

**Post-approval Reminders**

**For Study Teams**

**Approved Documents**

You must use the approved versions of your consent/assent and recruitment materials found under the documents tab  in the study workspace. These documents have been converted to PDF and include an approval header on the top of the document. Contact your IRB-HSBS staff owner if the approved documents do not appear under the tab or do not include the header. If your project involves an online consent process, such as a web-based survey, the IRB-approved consent language must be must be used and should include the HUM of the study.

**Obtaining Consent**

Provide the participant with the currently approved version of the consent document. For the consent document to be complete, the participant must sign, date, and respond to any other questions or checkboxes included in the consent document. The study team must **retain a complete copy of the signed consent document**, **not just the signature page.** A copy of the full consent document must be provided to the participant. It is important for the participant to retain a copy so that they know what they have agreed to do as well as to have the contact information for the study team and the IRB if they have any questions. If a signed consent is not required (waiver of documentation of informed consent), the participant should be provided with a copy of the consent information, if they wish to have one. For on-line consent forms, participants should be instructed to print or save a copy for their information.

**Other Reminders**

**Amendments -** Any changes to this study must be submitted via an Amendment (Ame) and approved by the IRB prior to implementation. This includes changes, even minor, to the consent and recruitment materials, the study protocol, the study instruments or the study team. Please refer to [Amendment Tip Sheet](https://research-compliance.umich.edu/sites/default/files/resource-download/amendment_graphic_7_12.pdf) for tips on creating amendments.

**Scheduled Continuing Review** - If continuing review is required for your project, you will receive notices from the eResearch system reminding you to submit your continuing review (CR) to the IRB at least **30 days prior** to the expiration date of the current approval period to give the IRB time to conduct its review. Failing to do so will result in a lapse of IRB approval, meaning that research activities must be stopped until the CR is approved.

**Adverse Events and Other Reportable Information or Occurrences (AE/ORIOS) -** Adverse events are events that involve physical, social, economic or psychological harm to subjects or others. Such adverse events may also indicate risks of harm to other subjects or to others. ORIOs are unplanned or unexpected occurrences associated with the research, such as a deviation from the approved research protocol, a significant subject complaint, or a data security breach such as the theft of a laptop. Report these events to the IRB using the AE/ORIO report in the eResearch system.

**For More Information**

[IRB-HSBS Website and Guidance page](https://research-compliance.umich.edu/human-subjects/irb-health-sciences-and-behavioral-sciences-hsbs/irb-hsbs-website-directory-and)

[Human Research Protections Program Operations Manual – Part 6 – Roles and Responsibilities of Investigators and Research Staff](https://research-compliance.umich.edu/operations-manual-roles-and-responsibilities-investigators-and-research-staff)