RESEARCH OVERSIGHT AND MONITORING GUIDELINES

Introduction

The Faculty of Medicine Research and Ethics Committee reviews research proposals of faculty members and students with the aim of ensuring the protection of research participants. Whereas the research conducted by faculty members will be subjected to the general guidelines in section I, students’ research will be subjected to both general (section I) and specific (Section II) guidelines that specifically address the roles of supervisors of students’ research. Section II offers guidance on how supervisors can effectively perform this role.

SECTION I: GENERAL GUIDELINES

Purpose of the guidelines:

The purpose of the research oversight and monitoring guidelines is to ensure that research projects approved by FOMREC conform to the research guidelines right from their implementation through to their completion. During each monitoring review, the trial conduct, procedure, and processes will be evaluated. The monitor will also assess the study staff’s knowledge and compliance with National and International regulations as well as GCP guidelines. The monitor will assess and recommend any training needs of the study staff. Any deficiencies with the staff and/or study will be identified and a corrective plan designed.

Types of Monitoring and Oversight Reviews:

1. For-cause monitoring review; this may arise when the IRB learns of any of the following:
   a. Multiple protocol violations, deviations, and/or departures from protocol
   b. Subject complaint (s)
   c. Staff complaint (s)
   d. Numerous reportable unanticipated problems
   e. Research non-compliance such as failure to submit reports
2. Routine, not for cause review (Sites selected without bias based on specific, objective criteria).

Contacting the site selected:

1. Contact will be made with the site to inform the Principal Investigator of the purpose and scope of the monitoring and oversight review. The dates and times will be agreed upon by all parties and then scheduled. The date of the review will not exceed 30 days from the initial request.
2. Defined personnel (i.e. study coordinator, data manager, etc.) will be requested to be accessible during the monitoring visit.
3. The Principal Investigator will receive a formal written confirmation of the date and time of the review. Within the written confirmation, specific documents will be requested for review.

**Conducting a Research Oversight and Monitoring visit:**

The following methods will be employed in conducting the visit:

1. Interview staff to receive detailed information on how the study is being conducted including verification of the administration of informed consent. The responsibilities and roles of the staff members will be discussed. The objectives of the monitoring and oversight visit will be discussed and timelines established for intermittent meetings and follow-up during and after the review.

2. Tour of the facility to examine the equipment being used and their location (e.g. calibration logs and maintenance logs). Storage areas for case report forms and test articles will be examined for accessibility and security.

3. Random sampling of subject data will be done to verify protocol compliance, source documentation, case report form completion and signing of Informed consent document.

4. Review and observation of study staff work practices will be performed to assess the following:
   1. Standard Operation Procedures for conducting clinical research,
   2. the process by which informed consent is administered,
   3. the recruitment process, reporting of serious adverse events,
   4. drug accountability
   5. the randomization and blinding process.

7. Hold initiation and closing (exit) meetings during the scheduled monitoring and oversight visit. The purpose of the visit and all significant findings and follow-up items will be discussed. The study staff will be able to respond to the findings and note any corrective action already taken during the review.

**Specific Review Areas during the Research Oversight and Monitoring Visit**

During the research oversight and monitoring visit, the team should review and report on the following areas and any other area they deem relevant basing on the terms of reference provided to them by the IRC Chairperson:

1. Review Informed Consent Form (ICF):
   - Ensure that every subject was adequately informed and consented to the study before any study procedures were completed
   - Sample out some participants’ files and check if the consent form was adequately signed and that it is the right version duly stamped by the IRC
2. Check for Serious Adverse Events (SAEs):

- Check if any AEs, or SAEs have occurred, check for their nature and if the event has been reported.

3. Check for Protocol Compliance:

- Verify that the investigator follows approved protocol by looking at the approval letter and protocol version in use
- Verify that only eligible subjects are enrolled
- In your chart and source document review, verify that subjects were assigned at the right times and the right procedures were conducted as per the protocol.
- Check for any deviations from protocol, and if deviations have occurred, check if they have been reported to the IRC.
- Look at the forms for reporting deviations with particular interest in knowing cause and mitigation, if any.

4. Verifying that the investigator provides all the required reports, notifications, applications, and submissions, and that these documents are accurate, complete, timely, legible, dated, and identify the trial.

5. Compare source documents to Case Report Forms (CRFs):

- Check for completeness of the CRFs and that the information in the source documents matches that in the Case Report Forms and other trial related documents.
- Any dose and/or therapy modifications are well documented for each of the trial subjects.
- Adverse events, concomitant medications, and intercurrent illnesses are reported on the CRFs in accordance with the protocol.
- Visits that the subjects fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs.
- All withdrawals and dropouts, from the trial, of enrolled subjects are reported and explained on the CRFs.
- Verify that the source is complete, neat, attributable (who wrote it? Is it initialed and dated), contemporaneous (was it written at the time the procedure was completed?), valid (is the data collected possible?), etc.
5. Review Investigational Product (IP):

- Verify that the storage times and conditions of the product are acceptable, that only eligible subjects receive it in doses specified in the protocol, subjects are provided with the necessary instructions for using, handling, storage and returning it. In addition, verify that the receipt, use and return of IP at the trial site is controlled and documented, disposition of unused IP at the trial site is in accordance with the applicable regulation and sponsors’ authorized procedure.
- Verify the temperature logs, storage facilities, administration records, IVRS entries/reports for subject-specific IP accountability
- Speak to the relevant personnel.

6. Regulatory Binder / Essential Documents Review:

- Ensure that the investigator receives the current IB, all documents and supplies needed to properly conduct the trial.
- Determine if any forms need to be updated or pooled for the Trial Master File. The Trial Master File is meant to be an exact replica of all the documentation at the site. Specific information regarding the contents of the essential documents binder is covered in section 8 of the guidelines.

7. Confirm Site Adequacy / Site Status: Determine if there are new staff at the site or if staff have left. Can the site manage with current staff? Has the site or the lab moved? Confirm that there are adequate study supplies

8. Study-Specific Monitoring Tasks: Depending on the protocol, you may need to perform additional tasks such as shipping materials back to headquarters (for example lab specimens, x-rays, etc.), calibrating or reviewing calibrations of equipment, site training, checking eDiary compliance, etc.

9. Review Ongoing or Pending Issues from Previous Visits: At some point during every visit work with the staff to resolve any items identified at previous visits as ongoing issues. Indicate in your report once these are resolved.

10. Review of findings with the site: Whether or not you find issues during your visit, keep the site staff posted on your progress and how things are going. Especially, if the Principal Investigator is not available during the visit, be sure to summarize everything accurately and completely in your follow-up letter.

11. Verify that the investigation team has adequate qualifications and resources (e.g. office space, laboratories and equipment) to implement the study, and that these will remain adequate through out the study.

12. Ensure that the study project is coordinated and managed properly

- The sight holds regular meetings to adequately inform the trial staff about the trial.
• Verify that the trial staff are performing specified trial functions according to the protocol by cross-checking with the responsibility log
• Verify Standard Operating Procedures are in place

13. Verify the adequacy of the laboratory facility and equipment

• Verify for compliancy to GLP
• Verify whether the equipment and apparatus have been validated and serviced
• Verify how specimens are handled
• Inspect the documentation.

Monitoring and Oversight Visit Report

A research oversight and monitoring visit report will be generated and presented to the IRC Chairperson at the conclusion of the visit. The IRC Chairperson will advise the monitoring team of any follow-up procedures depending on the observations and issues reported. A follow-up letter will be forward to the Principal Investigator. If response is required of the follow-up letter and is not received within 30 days of receipt by the Principal Investigator, notification will be forwarded to the Committee or any other responsible higher authority.

The report will state the current operations within the study being monitored. The report will include noted deficiencies and record the resolution or corrective actions. If improvement, training, or education is needed, the specific area in need will be suggested to the IRC Chairperson.

The letter will serve as documentation for any government audit or inspection.
SECTION II: GUIDELINES FOR STUDENT RESEARCH SUPERVISION

Areas to be addressed by departments as students prepare for their final dissertations
Before students embark on their dissertations or research project it is important that they are prepared for the process. Supervisors and students should work together to identify the learning objectives and outcomes of projects and dissertations. The benefits of such a requirement, including what skills will be developed and at what level will enhance the overall quality and output of students’ research projects.

Supervisors/tutors should ensure that students are aware of the purpose and likely demands of the dissertation/research project, and what they are seeking to achieve by completing the project. For example, will successful completion prepare them for further study or research and will they be equipped with suitable employability skills?

Where students have a choice of different kinds of projects, such as data analysis projects, laboratory based practical projects or literature reviews, tutors should ensure that students are in a position to make informed choices for their future careers. Departments should make clear what students might be expected to learn by undertaking such a detailed individual project, and what specialist and transferable skills they will be able to develop during the project. This information can be outlined by the learning outcomes in the module descriptions and should be included in a research project or dissertation handbook.

The Supervisor’s Role
The primary role of a supervisor is teaching. Supervisors must ensure that the students complete their dissertation with grounding of both specialist and transferable skills, and an understanding of scientific method, creativity, problem spotting and problem solving. Before committing yourself to take on student supervision, ask yourself whether you have the time to devote to supervising the student, and whether you have the resources to adequately train the student, and that the research environment is adequate.

What the students expect of the Supervisor
1 Regular and meticulous guidance throughout the research project by providing the following:
   • Background reading
   • Technical help either personally or by arranging for help from others
   • Theoretical help; defining and refining objectives and rationale of the project

2 Have regular meetings with the student
   • The supervisor should regularly meet with the student and minutes of such meetings should be documented and made accessible during IRC monitoring
   • During such meetings, the supervisor should provide constructive feedback on the draft chapters as appropriate both in terms of the timeframe and content.
Note: Supervisors should progressively review all chapters as they are completed to minimize the reworking of the dissertation at the end of the process.

The following meetings are mandatory but it is advisable to meet more frequently

<table>
<thead>
<tr>
<th>Scheduled Meetings</th>
<th>Purpose</th>
<th>Output of the meetings</th>
</tr>
</thead>
</table>
| Initial meeting    | • Have initial contact with student  
                      • Agree on area of research  
                      • Agree on the process  
                      • Guidance on the standard of performance expected during the project  
                      • Guidance on the structure, approach and content of the dissertation  
                      • Provide background reading  
                      • Set reasonable tasks for the student to accomplish before next meeting  
                      • Set date of next meeting and desired output  |
|                    | • Establish rapport  
                      • Identify study objectives  
                      • Next meeting date  
                      • Minutes of meeting  |
| Feasibility evaluation | • Assess feasibility of the project  
                          • Agree on the title to the project  
                          • Discuss requirement for accomplishing the project in terms of time, equipment, knowledge (areas the student will require specialized training)  
                          • Set reasonable tasks for the student to accomplish before next meeting  
                          • Set date for next meeting and desired output for the next meeting  |
|                    | • Refine study objectives  
                      • Draft of proposal  
                      • Next meeting date  
                      • Minutes of meeting  |
| Progress monitoring meetings 1 (at least monthly for the duration of the project) | • Review draft write up of the proposal and make corrections  
                                                                                      • Ensure that the proposal is ready for Departmental presentation and IRC review by cross-checking with what is required by the IRC  |
|                    | • Refined draft proposal  
                      • Presentation to the department  
                      • Presentation to the IRC  |
| Progress monitoring meetings 2 | • Review comments from the IRC  
                                 • Agree on how to address them  
                                 • If proposal does not have to be resubmitted to the IRC, draw plan for implementing the project  |
|                    | • Refined proposal  |
| Report Approval meeting | • Submit corrected proposal to IRC  |
|                    | • Approved proposal  |
3. Ensure that the student has received adequate skills and knowledge through out the project

4. Ensure that the student maintains the student log accurately

5. Provide guidance about the ethical standards and the University policies and procedures associated with research and ensure that the project is conducted in an ethical and professional manner

6. Ensure that the work reported in the Dissertation Project is the student's own, except where due reference is made in the text of the dissertation, and that any editorial assistance in the writing of the dissertation is appropriately acknowledged.

7. Encourage the student to show initiative so that the student will be able to pursue independent research with confidence, particularly afterward the program.