SECTION: Routine Review

SUBJECT: Purpose and Review Processes

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I. Purpose

The purposes of Routine Reviews are as follows:

A. Contribute to excellence in U-M human subject compliance protections by facilitating safety in research and by assuring rights and welfare of study participants are met; and, by providing feedback and education to investigators and the Human Research Protection Program (HRPP) regarding current practices of human subject research compliance.

B. Assist investigators and their staff by:
   1. Reviewing institutional, state, and federal policies, and best practices that apply to the study;
   2. Evaluating the conduct of the study; and
   3. Ensuring proper record-keeping of all study related documents.

II. The Overall ORCR Study Review Process

Studies are reviewed comparing ways in which a study is being conducted with the IRB approved eResearch application and applicable institutional policies including but not limited to: IRB Policies and Procedures, the U-M HRPP Operations Manual, HRPP guidance, federal human subjects protections regulations and guidance, and applicable state laws.

Each review is tailored to the nature and scope of the study and may include, but not limited to, a systematic review of:

- Study team roles and responsibilities;
- Recruitment procedures;
- Screening and eligibility determination process;
- Consent process and documentation;
- Implementation of various study procedures;
- Study document management and record-keeping;
- Data safety and monitoring;
- IRB reporting requirements;
- Data confidentiality procedures;
- PI oversight; and
- Study team training.

ORCR will promptly report to the IRB of Record and to the HRPP Associate Director any review observations that might be considered serious or continuing noncompliance with human study participant protections. ORCR follows the noncompliance policy in OM Part 12, II.

III. Procedures

ORCR study selection

Study selection criteria are based on areas of research risk identified by U-M Human Research Protection stakeholders such as the IRBs or the ORCR Advisory Committee, from risk areas identified at peer institutions, and from concerns of federal agencies.

Investigator notification

1. After a study has been identified for review, an ORCR reviewer is assigned.
2. The principal investigator (PI) is emailed notification of the ORCR review as well as the study coordinator, U-M IRB, the Research Associate Dean, Associate Chair for Research or Department Chair, the Executive IRB Director, and the HRPP Associate Director. The ORCR team will also receive a copy of the notification and will be available to answer questions at any time during the review process.

Scheduling the review

1. ORCR requests PIs to contact them within five business days of review notification. If a PI has not responded at five days, a second notification letter will be sent to the investigator.
2. The PI may, at his or her discretion, designate another person to serve as a point of contact with ORCR to set up the review schedule.
   a. The review should be within four weeks from the time the study review notice is sent.
   b. PI or designee should plan for adequate space to review research records on-site.
3. ORCR will make every effort to work with investigators to schedule reviews at a time least disruptive for them and their staff.
4. The PI is required to attend the initial discussion with ORCR and may invite research staff, students, and/or research assistants to attend, as appropriate to their roles as key study personnel.
   a. For Sponsor-Investigator studies, the sponsor must be present if they are a different individual than the PI.
5. If the PI is a student, the Faculty Advisor must also be in attendance.

Review preparation

1. ORCR reviews the eResearch application and IRB approved study documents prior to any on-site meeting or discussion.
2. ORCR may request additional information such as confidentiality protections or enrollment numbers, depending upon the type of study and nature of the review.
3. ORCR may request access to electronic records related to the study, such as records maintained in Dropbox or REDCap.
4. The PI or designee should ensure that all subject study records are available, are up-to-date and are organized for the review. ORCR will notify the investigator if any specific research records, for example, biospecimen disposition, will be requested for ORCR review.

On-site review

1. The study review generally includes a discussion meeting and on-site research record review. The length of time set up for the review may vary depending on the complexity of the research study and is determined by the ORCR reviewer, but is generally set up for one hour.

2. The PI is not required for the on-site record review; however, a study team member familiar with study records must be readily accessible to promptly answer ORCR questions that may arise during this part of the review.
3. The ORCR associate meets with the PI and key study personnel invited by the PI to participate. Discussion focuses on key study practices such as recruitment, obtaining informed consent, protocol adherence, identification of any possible subject safety issues, and record-keeping best practices. ORCR provides practical advice about implementing human subject protections that is tailored to the unique aspects of the study.
4. The ORCR associate conducts an on-site review of research study records and confidentiality protections. All subject study records should be available for review.
5. Any safety issues that could result in an immediate risk of harm to study participants are reported promptly to the IRB.

ORCR Report

1. ORCR develops a draft report of factual observations noted during the review. This draft is vetted with the U-M HRPP Associate Director, the IRB and the ORCR team. The PI is also provided with the opportunity to review and comment on the draft report.
2. The final report is prepared and disseminated to the PI, IRB Director and IRB Chairs, the Executive IRB Director, the Research Associate Dean, and/or Associate Chair for Research/Department Chair, the HRPP Associate Director, the ORCR team, and study team members present at the review.
3. The PI is asked to upload the final ORCR report as an ORIO in the eResearch study application to document the routine review.

Follow-up on corrective actions

When there are corrective actions, ORCR will monitor progress of completion of the actions. Generally corrective actions are expected to be completed within 30 days of issuing the final report.

Close-out

ORCR will send a close-out memorandum to the PI when all corrective actions have been completed and after the IRB has approved any IRB related corrective action submissions. ORCR uploads the close-out memo to the Managed Documents section of eResearch.