STANDARD OPERATING PROCEDURE

POST APPROVAL

HUMAN RESEARCH ETHIC COMMITTEE UPSI

1.0 OBJECTIVES

The objective of this Standard Operating Procedure (SOP) for post-approval submissions is to ensure a structured, and standardized process for managing modifications and updates to approved research protocols. This SOP aims to uphold the integrity and ethical compliance of ongoing studies by providing clear guidelines for Principal Investigator on how to submit renewal and amendments application, adverse event report, and monitoring of post approval. This SOP also describes how UPSI Human Ethic Committee (JKEPUM) processes post approval submissions by the Principal Investigator.

2.0 SCOPE

This SOP is applicable to all renewal applications, amendments involving modifications to approved study components (such as methodology, respondent selection, and study location, ect.), adverse event (AE) reports, and monitoring reports, including site visit assessments.

3.0 RESPONSIBILITIES

- The Principal Investigator (PI) is responsible for ensuring compliance with post-approval review requirements, including the timely submission of all reports specified in the JKEPUM approval letter.
- The secretariat is responsible for receiving and processing all submissions, as well as addressing inquiries from PI, research participants and other relevant stakeholders.
- In cases where a site visit is deemed necessary, the Chair is responsible for establishing a site visit committee. The designated members of this committee are tasked with conducting the site visit and preparing a report for presentation at the JKEPU meeting. The secretariat staff is responsible for coordinating the logistics of the site visit. Additionally, the Chair of the site visit committee must be a member of the application panel.

4.0 RENEWAL APPLICATIONS, AMENDMENTS OF ETHICAL APPROVAL

4.1 Renewal

4.1.1 Ethical approval is granted for a period of at least one year. For the renewal process, the Principal Investigator need to submit the Human Research Subject Renewal Form (BE03) three (3) months prior to expiry date.

4.1.2 Chair will be present renewal application to JKEPUM members for deliberation.

4.1.3 The newly approval will supersede previous versions of the ethical clearance related document.

4.2 Amendment

4.2.1 An amendment refers to the process of requesting modifications, changes, or updates to study documents after obtaining ethical approval. Ethical clearance amendments are facilitated by submitting the Human Research Subject Amendment Form (BE04) along with the revised documents to the JKEPUM Chair.

4.2.2 The amendment should be applied based on the items below:

- Procedure of the research
- Any changes in inclusions/exclusion criteria.
- Significant change in the number of subjects, study location.
- Additional treatment/intervention or the deletion of treatments.
- Changes in method of dosage formulation, (e.g. oral changed tointravenous).
- Significant decrease or increase in dosage amounts.

4.2.3 The Principal Investigator shall be formally notified of the decision rendered by JKEPUM, specifying the amended documents that have been approved for use. The PI may be required to revise the application, provide additional information, or submit supplementary documents as deemed necessary.

4.2.4 The newly approved documents will supersede previous versions of the ethical clearance.

5.0 ADVERSE EVENT REPORTS/ *LAPORAN KEJADIAN/KESAN TIDAK DIINGINI*

5.1 An adverse event is any undesirable and unintended, although not necessarily unexpected, negative consequence for the subject from participation in the study. Adverse events include all types of harm-physical, psychological, social, legal, or economic.

5.2 The Principal Investigator must report any adverse advents or unexpected event that occurs in the process of conducting research involving human subjects to the JKEPUM committee through Human Research Subject Adverse Report Form (BE05).

6.0 ETHICS MONITORING (SIDE VISIT)

6.1 Selection of research project for monitoring

6.1.1 The selection of research for the monitoring, will be based on:

A. Risk level and participant safety

- Research involving vulnerable populations, including children, pregnant women, individuals with disabilities, and indigenous communities (e.g., Orang Asli).
- Studies involving high-risk interventions, such as drug trials, invasive procedures, genetic testing, or psychological interventions.

- Research involving the collection of biological samples, such as blood, saliva, or tissue, particularly when invasive methods are used.
- Studies with potential physical, psychological, social, or legal risks to participants.

B. Study design and methodology

- Clinical trials or interventional studies that require ongoing risk assessment and safety monitoring.
- Research involving deception or withholding of information from participants that could impact informed consent.
- Studies using experimental methodologies that lack sufficient precedent in the literature or require close oversight.
- Projects with longitudinal designs, where data collection spans multiple years or involves continuous monitoring of participants.

C. Data sensitivity and confidentiality risks

- Research handling sensitive personal data, such as health records, genetic information, or confidential legal/social history.
- Studies involving large-scale surveys or interviews on controversial topics (e.g., mental health, political views, sexual behavior).
- Research using audio, video, or photographic recordings of participants, especially without full anonymization.

D. Study location and environment

- Research conducted in high-risk settings, such as hospitals, prisons, disaster zones, or conflict-affected areas.
- Studies involving fieldwork in remote locations with limited access to healthcare or emergency support.
- Research conducted in international or cross-border settings, where ethical guidelines may vary.

6.2 Notification to the Principal Investigator regarding the schedule of the site visit for monitoring

6.2.1 The JKEPUM Chair, through the Secretariat, informs the PI at least twenty-one (21) working days before the scheduled visit through a letter.

6.2.2 The letter provides site visit schedule details and instructions on what the PI needs to prepare such as documents and files that will be used for the site visit, as well as orderly preparation of the site.

6.3 Appointment of a Monitoring committee (site visit)

6.3.1 A monitoring committee (site visit) is organized for each site visit.

6.3.2 The members of this team are assigned by the JKEPUM Chair.

6.3.3 The site visit committee should consist of at least two (2) peoples: one (1) Chairman from JKEPU member,one (1) JKEPUM Member.

6.4 Conduct of site visit

6.4.1 Upon arrival at the study site, the site visit committee uses Human Research Subject Site Visit Report Form (BE06) to do the following:

- Review the ethical clearance.
- Review the informed consent documents and verify if the site isusing the most recently approved version.
- Ask the PI or staff to explain the informed consent process.
- Review the post-approval documents and verify if the site is using the most recently approved version, or that these have been approved.
- Verify security, privacy, and confidentiality of the documents at thestudy site.
- Observe facilities in the study site.
- Make an overall determination of the protection of the rights, safety,and welfare of human participants in the study

6.4.2 At the end of the visit, the site visit committee will:

- Discuss the findings with the research team
- Solicit feedback

6.4.3 Presentation of findings

- The site visit committee chair presents the findings to the JKEPUM.

7.0 STORAGE OF RECORDS

7.1 The Secretariat files a copy of all the documentation in the study file.

WORKFLOW

1. **RENEWAL & AMENDMENTS**

Activity	Responsibility
Receive and manage submission of documents ↓	Secretariat
Present in JKEPUM meeting ↓	JKEPUM Chair
Communicate with Principal Investigator ↓	Secretariat
Manage documentation	Secretariat

2. ADVERSE EVENT REPORT

Activity		Responsibility
Ensure completeness and receive adverse event (AE) report ↓		Secretariat
Forward reports to JKEPUM Chair to assess urgent/non urgent/		Secretariat
URGENT	NON-URGENT (Assign to previous reviewer) ↓	JKEPU Chair
If the report needs immediate action, JKEPUM Chair to assess/ recommend for immediate action ↓	Forward to Previous Reviewer within 48 hours after receipt ofreports	Secretariat
	Submit review to the secretariat seven (7) working days afterreceipt of AE report ↓ Conduct Meeting	Reviewer, Secretariat, JKEPUM Chair, Members
↓	↓	Secretariat
	Present review in the JKEPUM meeting ↓	Previous Reviewer/ JKEPUM Chair
Communicate results to principal investigator ↓		Secretariat
If no further action send notification of decision to Principal Investigator		Secretariat

If recommend further action send notification with recommendations to PI	Secretariat
Manage ethical clearance files	Secretariat

3. SITE VISIT

Activity	Responsibility
Select study sites/project for monitoring. ↓	JKEPUM
Notify PI of date of site visit/project ↓	JKEPUM Chair
Create site visit/monitoring Committee ↓	JKEPUM
Conduct site visit ↓	Monitoring Committee (Site Visit)
Present findings during JKEPU meeting ↓	Monitoring Committee Chair
Communicate results of site visit and subsequent panel action to PI ↓	Secretariat
Manage site visit documents	Secretariat

LIST OF FORM

No	Code	Name/Nama
1	UPSI/PPPI/UPP/BE03	Human Research Subject Renewal Form
2	UPSI/PPPI/UPP/BE04	Human Research Subject Amendment Form
3	UPSI/PPPI/UPP/BE05	Human Research Subject Adverse Report Form
4	UPSI/PPPI/UPP/BE06	Human Research Subject Site Visit Report Form