## 1. Policy Statement

In the course of review of protocols by the UREC, it is determined that certain studies require close and regular observation for compliance with ethics guidelines and protocols approved by the UREC. Furthermore, it is possible that the need for such monitoring is also determined during the execution of the project (e.g. reported complaints associated with the execution of the project). This process will involve site visits and evaluations by a designated Monitor.

### 1.1 Criteria for Eligibility for Monitoring

A Monitor may be assigned to a research study under any of the following conditions:

#### 1.1.1 Pre-Approval

- The risk level of the study is greater than the probability and magnitude of physical and psychological harm that is normally encountered in daily life, or in the performance of routine medical, dental, or psychological examination of healthy persons (i.e. "greater than minimal risk").
- The participant is involved in the execution of the project more than once over a period of time, and so the participant is exposed to repeated or prolonged risk (e.g. intervention studies).
- The protocol involves a vulnerable population.
- The PI declares the need for Monitoring and the reviewer/s agree/s with this assessment.

#### 1.1.2 Post-Approval

- The researchers are delinquent in submitting continuing review requirements such as progress reports (if required) or protocol amendment applications.
- There are reports of non-compliance with the agreed upon protocols (i.e. initial and/or continuing amendment protocols).
- There are complaints from study participants or other stakeholders.
- There is a significant number of reports regarding adverse events associated with the execution of the project.

**1.2 The Monitors**

There should be two Monitors assigned to a study. One Monitor should be one of the primary reviewers of the original research protocol (except for the Chair or the Vice-Chair). The other Monitor should be either a member of the subcommittee for review of unanticipated problems and adverse events (see SOP 3.3) or any other member of the UREC. The Monitor will be responsible for:

- Visiting the study site or the office of the researchers and conducting the interview of the PI and observation of the study site (if applicable).
- Making an overall determination of the safety and welfare of human participants.
- Discussing his/her findings with and soliciting feedback from the researchers.
- Reporting his/her findings at a special plenary meeting of the UREC.

## 2. Objectives and Scope of Activities in SOP 1.1

The procedures outlined in this section ensure that studies that require monitoring are identified and monitored through a systematic, consultative, and transparent process.

The procedures are applicable only to the types of research protocols described in the policy statement of this SOP.

## 3. Workflow of the Monitoring System and Persons Responsible

| WORKFLOW OF MONITORING SYSTEM | RESPONSIBILITY | WORKING DAYS |
|---|---|---|
| Step 1: Recommend Monitoring of a research protocol | UREC Reviewers or UREC Chair or UREC Vice-Chair or UREO Director | |
| Step 2: Approve Monitoring for the research protocol | UREO Director | 0-5 days from recommendation |

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| Step 3: Inform the PI of the decision to assign Monitors to the study | UREO OA | 0-3 days from approval |
| Step 4: Assign the Monitors | UREO Director | 0-3 days from approval |
| Step 5: Indicate acceptance or non-acceptance of assignment | UREC Members | 0-5 days from notice of assignment |
| Step 6: Record final assigned Monitors to the study | UREO OA | 0-3 days from acceptance of assignment |
| Step 7: Determine date/s of site visit/s by the Monitors | UREC Monitors, UREO Director, UREO OA | 0-5 days from notice of assignment from UREO OA |
| Step 8: Notification of PI of the date/s of the site visit/s | UREO OA | 0-3 days from determination of date/s of site visit/s |
| Step 9: [If applicable] Request alternative date/s for the site visit/s | Principal Investigator | 0-5 days from notification of date/s of site visit/s |
| Step 10: Conduct the site visit/s | Monitors | As scheduled |

| | | |
|---|---|---|
| Step 11: Present findings during plenary meeting | Monitors | 0-10 days after site visit |
| Step 12: Communicate to the PI the results of the site visit and decision by the UREC | UREO OA | 0-3 days after the plenary meeting |
| Step 13: Respond to the UREC's recommendations | PI | 0-10 days after communication of the UREC's decision |
| Step 14: Deliberate on the PI's response/action | UREC, UREO OA | 0-10 days after researcher's response |
| Step 15: Document and file all reports and decisions on the Monitoring of the protocol | UREO OA | |

## 4. Description of Procedures

### 4.1 Recommend Monitoring of a research protocol

This recommendation may be made by at least one (1) primary reviewer during the initial review of the protocol, whether out of his/her own volition or in support of the PI's declaration of the need for Monitoring. He/she must indicate this in his/her PAF (specifically in section G item 1).

Alternatively, this recommendation may be made by the UREC Chair or Vice-Chair. He/she must indicate this as an additional comment from the Chair/Vice-Chair in the letter to the PI communicating reviewer comments.

The recommendation may also be made by the UREC Chair or Vice-Chair or the UREO Director at any time during the period of eligibility of ethics clearance for a study, should situations (e.g. reported complaints) arise that warrant Monitoring.

**4.2 Approve Monitoring for the research protocol**

The UREO Director studies the protocol and decides accordingly on the recommendation. If the recommendation is made during the initial review of the protocol, this must be accomplished within the timeframe of review by the reviewers (see Step 2 in SOP 4.2 and Step 3 in SOP 4.3).

**4.3 Inform the PI of the decision to assign Monitors to the study**

If the recommendation is made during the initial review of the protocol, this must be communicated to the PI in the final decision letter sent by the UREO OA. Otherwise, the UREO OA will send a special letter to the PI communicating this decision.

**4.4 Assign the Monitors**

The UREO Director requests 1) one of the primary reviewers and 2) either a member of the subcommittee for review of unanticipated problems and adverse events or any other member of the UREC to be the official Monitors for the study through an email. The aforementioned have up to 5 working days to respond to the request.

**4.5 Indicate acceptance or non-acceptance of assignment**

The UREC members invited to be Monitors indicate via replying to the email invitation their acceptance or non-acceptance of the assignment as Monitors. Conditions for non-acceptance include conflict of interest, inability to perform function in due time due to illness, leaves, etc.

If the aforementioned decline the assignment as Monitors, the UREO Director will forward the request to another member of the subcommittee for review of unanticipated problems and adverse events (if applicable) or any other member of the UREC with no conflict of interest until two such members have accepted the assignment.

**4.6 Record final assigned Monitors to the study**

The UREO OA sends the Monitoring Report Form to the Monitors upon acceptance of the assignment. He/she tracks the progress of the Monitoring, from the conduct of the site visits to final communication to the PI.

**4.7 Determine date/s of site visit/s by the Monitors**

In consultation with the UREO Director, the Monitors determine 1) how many site visits are necessary for the project and 2) when these site visits will be within the period of eligibility of ethics clearance. For scheduling purposes, the UREO OA may facilitate coordination between the Monitors and the PI.

**4.8 Notification of PI of the date/s of the site visit/s**

The UREO OA formally notifies the PI of the Monitoring plan via email. This plan includes the identities of the Monitors, the number and dates of the site visits, and what the site visits will entail and what materials the PI needs to prepare (see 4.10).

**4.9 Request alternative date/s for the site visit/s**

Should it be necessary, the PI may request other date/s for the site visit/s. The UREO Director and the Monitors will decide on the merit of the request and decide accordingly. This decision will be communicated immediately by the UREO OA to the PI.

**4.10 Conduct site visit/s**

The Monitors use the Monitoring Report Form as a guide to the conduct of the site visits. The formal site visit should consist of the following:

- Review the approved protocol and verify that no amendments have been made to it or carried out without prior approval by the UREC.
- Ask the PI to explain how they have carried out the informed consent process.
- Review the informed consent forms and related documents and verify that they are up to date, consistent with the described informed consent process, and properly signed by the participants and the PI.

- Assess the security, privacy, and confidentiality of documents, particularly those related to the participants, such as but not limited to the absence of identifiable information in documents other than the informed consent form, the existence of a document linking codes to participants' identities, physical and digital locks, etc.
- Inspect the site for adequacy of facilities for ensuring the proper execution of interventions and the safety and welfare of participants.
- If applicable, interview the PI and his/her staff on the occurrence of unanticipated problems and adverse events and how they responded.
- Make an overall assessment of the safety and welfare of human participants.
- Solicit feedback from the PI on the Monitors' initial assessments.
- Accomplish and submit the Monitoring Report Form no more than five (5) working days after the site visit.

**4.11 Present findings during plenary meeting**

A plenary meeting must be scheduled no more than 10 working days after the conduct of the site visit by the Monitor. A copy of the accomplished Monitoring Report Form must be furnished to the UREC members along with the invitation to the meeting. The meeting is presided over by the UREC Chair. During the meeting, the Monitor makes a short presentation of his/her findings, after which the UREC members may ask questions.

At the end of the plenary meeting, the UREC may recommend the following actions on the protocol: no further action, request information, or recommend further action. The recommendations must proceed via consensus or general agreement of the whole body (i.e. all members present find the decision to be acceptable). If consensus is not reached, a decision is made via a voting process (e.g. raising of hands), wherein the decision of the majority is passed. Only UREC members who are present during the deliberations on the protocol can vote. The UREO OA and UREO Director do not vote.

**4.12 Communicate to the PI the results of the site visit and decision by the UREC**

The formal communication with the PI, to be sent as a letter by the UREO OA, should detail the decision of the UREC and instruct the PI on what to submit, if any.

**4.13 Respond to the UREC's recommendations**

The PI is given up to 10 working days to respond to the recommendations (due date depends on the complexity of the recommendations). The resubmission of modified documents and the response to questions and comments is sent to the UREO OA.

**4.14 Deliberate on the PI's response/action**

The UREC members will be immediately informed of the PI's response to the recommendations. Communication with the PI will continue via email until the UREC finds the response satisfactory.

**4.15 Document and file all reports and decisions on the Monitoring of the protocol**

The UREO OA records this in the database and files all pertinent documents in digital folders.

## 5. Forms and Templates

AdMUREC Form 1 - Application Form for Initial Ethics Clearance: Expedited or Full Review
AdMUREC Form 3 - Protocol Assessment Form
AdMUREC Form 6 - Monitoring Report Form
Template of letter requesting minor / major modifications
Template of ethics approval letter
Template of letter on UREC recommendations based on Monitoring

## 6. History of the SOP

| Version No. | Date | Authors | Main Change |
|---|---|---|---|
| 01 | 2022 May 11 | Ronald Allan L. Cruz, Nico A. Canoy, Eduardo Valdez, Joseph Johnson, Alfred Pawlik | |