SECTION: Routine Review

SUBJECT: Purpose and Review Processes

NUMBER: 101.0
LAST UPDATED: January 2025
NEXT REVIEW DATE: January 2027
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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 protocol, federal regulations, and applicable institutional policies including but not limited to: applicable 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 is 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. This email notification is also sent to the study coordinator (if applicable), U-M IRB, the Research Associate Dean, Associate Chair for Research or Department Chair, the HRPP 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.
3. The notification contains a link to schedule a remote interview with the ORCR reviewer and a link to complete a remote review questionnaire.

Scheduling the interview

1. ORCR requests PIs to schedule the interview using the link provided and complete the remote review questionnaire within five business days of review notification. If a PI has not responded at five days, a follow-up email will be sent to the PI.
2. The PI may, at their discretion, designate another person to serve as a point of contact with ORCR to schedule the interview.
    a. The interview should be scheduled within three weeks from the time the review notification is sent.
    b. The interview will occur remotely, utilizing approved U-M technology. If a remote interview is not possible, the interview will be scheduled to occur in person.
3. ORCR will make every effort to work with investigators to schedule interviews 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.
6. The interview 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.

Review preparation

1. ORCR reviews the eResearch application and IRB approved study documents prior to the scheduled interview.

2. ORCR will request to review research records electronically, based on information provided in the remote review questionnaire.
    a. If research records are not available to be reviewed electronically, the PI or designee should plan for adequate space to review research records on-site. 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 PI or designee should ensure that all 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.

Record review

1. The length of time for the record review may vary depending on the complexity of the research study and is determined by the ORCR reviewer.
2. The ORCR reviewer conducts a review of available research study records and confidentiality protections. All subject study records should be available for review.
3. 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 ORCR team, the U-M HRPP Associate Director, and the U-M IRB staff and chairs. The study team who attended the review 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, IRB Chairs, the HRPP Director, the Research Associate Dean, and/or Associate Chair for Research/Department Chair, the HRPP Associate Director, the ORCR team, and the study team members present at the review.
3. The PI is asked to upload the final ORCR report as a part of an ORIO submission 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 Documents section of eResearch.