐ / ☐☐-☐☐	
PROTOCOL TITLE:			
PRINCIPAL INVESTIGATOR:			
PHONE :		E-MAIL:	
INSTITUTE:			
SPONSOR:			
IRERC APPROVAL DATE:		DATE OF LAST RE-PORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICI-PANTS:		NO. ENROLLED:	
SUMMARY OF RE-SULTS			
ACCRUAL DATA:			
P.I.SIGNATURE:		DATE:	

Table of Contents

1. PURPOSE

The purpose of this SOP is to provide instructions on the review and follow-up reports of Serious Adverse Events (SAE) and unexpected event for any active study approved by the WRU-IRERC. The **SAE** must be reported by the investigators or sponsors within 10 working days after the incident occurred and unexpected events should be included in the continuing review report submitted to WRU-IRERC.

Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the WRU-IRERC to ensure adequate protection of the welfare of the study participants and the environment. The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of subjects in the study.

2. SCOPE

This SOP applies to the review of SAE and unexpected events reports submitted by investigators, **Data Safety Monitoring Board (DSMB**), sponsor, local safety monitor, IRERC members or other concerned parties.

3. RESPONSIBILITY

The primary responsibility of the IRERC is to review and address **SAE** and unexpected events involving risks to subjects or others as well as ethics complaints. In addition, the Committee is authorized to offer mediation under appropriate circumstances. IRERC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements. The IRERC Secretariat is responsible for first screening the assessment of the reports and seeing whether they need a review of full Committee, Chairperson, other qualified IRERC members or experts.

4. FLOW CHART

No.	Activity	Responsibility
1.	SAE related activities before an IRERC meeting	IRERC Secretariat, members
	↓	
2.	Review and determine the review channel	IRERC Secretariat,
	↓	
3.	Review and discuss	IRERC members and Chairperson
	↓	
4.	Decide what action should be taken.	IRERC members and Chairperson
	↓	
5.	Inform investigator or clinical trial office	IRERC Secretariat and Chairperson

5. DETAILED INSTRUCTIONS

5.1 Before each IRERC meeting

5.1.1 Review and determine the review channel

- IRERC Secretariat or members review the reporter's assessment (SOP ANNEX: AF 01-018 and AF 02-018) to determine whether the report requires review by full committee or by the Chairperson or other qualified IRERC member(s).

5.1.2 Criteria for the review

- The **review criteria** are as follows:
  - Assessment of adverse experience is unknown or unlikely
    - Report is forwarded to the Chairperson for review and determination if report should be reviewed at the convened meeting by full committee.
  - Assessment of adverse experience is possibly caused by, or probably caused by the investigational product.
    - The report is added to the agenda for review at a convened meeting by full committee.
  - An adverse experience/Investigational New Drug (IND) Safety Report has been previously seen by full committee but being resubmitted by another investigator participating in the multi-study site (as part of a multi-center/site study).
    - This notification does not require full committee review.
    - Reviewed by the Chairperson or other qualified IRERC members and secretariat

5.2 During the IRERC meeting

5.2.1 Review and discuss

- After reading and reviewing the report, the Chairperson or designee entertains discussion on the study and similar adverse experiences or advisories.
- If appropriate to the discussions, the Chairperson or another committee member may call for a consensus on whether to:

- ❖ *Request an amendment to the protocol or the consent form.*
- ❖ *Request further information.*
- ❖ *Suspend or terminate the study.*

5.2.2 Decide what action should be taken.

- ➢ If any of the above *actions are taken*, the IRERC Secretariat or designee notifies the investigator of the action taken.
- ➢ If the IRERC *takes no action*, a notation is made in the minutes and the study is allowed to continue.

5.2.3 Inform investigator or clinical trial office

- ➢ The IRERC secretariat member drafts a formal letter to the investigators or the clinical trial office to notify them of the action they should take according to the IRERC decision.
- ➢ Get the Chairperson to approve, sign and date the letter.
- ➢ Send the letter and record the delivery date.

6. GLOSSARY

Adverse Event	Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Adverse Drug Reaction	In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship can not be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.
IND	**Investigational New Drugs** means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.

SAE (Serious Adverse Events)	The adverse event is SERIOUS and should be reported when the patient outcome is: **Death** - Report if the patient's death is suspected as being a direct outcome of the adverse event. **Life-Threatening** - Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death. *Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.* **Hospitalization** (initial or prolonged) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. *Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.* **Disability** - Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. *Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.* **Congenital Anomaly** - Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. *Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.* **Requires Intervention to Prevent Permanent Impairment or Damage** – Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient. *Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.*
Unexpected ADR	Unexpected **Adverse Drug Reaction** is an adverse reaction, the nature or severity of which is not consistent with the informed con-

	sent/information sheets or the applicable product information (e.g., investigator's brochure for the unapproved investigational product or package insert / summary of product characteristics for an approved product.

7. ANNEX

ANNEX 1	AF 01-018	Serious Adverse Event Report
ANNEX 2	AF 02-018	Unexpected Adverse Drug Reaction Report

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
AF 01-018/01.0

Serious Adverse Event Report

Principal Investigator:……..	Application No: ☐☐☐ / ☐☐ - ☐☐
Study Title:……	Protocol No.:
Name of the study medi-cine/device……..……	Report Date (dd/mm/yy):…… ☐ Initial ☐ Follow-up Onset dated (dd/mm/yy): ……
Sponsor:……	Date of first use (dd/mm/yy): ……..

Subject's initial/number:	Age:	☐ Male ☐ Female

Subject's history:	Laboratory findings:

SAE:	Treatment: Outcome: ☐ resolved ☐ on-going

Seriousness: ☐ Death ☐ Life Threatening ☐ Hospitalization –○ initial ○ prolong ☐ Disability / Incapacity ☐ Congenital Anomaly ☐ Other……	Relation to ○ Drug ○ Device ○ study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related ☐ Unknown

Changes to the protocol recommended?	☐ No ☐ Yes , attach proposal
Changes to the informed consent form recommended?	☐ No ☐ Yes , attach proposal

Reviewed by:…… Com-ment:…… …… ……	Date:…… Action:……

ANNEX 2
AF 02-018

Unexpected Adverse Event Summary Report

Principal Investigator: …….. Application No ☐☐☐ / ☐☐ - ☐☐
Study Title: …….. Protocol No.: ……
Name of the studied medicine/device……..…… This report covers the period :
Sponsor: ……... From……To……

#	Description of Unexpected Adverse Events	Date of Event (D/M/Y)	Date start and end of Tx (D/M/Y)	F or M	Initial	Age (Y)	Serious Yes No	Related to Study Yes No	Connected medication	Intervention
							☐ ☐	☐ ☐		
							☐ ☐	☐ ☐		

Comment:

Reviewed by: …….…… Date (D/M/Y): …….

Table of Contents

1. PURPOSE

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of its performance or compliance to Good Clinical Practice (GCP) and other ethical guidlines.

2. SCOPE

This SOP applies to any visit and/or monitoring of any study sites as stated in the IRERC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

3. RESPONSIBILITY

It is the responsibility of the IRERC to perform or designate some qualified agents to perform on its behalf on-site inspection of the research projects it has approved.

The IRERC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

4. FLOW CHART

No.	Activity	Responsibility
1	Selection of study sites ↓	IRERC members and Chairperson
2	Procedures before the visit ↓	IRERC members and/or representative
3	Procedures during the visit ↓	IRERC members and/or representative
4	Procedures after the visit ↓	IRERC members and/or representative
5	Present the findings to the Full committee	IRERC members and/or representative

5. DETAILED INSTRUCTIONS

5.1 Selection of study sites

- Review periodically the database files of the submitted/approved study protocols.
- Select study sites needed to be monitored based on the following criteria:

- ❖ When the Werabe University IRERC has never approved the principal investigator for a research project, a study visit should be planned for at the appropriate time after the study starts.
- ❖ New study sites

- ➢ Reports of remarkable serious adverse events
- ➢ Number of studies carried out at the study sites.
- ➢ Frequency of protocol submission for IRERC review
- ➢ Non-compliance or suspicious conduct
- ➢ Frequently fail to submit final reports

5.2 Before the visit

The IRERC representatives will

- ➢ Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate a time for the site evaluation visit.
- ➢ Make the appropriate travel arrangements.
- ➢ Review the IRERC files for the study and site,
- ➢ Make appropriate notes, or
- ➢ Copy some parts of the files for comparison with the site files.

5.3 During the visit

- ➢ Get a checklist AF 01-019 (ANNEX 1).
- ➢ The IRERC representatives will
  - ❖ Review the informed consent document to make sure that the site is using the most recent version,
  - ❖ Review randomly the subject files to ensure that subjects are signing the correct informed consent,
  - ❖ Observe the informed consent process, if possible,
  - ❖ Observe laboratory and other facilities necessary for the study at the site.

- ❖ Review the IRERC files for the study to ensure that documentation is filled appropriately.
- ❖ Collect views of the study participants.
- ❖ Debrief the visit report/comments.
- ❖ Get immediate feed back.

5.4 After the visit

The IRERC representative will:

- ➢ Write a report/comment (use the form AF 01-019, see ANNEX 1) within 2 weeks describing the findings during the audit
- ➢ Forward a copy of the site visit to the 'site monitoring' file for Full committee review.
- ➢ Send a copy of the report to the site for their files, and
- ➢ Place the report in the correct site files.

5.5 Present the inspection results to the committee

- ➢ Consult with the IRERC secretariat.
- ➢ Schedule the presentation in the meeting agenda.
- ➢ Present the results of on-site inspections to the committee.

6. GLOSSARY

IRERC representatives	Many IRERC rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to IRERC.
Monitoring visit	An action that IRERC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

7. ANNEX

ANNEX 1 AF 01-019: Checklist of a Monitoring Visit

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
AF 01-019/01.0

Checklist of a Site Monitoring Visit

Application No.: ☐☐☐ / ☐☐ - ☐☐	Date of the Visit (dd/mm/yy):
Study Title:	
Principal Investigators:	Phone:
Institute:	Address:
Sponsor:	Address:
Study site (setting):	Address:
Total number of expected subjects:	Total subjects enrolled:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Are informed consents recent? ☐ Yes ☐ No	Comment:
Any adverse events found? ☐ Yes ☐ No	Comment:
Any protocol non-compliance /violation? ☐ Yes ☐ No	Comment:
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:
Duration of visit: …….hours	Time started (hh:mm): ……. Time finished (hh:mm): ……..

Any additional/detail comments:	
Name of IRERC members/ representatives and accompanies	
Completed by: …….. Signature: …….	Date (dd/mm/yy): …….....

Table of Contents

1. PURPOSE

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of *Werabe University* IRERC meetings.

2. SCOPE

This SOP applies to administrative processes concerning the preparation of the agenda for all regular IRERC meetings, divided into three stages: before, during and after the meeting.

3. RESPONSIBILITY

It is the responsibility of the Secretariat staff to prepare the agenda for the IRERC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the agenda and the minutes sent to him/her.

4. FLOW CHART

No.	Activity	Responsibility
1	Before each committee Meeting	Administrative staff IRERC Secretariat
	↓	
2	During the Meeting	IRERC Secretariat, Members and Chairperson
	↓	
3	Voting	IRERC Members without conflict of interest / Chairperson
	↓	
4	After the committee Meeting	IRERC Secretariat / Chairperson
	↓	
5	Preparing the Meeting Minutes	IRERC Secretariat staff / Chairperson

5. Detailed instructions

5.1 Before each Board meeting

5.1.1 Check for filled up forms for completeness.

- An administrative staff member:
  - Reviews the new study application for completeness.

- Documents the review by completing the appropriate checklist. If incomplete, the staff member attempts to obtain the information from the person who submitted the application package.

5.1.2 Consider the appropriate review channel of each protocol

- Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel.
  - SOP# WRU-IRERC 009 for Initial Review of Submitted Protocols
  - SOP# WRU-IRERC 010 for Expedited Review
  - SOP# WRU-IRERC 011 for Review of Resubmitted Protocols
  - SOP# WRU-IRERC 012 for Review of Protocol Amendments
  - SOP# WRU-IRERC 013 for Continuing Review of Study Protocols
  - SOP# WRU-IRERC 014 for Review of Final Reports
  - SOP# WRU-IRERC 015 for Review of Intervention in Protocol Deviation / Non-compliance / Violation
  - SOP# WRU-IRERC 016 for Review of Response to Research Participants' Requests
  - SOP# WRU-IRERC 017 for Review of Protocol Terminations

5.1.3 Assign protocol reviewers

- Assign at least two reviewers (for technical and ethical reviews) for initial review of each submitted protocol by the IRERC Secretariat.
  - *The technical reviewer prepares a brief protocol summary, including a statement of the purposes, the evaluation parameters, and the methodology of the protocol. The ethical reviewer examines the consent form for completeness of information and protection of human subjects.*
- The assignment should be based on the information provided in SOP# WRU-IRERC 005 and WRU- IRERC 006.

5.1.4 Prepare meeting agenda

Schedule the review as soon as possible after submission, either at the time of the next scheduled meeting or ***within 4 weeks after submission.***

- Arrange extra IRERC meetings to accommodate protocol reviews.
- Consult the Chairperson to schedule the meeting date.
- Prepare the meeting agenda, according to the format shown in ANNEX 1 (AF 01-020).
- Schedule protocols in the agenda on a first-come first-serve basis.
- Include "request to appeal" items in the agenda, upon receipt of the correspondence, preferably during the next convened committee meeting.
- Prepare invitation letters to the reviewers and the members.
    - Allow at least 3 weeks for the review process.
- Specify the due date for the return of comments.
- Include a protocol assessment form (AF 01-008) with the protocol package along with the invitation letter, a response form and the meeting agenda.
- Write down the running number of the protocol in the square boxes at the bottom right corner of the form AF 01-008.
- Sign the second page of the form AF 01-008.
- Prepare the package for delivery.
- Record the name of the assigned reviewers in the appropriate database or the review assignment file.

5.1.4 Distribution of Protocol Packages to the IRERC Members

- Keep in mind Procedure for Maintaining Confidentiality of IRERC documents (SOP#WRU-IRERC 024) when preparing and distributing documents.
- Distribute copies of the protocol submission packages to the assigned reviewers and IRERC members by either electronic mail (if electronic submission protocols), telefax, or by post *two weeks in advance of the scheduled meeting.*

- Keep copies of "sent" e-mail, fax cover memos and/or letters accompanying posted materials in the Correspondence section of the respective protocol file.
- Verify (verbally, by e-mail, by fax or by mail) with the members whether the protocol packages are received.

5.1.5 Prepare for the meeting

- Make a room reservation on the schedule meeting date and time.
- Make sure that the room, equipment and facilities are available in good running condition and cleaned for the meeting day.

5.2 During the meeting

- The IRERC may allow investigators, project managers, sponsors, etc., to attend the portion of the committee meeting related to their studies.
- At the discretion of the Chairman, guests may be allowed to observe the Board meetings.
- These guests may include a potential client, students, etc.
- Guests are required to sign a confidentiality agreement (AF 02-004, see ANNEX 2 of WRU-IRERC 004).
- The Secretariat reports on the minutes of the previous meeting and presents the agenda for discussion.
- The Secretariat records the discussions and the decisions made during the meeting.
- The Chairperson may inform members and attendees of the rules being followed during meetings. .
- The meeting proceeds in the order organized in the agenda; however, the Chairperson may allow some switching depending on the situation.
- The approval process starts when one of the reviewers gives a brief about the study and presents his/her observations and comments.
- In case the reviewer cannot be present during the meeting, a member of the Secretariat or a WRU-IRERC member may give the briefing about the study by reading the comments and evaluation of the reviewers.

- ❖ The other members give their comments right after the presentation and the discussion about the study takes place.
- ❖ Investigators may be allowed to present their projects in brief and clarify any questions the IRERC members may have.

5.3 Voting

- ❖ In order to avoid conflict of interest, only those committee members who are independent of the investigator and the sponsor of the trial will vote on the research-related matters.
- ❖ All voting will take place after the observers / presenters / committee members with a conflict of interest leave the meeting room.
- ❖ The Chair determines if the number of voting committee members is sufficient to constitute a quorum and proceeds accordingly.
- ❖ A committee member makes a motion to recommend action on a protocol or issue being discussed.
- ❖ The motion is seconded and voting takes place.
- ❖ A motion is carried out once the majority of WRU-IRERC members vote in favor of the motion.
- ❖ If decisions cannot be reached based on the majority vote (i.e all options get equal vote) a decision on which the chairperson is constituted will be the final decision option.

N.B consensus and re-discussions should always be sought when voting and/or decision discordance happen. Additionally, in case of highly ethical concerned studies the decision should be preferred to avoid risk and protect participants.

5.4 After the Board meeting,

- ❖ As soon as possible after each meeting, a copy of the minutes is sent to a senior administrative staff member for quality control and review.
- ❖ The senior administrative staff member indicates review by signing and dating the minutes.
- ❖ Following staff review, the minutes are given to the Chairperson or designee for review and approval.
- ❖ The Chairperson indicates approval by signing and dating the minutes.
- ❖ A member of the administrative staff maintains the official copies of the minutes in accordance with departmental archiving procedures.

5.5 Preparing the Minutes and the Decision Forms

5.5.1 Assembling the meeting minutes and the decision form

- ➢ Use the format as shown in ANNEX 2 (Form AF 02-020) to write a minute.

- Compose the summary of each meeting discussion and decision in a concise and easy-to-read style.
- Make sure to cover all contents in each particular category.
- Check spelling, grammar and context of the written minutes.
- Finish the minutes within two weeks after the meeting.

5.5.2 Contents of the IRERC Meeting Minutes

- The official minutes of the committee meeting consist of, but are not limited to, the following:
  - Name of person preparing the minutes
  - Location where the meeting was held (city, state)
  - Meeting date
  - Attending committee members and guests
  - Agenda items
  - Individual serving as Chairperson of the meeting
  - Determination of a duly constituted quorum by the Chairperson to proceed with the meeting
- Requirements for each study or activity requesting Approval:
  - Sponsor's name;
  - Protocol number/date/version of protocol, when available;
  - Investigator's name;
  - Advertisements;
  - Name of committee member presenting study materials;
  - Discussion as deemed appropriate by the Chairperson
  - Number of members voting 'yes', 'no', or 'abstention'
  - Number of abstentions and the reason for the abstention;
  - Reference to the investigator approval letter that lists all changes requested by the committee
  - Determination of the next requested continuing review.
- Requirements for each study or activity requesting Expedited Review:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;
  - Lists of expedited approval requests and outcomes.
- Required for each Continuing Review Report:
  - Sponsor's name;
  - Protocol number, if applicable;
  - Investigator's name;

- Indication of the committee's determination to continue, terminate, or amend the study;
- Lists of recommendations or actions to be taken up with the investigator, if applicable.

➢ Required for each Adverse Event notification and Final Report:
- Sponsor's name;
- Protocol number, if applicable;
- Investigator's name;
- Actions deemed appropriate by the committee's review.

➢ Required for Termination of Approval:
- Sponsor name's;
- Protocol number, if applicable;
- Investigator's name; reason for termination

5.5.3 Approval of the minutes and the decision

➢ Check the correctness and completeness of the minutes.
➢ Get the Chairperson of the WRU-IRERC to sign and date the relevant sections of the minutes of the WRU-IRERC meeting and the decision form.

5.5.4 Filing the minutes

➢ Place the original version of the minutes and the signed decision form in the IRERC files for the specific protocol.
➢ Place all correspondence in the appropriate file.
➢ Place a copy of the approval letter in the "minutes" file to inform the Committee Members of the Expedited approval.
➢ Document the appeal requests in the meeting minutes.

5.5.5 Distributing the minutes and the decision

➢ Send a copy of the relevant sections of the minutes and the decision form to the applicants for their records by mail or other means.
➢ Send the approved minutes to the IRERC members.
➢ Send the decision of the IRERC for an appeal request to the person concerned in writing.
➢ Record the receivers and the delivery date.

6. GLOSSARY

Agenda	A list of things to be done; a program of business at a meeting
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Quorum	Number. of IRERC members required to act on any motion presented to

	the Board for action.
Majority vote	A motion is carried out if one half plus one member of the required quorum votes in its favor.

7. ANNEX

ANNEX 1	AF 01-020	Agenda format
ANNEX 2	AF 02-020	Form of IRERC Meeting Minutes

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

AF 01-020/01.0

Format of an Agenda

Agenda of the IRERC **Meeting**
No……./year
Location of the meeting
Meeting Date
Meeting time

The committee meeting will proceed in the following sequences:

Period 1 Issues to be informed to the members.

Period 2 Approval of the last meeting minute

Period 3 Protocol Presentation, Review, Discussion and Voting

Period 4 Issues to be reported for Consideration

Period 5 Other issues of interest to the members

Program of Studies Protocols to be considered:

Time	Project	Investigator/Institute	Reviewers

ANNEX 2

AF 02-020/01.0

Form of IRERC Meeting Minutes

Meeting No.:	Meeting date:
☐ Regular meeting	☐ Emergency meeting
Location where the meeting is held (city, state)	
Agenda items:	
Starting time:	Adjourned time (if applicable):

Attending IRERC members and guests:

1. 8.
2. 9.
3. 10.
4. 11.
5. 12.
6. 13.
7. 14.

Individual serving as Chairman of the meeting:

Determination of a duly constituted quorum by the Chairman to proceed with the meeting.

Prepared by:…… Reviewed by:……..

Date: …… Date: ……..

Approved by: ……

Date: ……..

Table of Contents

1. PURPOSE

The purpose of this SOP is to identify the administrative process for preparing for an emergency meeting and to provide instructions on the review and approval of study activities using the Emergency Meeting Procedure.

2. SCOPE

This SOP applies to emergency IRERC meetings. Emergency meetings may be scheduled to review/approve safety / life threatening issues, new studies, additional investigators, continuing review, protocol amendments and other study activities that require full committee review.

For routine medical research studies, a physician may be invited to attend the meeting to provide necessary detailed information on medical care given to participants.

3. RESPONSIBILITY

The IRERC Chairperson may call for an emergency meeting as appropriate.

4. FLOW CHART

No.	Activity	Responsibility
1	Before the committee meeting	IRERC Secretariat
	↓	
2	During the meeting	IRERC Members and Chairperson
	↓	
3	After the meeting	IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Before the committee meeting

- Decide to call an emergency meeting based on the following criteria:
  - Urgent issues (if delay will affect or have impact to the public benefit, national economics, etc.)
  - Occurrence of unexpected serious adverse events.
  - A matter of life and death
  - Other appropriate reasons.
- Contact and inform IRERC members, including the invited persons about the meeting.
  - At least one scientific member

- ❖ A non-scientific member
- ❖ A member with expertise on the item to discussed
- ❖ For routine medical research studies, a physician may be invited.

- ➢ Invite at least one expert to look at the document, as appropriate.
- ➢ Set up a conference call by dialing the number…….……. and enter the profile number and pass code, if applicable.
- ➢ Prepare packets for distribution to the members.
- ➢ Attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendant confirmation form to the packets.
- ➢ Refer to the relevant SOPs (i.e. SOP # WRU-IRERC 009 - Initial Review of Application Protocol, SOP# WRU-IRERC 010 - Expedited Review, SOP# WRU-IRERC 013 - Review of Protocol Amendments, etc.)

5.2 During the meeting

- ➢ Determine if there is a quorum.
- ➢ Follow the related SOPs.,
  - ❖ SOP# WRU-IRERC 003 for Constituting an Ethics Committee
  - ❖ SOP# WRU-IRERC 007 for Management of Protocol Submission
  - ❖ SOP# WRU-IRERC 008 for Use of Assessment Form
  - ❖ SOP# WRU-IRERC 009 for Initial Review of Submitted Protocols
  - ❖ SOP# WRU-IRERC 010 for Expedited Review
  - ❖ SOP# WRU-IRERC 011 for Review of Resubmitted Protocols
  - ❖ SOP# WRU-IRERC 012 for Review of Protocol Amendments
  - ❖ SOP# WRU-IRERC 013 for Continuing Review of Study Protocols
  - ❖ SOP# WRU-IRERC 014 for Review of Final Reports
  - ❖ SOP# WRU-IRERC 015 for Review of Intervention in Protocol Deviation / Non-compliance / Violation
  - ❖ SOP# WRU-IRERC 016 for Review of Response to Research Participants' Requests
  - ❖ SOP# WRU-IRERC 017 for Review of Protocol Terminations
  - ❖ SOP# WRU-IRERC 020 for Preparation of Meeting, Agenda, Minutes and Action letters

- ❖ SOP# WRU-IRERC 029 for Review of New Medical Device Studies

5.3 After the meeting

- ➢ Follow the related SOPs in 5.2.

6. GLOSSARY

Emergency meeting	A WRU-IRERC meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full WRU-IRERC review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion and voting portions of the meeting. Emergency meetings may be held via teleconference, if applicable.

7. ANNEX

---

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

Table of Contents

1. PURPOSE

The purpose of this SOP is to ensure proper completion, distribution and filing of verbal and written communication and other study-related or process-related information done with investigators, sponsors, volunteer subjects, institutes and/or relevant government agencies (FDA, etc.).

2. SCOPE

This SOP applies to all communicating activities related to the studies under the approval of the *Werabe University* IRERC.

3. RESPONSIBILITY

It is the responsibility of all IRERC administrative staff, Committee members, secretariat and chairperson conducting activities with *Werabe University* IRERC to complete a written communication record for telephone or interpersonal discussions related to past, present and/or future studies and/or processes involving the IRERC.

4. FLOW CHART

No.	Activity	Responsibility
1	Communication recording mechanism	IRERC secretariat / members / Chairperson
	↓	
2	Contents of a written record	IRERC secretariat / members / Chairperson
	↓	
3	Distribution of the record	IRERC secretariat / members / Chairperson

5. DETAILED INSTRUCTION

5.1. Communication recording mechanism

- Individuals may utilize different communication recording mechanisms that may be handwritten, typed or computer-generated.

5.2. Contents of a written record

- The record should contain, but is not limited to, the following information:
  - Date of communication
  - Study information, i.e., sponsor, protocol number, investigator, etc.
  - Name of person contacted
  - Contact address, telephone number, and e-mail

- Summary of the communication made
- Notation of any follow-up necessary
- Signature of individual completing record

5.3. Distribution of the record

- Upon completion of the records, the individual distributes copies to:
  - The study file
  - Others, as appropriate
  - Secretariat or administrative staff for filing

6. GLOSSARY

Communication	A verbal and written message conveying process for study-related or process-related information done with investigators, sponsors, volunteer subjects, institutes and/or relevant government agencies (FDA, etc.).

7. ANNEX

Annex 1 AF 01-022 Communication Record Form

8. REFERENCE

8.3 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

8.4 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1
AF 01-022/01.0
Page 1 of 1

Communication Record Form

		Date:	
Means of Contact	☐ Telephone ☐ Fax ☐ e-mail ☐ In Person		
Status of Contact	☐ In coming call ☐ Outgoing call		
Person contacted:	☐ Reviewer ☐ IRERC member ☐ Chairperson ☐ Secretariat ☐ Sponsor ☐ Investigator ☐ Media ☐ Subject ☐ Institute ☐ Regulatory		
Name:			
Telephone No.		Fax No.	
e-mail			
Protocol No.			
Title :			
Communication Issues / Reason for making contact:			
Follow-up Action :	☐ Return call ☐ will call again ☐ None ☐ See notes ☐ Circulation ☐ Confidential		
Summary of Communication:			
Recorded by:			

Table of Contents

1. PURPOSE

To provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the IRERC of *Werabe University*

2. SCOPE

This SOP applies to all active study files and their related documents that are maintained in the IRERC office.

3. RESPONSIBILITY

It is the responsibility of IRERC Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

4. FLOW CHART

No.	Activity	Responsibility
1	Organize the contents of the active study files	IRERC Secretariat
	↓	
2	Maintain the active study files	IRERC Secretariat

5. DETAILED INSTRUCTION

5.1 Organize the contents of the active study files

- Get the master copy of the study files.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum, the following documents:
  - Original applications and any updates received during the study.
  - Investigator's brochures or similar documents
  - Approval letters and other correspondence sent to the investigator.
  - Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
  - Adverse experience reports or IND safety reports received
  - Continuing review reports
- Use a folder with the following on the cover:
  - The name of the sponsor

- The protocol number
- The number assigned by the IRERC Secretariat. Put the following into each folder with the following information:
- Sponsor with address and contact phone/e-mail id of contact person, protocol number, investigator name (with address, e-mail, telephone and fax) and title
- Application form of the IRERC Protocol, Case Report Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data, any other material submitted by the investigator
    - Correspondence
    - Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
    - Revisions/Amendments
    - Adverse Events
    - Continuing Review, if applicable
    - Final report

5.2 Maintain the active study files

- Assign the approved study files with unique identifiers (on a sheet of paper) established by a member of the IRERC Secretariat
- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package.
- Keep all active and potential study packages in a secure file cabinet.
    - Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the IRERC.
    - Send all closed study files to archive.
    - Store the closed study files for ***at least 5 years*** after the study closure.

Note: For studies with multiple study sites, a member Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.

6. GLOSSARY

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved

	study.
CRF	Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.
IND	Investigational New Drug is a drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites.
ICD	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Master file	A file for storage of the originally signed and dated documents

Table of Contents

1. PURPOSE

To provide instructions for storing inactive study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors.

2. SCOPE

This SOP applies to archiving the study files and administrative documents that are retained for at least five years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. RESPONSIBILITY

It is the responsibility of Werabe University IRERC Secretariat for maintaining inactive study files and administrative documents.

4. FLOW CHART

No.	Activity	Responsibility
1	Prepare documents for archiving	IRERC members and Secretariat
	↓	
2	Archiving documents	IRERC Secretariat
	↓	
3	Retrieving Documents	IRERC Secretariat

5. DETAILED INSTRUCTION

5.1 After receiving the final report

- WRU-IRERC Secretariat and Members review the Final Report of the study.
- A member of the Secretariat should
  - Remove the contents of the entire file from the active study filing area.
  - Verify that all documents are present in an organized manner.
  - Obtain an archive number from the WRU-IRERC Archives
  - Enter the number into the file and the data base.
  - Place the file in a storage container
  - Send to the archives.
- Hold the files of multi-center studies, until all the study sites are closed.
- Place in a storage container together.

- Send to the archive.

5.2 When archiving administrative documents

A staff of the WRU-IRERC Secretariat should:

- Perform inventories of miscellaneous administrative documents
- Perform inventories of miscellaneous administrative documents
- Place the documents in the appropriate storage container, and
- Send it to the appropriate storage facility so that it may be easily retrieved.

Note: The WRU-IRERC Secretariat maintains past Committee membership information as well as the active administrative documents.

5.3. Retrieving Documents

- Keep in mind the SOP/025/01.0 (Maintaining Confidentiality of Ethical Review Committee Documents)
- Retrieval of documents can only be done with a request form (AF/01-024/01.0, see ANNEX 1) signed and dated by the WRU-IRERC Chairperson or the Secretariat.
- The requestor must also sign and date the log of request (AF/02-024/01.0, see ANNEX 2)
- The Secretariat retrieves archived documents in compliance with the procedures of the WRU-IRERC Archives of WRU and refers to the inventory kept by WRU.
- Return the file back to its place.
- Record, sign and date when the document has been returned and kept.

6. GLOSSARY

Administrative Documents	Documents include official minutes of Committee meetings (as described in SOP/021/01.0) and the Standard Operating Procedures, both historical files and Master Files as described in SOP/001/01.0.
Inactive Study Files	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each

study approved by the WRU-IRERC for which a final report has been reviewed and accepted.

7. ANNEXS

ANNEX 1	AF 01-024	Document Request Form
ANNEX 2	AF 02-024	Log of Requested WRU-IRERC documents

8. REFERENCES

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2011.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.

ANNEX 1

AF 01-024/01.0

Document Request Form

Name of Document requested:	Code:
Requested by:	Date:
☐ Chairperson ☐ Secretariat ☐ WRU-IRERC Member	
☐ Secretariat staff ☐ Authority ☐ Others……..	
Purpose of the request:	
Retrieved by:	Date:
Approved by:	Date:
Returned by:	Date:
Archived by:	Date:

ANNEX 2

AF02-024/01.0

Log of Requested WRU-IRERC Documents

#	Document	Requester	Date Requested	Retrieved by	Archived by	Returned Date

Table of Contents

1. PURPOSE

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle original documents and copies of documents in order to protect confidentiality of documents.

2. SCOPE

This SOP applies to all kinds of handling, distribution and storage of submitted study protocols, IRERC documents, and correspondence with experts, auditors and the general public.

3. RESPONSIBILITY

Confidentiality of study protocols, IRERC documents, and correspondence with experts and auditors is mandatory. IRERC members and staff have signed confidentiality agreements with the institute that enforces confidentiality.

If non-members of the IRERC need copies of documents, it is the responsibility of the IRERC member/staff requesting a copy on behalf of the non-members to maintain confidentiality of documents.

4. FLOW CHART

No.	Activity	Responsibility
1	Access to IRERC documents	IRERC members and Secretariat
	↓	
2	Classify confidential documents	IRERC members and Secretariat
	↓	
3	Copy confidential documents	IRERC Secretariat
	↓	
4	File Log of Copies	IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Access to IRERC Documents

The IRERC members and the staff of the Secretariat of the IRERC, who must read, understand and agree to the following:

5.1.1 Members of the IRERC

- Sign a confidentiality agreement (AF 01-004) with WRU-IRERC before the start of any activity for the IRERC

- ❖ Shall have access to all IRERC documents.
- ❖ Are free to request and to use original documents or copies of original documents.

5.1.2 Secretariat of the IRERC

- ❖ The secretary of the IRERC is a staff member of the *Werabe University*
- ❖ Sign a confidentiality agreement with WRU
- ❖ Have access to any document issued by or to the IRERC, according to SOP# WRU-IRERC 025 (Maintaining Confidentiality of IRERC's Documents).

5.2 Classify confidential documents.

Types of documents

The types of documents reviewed by IRERC members include:

- ➢ Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- ➢ IRERC documents (SOPs, meeting minutes, advice and decisions)
- ➢ Correspondence (experts, auditors, study participants, etc.)

Note: Copies of all versions of documents, including draft and sequential definitive versions are to be kept private and confidential with the exception of those made according to the following sections.

5.3 Copy confidential documents

Copies of documents, including draft and sequential versions, are considered to be confidential and are not permitted to be brought out *except when a document is needed for day-to-day operations.*

5.3.1. Copy Authorization

- ❖ Only members of the IRERC are allowed to ask for copies.
- ❖ Only staff members of the Secretariat of the IRERC are allowed to make such copies.
- ❖ The Secretary of the IRERC may ask for help, but is responsible for maintaining confidentiality of all documents.

5.3.2. Log of Copies

- ❖ A Log of Copies (see ANNEX 1 Form AF 01-025) must be kept by the Secretariat.

- The log should include: the name and signature of the individual receiving the copy; the initial of the IRERC Secretary who made the copy; the number of copies made and the date that the copies were made.

5.3.3. Copies requested by non-members of the IRERC

- Copies of IRERC's documents requested by non-members of the IRERC (including the Secretary) can only be given after the permission from the Chairperson of the IRERC and the person requesting for the document signs a confidentiality agreement form (AF 03-004).
- Copies made for non-members of the IRERC must be recorded in both the Log of Requests for Copies of IRERC's documents (Form AF 01-025) and the log of Copies of the Original Documents (AF 02-025).

5.4 File Log of Copies.

- The Log of Copies of Original Documents must be stored with the original documents.
- The Log of Copies of Original Documents is *not* a confidential document and can be reviewed upon request.
- A Log of Copies of Original Documents must be maintained.

6. GLOSSARY

Document	Documents mean the followings: • Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) • IRERC documents (SOPs, meeting minutes, advice and decisions) • Correspondence (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Non-members of the IRERC	Any relevant person/persons who presently is/are not a member/members of the IRERC such as authorities, monitors, auditors, subjects, etc.

7. ANNEX

ANNEX 1	AF 01-025	Log of Requests for Copies of IRERC's Documents
ANNEX 2	AF 02-025	Log of Copies of Original Documents

8. REFERENCES

8.5 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

8.6 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

ANNEX 1

AF 01-025/01.0

Log of Requests for Copies of IRERC's Documents

#	Documents re-quested	# of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

ANNEX 2

Form AF 02-025/01.0

Log of Copies of Original Documents

Title of the Document:……

……..

#	Name of Recipient	# of Copies	Reasons of the Request	Signature of Recipient	Secretariat Initials	Date

Note: *This log should be attached to the original documents.*

Table of Contents

1. PURPOSE

The purpose of this procedure is to guide how to prepare for an audit or inspection of the IRERC processes.

2. SCOPE

This SOP applies to every unit of the Werabe University IRERC Office.

3. RESPONSIBILITY

It is the responsibility of the Secretariat, the Members, and the Chairperson of the IRERC to perform all tasks according to the SOPs and to be well-prepared and available to answer questions during evaluation, audit or inspection visits of authorities and guests.

4. FLOW CHART

No.	Activity	Responsibility
1	Call for an Audit / Inspection	IRERC Chairperson / Director of the Institution
	↓	
2	Prepare for the visit	IRERC Secretariat / Members and Chairperson
	↓	
3	Welcome Auditor / Inspector	IRERC Secretariat / Members and Chairperson
	↓	
4	Correct the mistakes	IRERC Secretariat / Members and Chairperson
	↓	
5	Record the Event	IRERC Secretariat

5. DETAILED INSTRUCTIONS

5.1 Call for an Audit / Inspection

- Receive a notice of inspection visit
- The Chairperson informs the Secretariat / Director or Head of Institution.
- The Chairperson alerts every unit to get ready.

5.2 Prepare for the visit

- Get a checklist AF 01-027 (see ANNEX 1).
- Go through all steps on the list.
- Note and comment on each part.
- Emphasize on the studies with problems.
- Check if all documents are labeled and kept in the right order for easy and quick search.
- Check for any missing or disorganized records.
    - Background and training records of IRERC members
    - Application Submission Records
    - Protocol Assessment Records
    - Communication Records
    - Amendment Approval
    - Meeting Agenda, Minutes, Action letters
    - Active files
    - Continuing and Final reports
- Reserve a meeting room and all necessary facilities.
- Review the IRERC SOPs.
- Make sure that no omission or deviation exists.
- Make sure to have good reasons for any omission or deviation.
- Inform IRERC members about the inspection date if they are able to attend the audit/inspection meeting.

5.3 Welcome Auditor / Inspector

- The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room.
- Members and some key staff must also be present in the meeting room.

- The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data are needed.
- Answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the point.
- Find and get all information and files requested by the auditors/inspectors.
- Take note of the comments, recommendation of the auditors/inspectors.

5.4 Correct the mistakes

- Review comments and recommendations of the auditors/inspectors.
- Write a report and have it approved by the Chairperson.
- The Chairperson calls for the correction.
- Allow appropriate time for correction and improvement process.
- Carry an internal follow-up audit.
- Evaluate the outcome.
- Report the outcome to the Chairperson.

5.5 Record the Audit/Inspection Event

- Keep record of the report on the audit/inspection meeting in the audit/inspection file.
- Record also the findings from the internal follow-up audit in the internal audit file.

6. GLOSSARY

Audit	A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements
Inspection	The act by a regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or Contract Research Organization's (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities

7. ANNEX

ANNEX 1 AF 01-027 Audit and Inspection Checklist

8. REFERENCES

8.7 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

8.8 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.

8.9 World Health Organization, Surveying and Evaluating Ethical Review Practices, Feb. 2002

ANNEX 1
AF 01-027/01.0

Audit and Inspection Checklist

☐ Internal Audit ☐ External Audit	☐ Inspection	Date:
The date(s) which the audit/inspection has been agreed for:		
Will an interpreter be required? If yes, what arrangement has been made?	☐ Yes …… ☐ No	
Review the SOPs and note details of any omissions or deviations, with reasons		
Check the files for the presence of all signed documents. Note any that are missing and actions taken. ❑ Background and training records of IRERC members ❑ Application Submission Records ❑ Protocol Assessment Records ❑ Communication Records ❑ Amendment Approval ❑ Meeting Agenda, Minutes, Action letters ❑ Active files ❑ Continuing and Final reports		
Are any documents known to be missing form the study master file?		
Which personnel and members will be available? Give details of times and dates.		
What arrangements are there in the event the auditor/inspector needs to make copies of documents?		
Completed by:…….		Date:……..

Table of Contents

1. PURPOSE

This SOP provides guidance regarding definition of terms, abbreviations and titles used by the Institutional Research Ethics Review Committee (IRERC) and its administrators to facilitate use and understanding of the IRERC Standard Operating Procedures and activities.

The definitions are divided into two sections:

- Description/definition of individual roles as used in the IRERC SOPs
- Description/definition of terms and abbreviation used in the IRERC SOPs

2. SCOPE

This section applies to all IRERC SOPs and activities in addition to persons preparing and/or using the SOPs.

3. RESPONSIBILITY

It is the responsibility of the IRERC members to define or determine and approve the appropriateness of the description.

4. FLOW CHART

Activities	Responsible bodies
Description of individual titles and roles	IRERC members and Secretary
↓	
Definition of terms	IRERC members and Secretary
↓	
Addition / Correction of new titles and terms	IRERC members and Secretary
↓	
Approval of the new addendum	IRERC members / Chairperson

5. DETAILED INSTRUCTIONS

5.1 Description of individual roles

Chairperson

- A member of the IRERC who presides over a board meeting. He/she is responsible for expedited approvals on behalf of the Board.

Coordinator (Site)

- The person at the study site who is responsible for managing the study sometimes, the Principal Investigator is also the site coordinator and manager.

IRERC

The IRERC is a body established to review and monitor health research involving human participants. The primary purpose of such a review is the protection of the rights and welfare of the human subjects. In accordance with applicable national/international regulations, the IRERC has the authority to approve, require modifications to or disapprove research. The IRERC consists of at least five (5) to fifteen (15) regular members in addition to alternate members. Alternates are categorized and given equal status as regular members within the committee (i.e., community representative and law expertise etc.). The composition of the membership must reflect a diversity of specialties.

- Expertise and experience to provide adequate review of research activities.
- Consideration of gender.
- Sensitivity to attitudes and concerns of the community.
- Knowledge of applicable regulation, laws and standards of professional conduct and practice
- No member participates in the review process of any study project in which he/she has a conflicting interest.

IRERC Members

REIEB is constituted in accordance with the IRERC membership requirements. Individuals qualified to vote at a duly convened WRU IRERC meeting

Investigational New Drug (IND)

Investigational new drug means a new substance, antibiotic drug, or biological product that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms “investigational drug” and “investigational new drug” are deemed to be synonymous for purposes of this part.

Non-Local Review

Under certain circumstances, local review by an Institutional Research Ethics Review Committee (IRERC) may not be available, e.g., research conducted by investigators unaffiliated

with an institution. Local regulatory agencies such as Food and Drug Administration (FDA) may allow review of research by IRERCs in locations other than where the research is to be performed (e.g., independent or IRERC). Therefore, IRERC may review studies that are not performed on-site as long as the requirements are met.

Principal Investigator

Individual responsible for implementing and coordinating an investigational study

Secretariat

The IRERC staffs who is responsible for the day-to-day administrative functions and duties which support the activities and responsibilities of the members.

Vice Chairperson

A member of the IRERC who assists the Chairperson as needed in conducting meetings and expedited review.

Vulnerable participants

A category of research participants that includes children, prisoners, pregnant women, handicapped or mentally disabled persons and economically or educationally disadvantaged persons who are likely inclined to coercion or undue influence

5.4. Definition of Terms

Active study files

Supporting and approved documents, records containing communications and reports that correspond to each active (current) study approved by the WRU IRERC

Administrative documents

Documents include official minutes of Committee meetings as described in SOP, WRU IRERC meeting minutes and voting records and the standard operating procedures, both historical files and Master Files as described in the SOP, SOP distribution, implementation and file maintenance.

Deviation

Any instance in which the current approved WRU SOP cannot be or has not been followed.

Expedited approval

An approval granted only by the Chairperson of the WRU IRERC or a designated WRU IRERC member (not the full committee) for "minor" changes to current - approved research activities and for research which involves no more than minimal risk.

Final report

An obligatory review of study activities presented as a written report to the WRU IRERC after the last subject has completed all visits and all adverse experiences have been brought to appropriate resolution.

Historical file

A document file which was effectively used in the past and presently became obsolete or expired, but still had to be kept in a file for reference purposes.

Inactive study files

Supporting and approved documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communication and correspondence with the investigator and reports (including but not limited to progress reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the WRU committee for which a final report has been reviewed and accepted Inactive study files are archived for a minimum of three years following the completion of the study. These files can be retrieved as needed.

Investigational medical device

A medical device which is the object of clinical research to determine its safety or effectiveness

Master files

Original copies of documents such as SOPs, guidelines, instruction, manual with real signatures of preparers, reviewers and authorized persons are systematically stored in secured cabinets with limited access.

Medical Device

A medical device is any health care product that does not achieve any of its intended purposes by chemical action or by being metabolized. Medical devices include items such as diagnostic test kits, crutches, electrodes, prescribed beds, pacemakers, arterial grafts, intra-ocular

lenses, and orthopedic pins. Medical devices also include diagnostic aids such as reagents and test kids for *in vitro* diagnosis of disease and other conditions, (for example, pregnancy).

Minutes

The official record of events, activities and actions taken on agenda items presented to a duly constituted (quorum present) independent board review meeting. The minutes identify fully each protocol and/ or activity and record the outcomes of each voting action. The committee votes separately on each collective set or each item submitted for review: protocol, consent form, investigator and advertisement(s). The record notes the number for, number against, the number of abstaining votes and the reason for the abstention(s) without identifying the individual member's names.

New Study

A study protocol including the informed consent, investigator's qualifications, information on the drug or device and advertisements (if applicable) presented to WRU for approval for the first time and not previously approved by this Committee. This includes re-application for those studies denied approval by WRU.

Non-significant Risk Device (NSR)

A non-significant risk device is an investigational device that does not pose a significant risk.

Progress Report

An ongoing review of each investigator's study activities presented as a written report to obtain extended approval for the study from the WRU IRERC. Generally, these reports are due annually with the WRU sending a written notification reminding the investigator of this obligation. More frequent reports may be requested at the discretion of the WRU IRERC.

Protocol Amendment

A change to the study protocol during the planning or course of the trial

The amendment is a foreseen change to the study plan that requires formal approval by the sponsor.

Quorum

Attendance required arriving at a decision at any convened meeting of the board. If 5 is the minimum number of members prescribed in the SOP, 3 of the regular (or alternate) members,

including at least one physician and one layperson constitutes a quorum and should be maintained throughout the discussions and voting portions of the meeting.

Significant Risk Device (SR)

A significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of the subject, (2) is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of the subject, (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of the subject, or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of the participants.

5.3 Addition / Correction of terms

- Members are encouraged to propose any additional terms or make correction of any terms defined in this SOP at any time, if he/she feels clarification should be made.
- Write your proposal.
- Submit your proposal to the IRERC secretariat.

5.4 Approval of the addendum

- IRERC secretariat shall bring the proposal to a meeting.
- The proposal shall be discussed for further opinion.
- Agreement and approval shall be made at the meeting.

6. REFERENCE

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.