HEALTH RESEARCH ETHICS COMMITTEE GUIDELINES (KEPK)

COMPILED BY:

HEALTH RESEARCH ETHICS COMMITTEE

FACULTY OF HEALTH MUHAMMADIYAH UNIVERSITY OF PRINGSEWU LAMPUNG

FOREWORD

We express our gratitude to Allah Azza Wa Jalla for the blessings of health and time that have facilitated the compilation of the Health Research Ethics Committee Guidelines (KEPK) of the Faculty of Health, Muhammadiyah University of Pringsewu, Lampung. These guidelines serve as a reference for the Health Research Ethics Committee at the Faculty of Health, Muhammadiyah University of Pringsewu, Lampung, in conducting ethical review.

It is hoped that these guidelines will serve as a reference for researchers to consistently uphold and safeguard the life, health, privacy, and human dignity of individuals participating as research subjects, while ensuring their welfare and humane treatment of both experimental and non-experimental animals. This guideline refers to the 2017 Guidelines issued by the National Health Research and Development Ethics Committee (KEPPKN).

The Health Research Ethics Committee Guidelines of the Faculty of Health, Muhammadiyah University of Pringsewu, Lampung, are far from perfect.

Therefore, we welcome input and suggestions to improve them in the future. We hope these guidelines will be beneficial for the development of quality health science and research.

Pringsewu, March 2021
Chairman of KEPK

Nur Fadhilah, M.Kes

NBM 927 023

HEALTH RESEARCH ETHICS COMMITTEE GUIDELINES (KEPK)
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CHAPTER 1

INTRODUCTION

A. Background

The development of science and technology in the health sector is greatly influenced by research, which serves as a foundation for generating innovation and developing safe and effective services, policies, and interventions for the community. Health research plays a strategic role in improving the quality of health services, preventing disease, supporting rehabilitation, and strengthening the overall health system. Before research results can be applied to benefit humanity, a series of research stages involving both human and animal subjects is required to test the safety, effectiveness, and benefits of a procedure, intervention, or scientific innovation.

The involvement of humans as research subjects in the health sector has ethical consequences that require serious attention. Participation in research can pose risks, including physical discomfort, psychological impact, social stress, economic risks, and violations of privacy and the confidentiality of personal data. Furthermore, the use of experimental animals in health research also requires attention to animal welfare aspects (*animal welfare*) and the principle of humane treatment (*human care).* Therefore, identification, prevention, and management of research risks need to be carried out carefully, systematically, and proportionately, in accordance with research ethics principles that apply nationally and internationally.

In the context of health research, ethical issues are becoming increasingly complex as the quantity, quality, and variety of research conducted by universities, research institutions, hospitals, and healthcare institutions increase. Health research generally involves interventions with human subjects, the use of biological materials, clinical procedures, the collection of sensitive data, or procedures that have the potential to affect

the safety and well-being of research participants. Therefore, an ethical oversight and review mechanism is needed to ensure that research is carried out in a manner that respects the human rights, dignity, safety, health, and personal privacy of research participants.

The principles of research ethics are the main foundation for conducting health research. All research must support the principle of respect for human beings (respect for persons), usefulness (beneficence), not detrimental (non- maleficence), and justice (justice). This principle aims to ensure that research subjects' participation is voluntary, based on informed consent (informed consent), and does not pose a risk that is disproportionate to the benefits of the research. Thus, research not only produces scientific contributions but also protects the individuals and groups involved as research subjects.

Ethical responsibility in research is, in principle, the personal responsibility of each researcher. However, the increasing complexity of research and the involvement of various parties in its implementation mean that ethical oversight can no longer be solely the responsibility of individual researchers. Therefore, an institutional mechanism is needed through the establishment of an ethics committee with the authority to assess the ethical feasibility of a study. In line with this, the government has established a policy to establish a Health Research Ethics Committee (KEPK) through Decree of the Minister of Health of the Republic of Indonesia Number 1334/ Menkes/SK/X/2002 concerning the Establishment of a Health Research Ethics Committee as an instrument to improve the ethical quality of health research in Indonesia.

Faculty of Health, Muhammadiyah University of Pringsewu, Lampung, as a higher education institution that carries out the functions of education, research, and community service based on the Tridharma of Higher Education, is committed to ensuring that all health research is conducted responsibly and with quality, and that it meets research ethics standards.

As a form of implementing this commitment, the Faculty of Health, Muhammadiyah University of Pringsewu, established a Health Research Ethics Committee (KEPK) based on Decree Number LB.02.01/I/ 0651/2018 concerning the Establishment of the Health Research Ethics Committee of Muhammadiyah Pringsewu Health College, Lampung, which has now developed into the Health Research Ethics Committee (KEPK) of the Faculty of Health, Muhammadiyah University of Pringsewu.

KEPK Faculty of Health, Muhammadiyah University of Pringsewu, comprises various health disciplines, including nursing, midwifery, public health, and community health (layman), to ensure objectivity, independence, and balance in the ethical review process. The scope of KEPK's ethical review focuses on health research involving humans or animals as research subjects, including clinical research, health interventions, the use of biological materials, and other research that may pose physical, psychological, social, or biological risks to research participants.

Research outside the health sector, such as non-invasive and low-risk socio- humanities, education, language, culture, or literature studies, is not, in principle, included in the scope of formal ethical review by the KEPK Faculty of Health, as long as it does not involve vulnerable participants, interventions, or the collection of sensitive personal data. However, all research must still adhere to the principles of research ethics, such as voluntary participation, respect for privacy, data confidentiality, and protection of participant rights. Therefore, this guideline is prepared as an official reference for the Health Research Ethics Committee of the Faculty of Health, Muhammadiyah University of Pringsewu, in conducting ethical review of health research in a professional, accountable manner, and in accordance with applicable ethical standards.

B. Vision and mission

1. Vision

Becoming a professional KEPK to realize ethically sound research by 2022

2. Mission

1. Protecting humans, animals, and plants involved in health research
2. Honor all subjects who are included in the study
3. Increase the research results' benefits on the subject study

C. Position of KEPK

1. KEPK as part of an institutional organization that is authorized by a Decree and is administratively responsible to the Dean of the Faculty of Health, Muhammadiyah University of Pringsewu

2. KEPK works based on the laws and regulations of the Republic of Indonesia and in accordance with the values and principles of the community it serves.

3. KEPK has independent authority in selecting new members, free from any influence, including political, institutional, professional, industrial, or market pressure.

D. Role of KEPK

The role of the KEPK of the Faculty of Health, Muhammadiah University of Pringsewu, namely:

1. Protect and support human autonomy both as candidates and as research subjects;
2. Protect the welfare of prospective and research subjects, and

balance a number of relevant moral considerations when considering research proposals/protocols, including respect for autonomy, protection, and promotion of well-being.

E. Functions of KEPK

Its functions include:

1. KEPK carries out its functions by providing ethical approval after conducting an assessment of the research protocol, known to the head of the institution

2. KEPK has the right to propose sanctions to the head of the institution.

3. The KEPK has the right to withdraw/cancel ethical approval that has been granted if violations are later discovered during the research process. In principle, the KEPK considers sanctions inappropriate and prioritizes fostering an atmosphere of openness and mutual trust to facilitate coaching.

4. KEPK has the responsibility to implement quality health research through assessment and decision-making regarding the ethical feasibility of research.

5. The scope of the research ethics assessment carried out by the Ethics Committee of the Faculty of Health, Muhammadiah University of Pringsewu, for research in the health sector, whether carried out by lecturers, health professionals, researchers, or students,

F. KEPK Membership

Membership of the KEPK Faculty of Health, Muhammadiah University, Pringsewu, is regulated by the following provisions:

1. Members consist of various disciplines related to health, the field comes from various professions, and laymen (common people).

2. The existence of KEPK is determined through a Decree (SK) from the Head of STIKes for a work period of 4 years.

3. For research protocols that require a reviewer outside the KEPK team, who has been listed in the Decree, will be appointed, and others as needed by the Head of the KEPK Faculty of Health, Muhammadiah University, Pringsewu, with a Director's Decree

G. Requirements for processing ethical clearance: Candidate researchers who need ethical clearance must meet the following requirements:

1. Submit the protocol by filling out the protocol form, PSP, and informed consent, which have been prepared by the KEPK secretariat.

2. Fulfill the administrative requirements for ethical feasibility testing.

CHAPTER II

RESEARCH PROTOCOL ASSESSMENT PROCESS

The assessment of the research protocol carried out at the Faculty of Health, Muhammadiah University, Pringsewu, follows the standard application flow for Ethical Clearance as follows:

1. The applicant submitted an ethics review protocol (etching clearance) by completing the files:

a. Application letter signed by the leader/supervisor **(Form A)**

b. Research protocol and its attachments **(Form IA / Form II.A / Form III.A)**

c. Check list independent ethical review completed by the researcher **(Form IB / Form II.B / Form III.B)**

2. The Secretariat checks the completeness of the files, reviews the protocols, and categorizes the protocol status. The categorization of the research protocol status results in the following:

a. Small/few changes

That is, a review of a study is carried out through an accelerated procedure (exempted). The next stage is stage number 3. This process takes up to **5 days after submission.**

b. Normal

That is, the research requires quite a lot of changes, or there is a risk effect on the subject, but it is classified as low risk (low risk) (expedited). Protocol with status expedited will be forwarded to the reviewer for review and to follow stages b.1 – b.6. The research protocol assessment process is carried out within a maximum of **14 working days.**

c. Emergency (Full Board)

That is, research is categorized into high risk; it is feared that it will cause a high risk effect on the subject, so a meeting is required, full board, namely the presentation of the research protocol, which must be attended by prospective researchers, supervisors, the ethics committee team, consultants related to the scientific field for the relevant research title, and layman (full board). The next stage is c.1. **For a full board, it takes longer, so it can take up to 1 month.**

3. Meaning of the results of the study:

   a. Approved according to the submitted proposal

   This means it is approved, and no changes/modifications are required.

   b. Conditionally approved

   This means that changes and/or clarifications are required. Approval

of the proposal depends on an adequate explanation by the researcher; if this is not yet convincing, changes/amendments need to be made and then submitted/ submitted to the secretariat.

c. Not approved

This means additional information and/or rewriting is required. This requires more complete information, even rewriting, and being categorized as a new application for review by the KEPK.

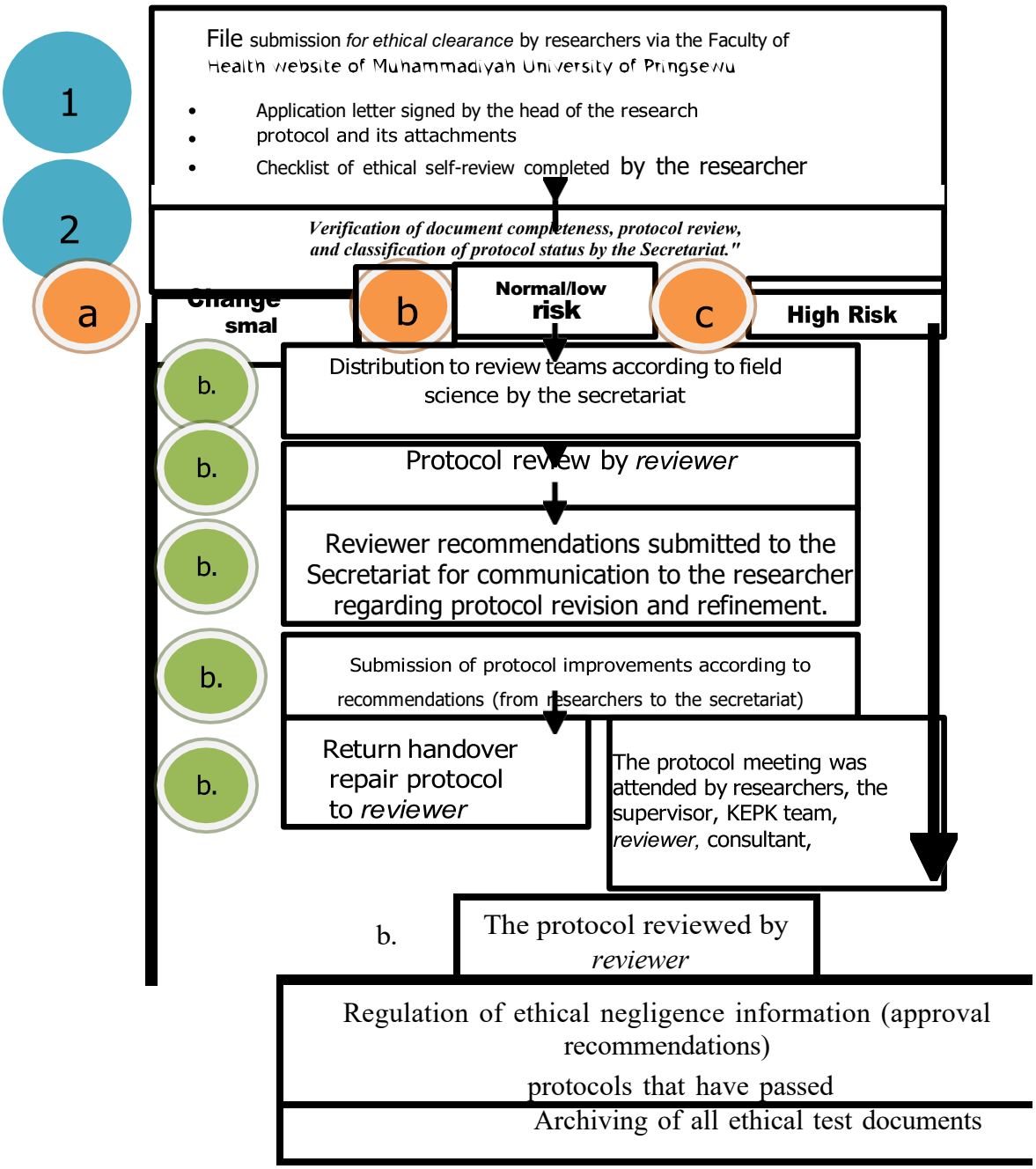
d. Rejected

This means that the protocol is ethically unacceptable and cannot be approved by the KEPK or supported by national standards, the WHO 2011 guidelines, or the WHO-CIOMS 2016 guidelines. Researchers may submit a new proposal that addresses the ethical issues raised by the Committee. The

Secretariat will issue ethical approval (ethical approval) if the protocol has met 7 ethical standards.

4. All research protocols are documented.

Standard application flow: Ethical ***Clearance***



Assessment Procedure by Reviewers

1. The reviewer receives the research protocol proposal from the KEPK secretariat.
2. Reviewers examine the proposer's research protocol, referring to 3 principles, 7 standards, 25 guidelines, 35 ICs, and 48 items.
3. Reviewers provide input on the research protocols that have been reviewed.

The decision-making procedure is carried out by *the full board*:

1. In KEPK meetings, members engage in discussions to express all important matters and opinions related to the protocol and related documents.
2. The KEPK leadership guided the discussion with respect for all members and allowed sufficient time for all considerations.
3. Only KEPK members who are present in full can participate in decisions.
4. The KEPK leadership is responsible for decision-making, especially in determining the time of agreement required to make a decision.
5. Researchers, funders, and other parties directly involved in the research protocol may not be present while the EC conducts ethical considerations.
6. Decisions are taken through voting or consensus; not necessarily do all members support the agreement, but it is possible that all members think that the agreement is less acceptable, and no member decides to reject the agreement.

CHAPTER III

FOLLOW-UP AFTER ETHICAL APPROVAL

AND DOCUMENTATION

A. KEPK Follow-up Procedures After Ethical Approval is Granted

KEPK's follow-up after ethical approval is granted follows:

The following procedures:

1. All meeting minutes are approved by the meeting chair and properly maintained. A summary of the meeting list is provided, and meeting minutes are easily accessible upon request.
2. All Amendments proposed by researchers are reviewed by the initial protocol reviewers.
3. Secretariat staff periodically send letters reminding researchers to submit KTDS progress reports and final research reports. This is documented.
4. There is evidence that all Progress Reports are reviewed by the initial reviewer.
5. There is evidence that All Serious Adverse Event Reports (SAD)/ Serious Adverse Event (SAE) is reviewed by the initial reviewer and discussed in a full meeting (included in the meeting agenda).
6. There is evidence that all Final Reports are reviewed by the initial reviewers.
7. There are documents showing that KEPK has carried out monitoring through site visits as a scheduled study (site visit) and a report in the full meeting.
8. There is evidence that KEPK always carries out monitoring through review of progress reports submitted by researchers.

B. Documentation

All documents related to the ethical review process of the KEPK Faculty of Health, Muhammadiyah University of Pringsewu, Lampung are documented manually and online.

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