

Institutional Review Board for Human Research (IRB) Amendment Checklist

This IRB Amendment Checklist is a tool to identify common amendment modifications submitted to the IRB. Not every modification is addressed in this checklist. Use this tool to identify the modification being made to the study and what may need to be changed in the eIRB smartforms and associated documents (i.e., informed consent form (ICF), protocol, etc.).

Common Changes

☐	Principal Investigator (PI)	☐ Study Personnel Smartform ☐ eIRB Communication Contact Smartform ☐ Conflict of Interest (COI) Smartform ☐ Protocol (if applicable) ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ ICF (if “Enrolling Subjects,” “Subjects receiving treatment/intervention,” or “Subjects in follow-up”) ☐ Section A – Purpose ☐ Volunteers Statement ☐ Search ICF for other mentions of PI (MS Word Hint: Use CTRL + F to search) ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ HIPAA (if separate from ICF) ☐ HIPAA Smartform – Upload HIPAA Clean copy (tracked changes go in Amendment Workspace) ☐ Recruitment Materials (if “Enrolling Subjects”) ☐ Search study application for other mention of PI (Hint: Use CTRL + F to search the printer version of the application) ☐ Add new PI’s CV and check off Statement of Assurance
☐	Study Title	☐ Study Identification Smartform – Question 1.0 ☐ ICF ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ Protocol ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ HIPAA (if separate from ICF) ☐ HIPAA Smartform – Upload HIPAA Clean copy (tracked changes go in Amendment Workspace) ☐ Recruitment Materials/other documents (if study title included)
☐	Number of Subjects	☐ Study Subjects Smartform – Questions 1.0 & 2.0 ☐ ICF ☐ Section A – Purpose

		☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ Protocol ☐ Number of Subjects section (Industry-sponsored/multi-site studies will only reflect the number of subjects for the entire study and not the number of local (MUSC) subjects.) ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace)
☐	Inclusion/Exclusion Criteria and/or Study Population	☐ Protocol ☐ Inclusion and Exclusion criteria/Study Population section ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ Study Subjects Smartform – Questions 6.0, 7.0, & 8.0
☐	Setting in which the research will be conducted	☐ Protocol ☐ Setting Section (Industry-sponsored/multi-site studies will not include the setting in which the research will be conducted) ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ Study Subjects Smartform – Question 3.0
☐	Recruitment Methods	☐ Protocol ☐ Recruitment Methods section (Industry-sponsored/multi-site studies will probably not include specific recruitment methods) ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ Study Subjects Smartform – Questions 9.0 & 10.0 ☐ For Cold Contact Recruitment: Cold Contact Recruitment Smartform and follow SCTR guidance ☐ If adding Ads/Recruitment Materials for the first time – check off Advertisements/Recruitment Materials on the Application Checklist Smartform ☐ Upload Ads/Recruitment Materials to Advertisement Smartform ☐ Ads/Recruitment Materials have eIRB watermark
☐	Study Design/Methods	☐ Protocol ☐ Study Design/Methods section ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ Study Procedures Smartform ☐ ICF ☐ Section B – Procedures ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ If adding Questionnaires/Surveys for the first time – check off Questionnaires/Surveys on the Application Checklist Smartform ☐ Upload Questionnaires/Surveys to the Questionnaire/Survey Smartform
☐	Risks to Subjects	☐ Protocol ☐ Risks section

		☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ ICF ☐ Section D – Risks and Discomforts ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ Study Risks and Precautions Smartform
☐	Remuneration	☐ Study Subjects Smartform – Question 4.0 ☐ Participant Remuneration Smartform ☐ ICF ☐ Section H - Payment to Participants ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ Ads/Recruitment Materials, if applicable
☐	Withdrawal of Subjects	☐ Protocol ☐ Withdrawal Section (Note: Industry-sponsored studies will probably not have a specific withdrawal section.) ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ ICF ☐ Section B – Procedures ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace)
☐	Consent Process	☐ Protocol ☐ Consent Process Section (Note: Industry-sponsored studies will probably not include specific consenting methods.) ☐ Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace) ☐ Consent Process Smartform – Questions 1.0 – 6.0
☐	Funding	☐ ICF ☐ Check ICF for all mentions if Sponsor has changed (MS Word Hint: Use CTRL + F to search ICF) ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ Funding & Sponsorship Smartform(s)
☐	Medical Records	☐ ICF ☐ Section E – Medical Records ☐ Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace) ☐ Privacy and Confidentiality Smartform – Questions 3.0 & 4.0
☐	ICF Specific Sections: Authorization to Use and Disclose Medical Information (ICF/HIPAA template) *This is the HIPAA section*	☐ No changes made to this section without prior approval from MUSC Legal Counsel. ☐ If changes are made to this section, MUSC Legal Counsel's documented approval uploaded to General Comments Smartform.

☐	ICF Specific Sections: MUSC Standard Paragraphs and Volunteers Statement	☐ No changes made to this section, other than PI information, without prior approval from MUSC Legal Counsel. ☐ If changes other than PI information are made, MUSC Legal Counsel's documented approval uploaded to General Comments Smartform.
☐	Study Personnel Changes	☐ Adding Personnel ☐ Names and roles listed in Amendment workspace description. ☐ CITI Training completed and valid. ☐ Study Personnel Smartform ☐ Removing Personnel*(see note) ☐ Names are listed in Amendment workspace description. * ☐ If amendment is to <u>only</u> remove personnel from <i>Co-I and Other Study Team Members section(s)</i> , do not submit an amendment. Use "Delete Approved Study Personnel" button to remove the study personnel. Amendments must still be submitted for removal of PI and Main Study Coordinators. ☐ eIRB Communication Smartform, if applicable

Tips for Amendments

☐	If updating the Protocol, update Questions 3.1 & 3.2 on Protocol Smartform to match Protocol version and date.
☐	If updating the ICF/HIPAA, update the version and date.
☐	Clean copy(ies) of revised documents uploaded into smartforms using "Upload Revision" button.
☐	Only use "Add" button if adding a brand new document to the study.
☐	<u>External IRB amendment</u> – Update any applicable documents on the External Documents Smartform.
☐	<u>sIRB amendment</u> – Revise the lead study consent as well as any applicable templates. Once these revisions are approved, the relying site documents (RSDs) can be submitted for approval. ☐ Lead study documents use the MUSC watermark. ☐ RSDs (relying site documents) use the MUSC watermark for remote/relying site documents.
☐	Check the 'study status' of the study before submitting an amendment to update ICFs and/or recruitment materials. If a study is closed to enrollment and subjects are no longer receiving treatment or in follow-up, you may not need to update these materials.
☐	<u>IRB III Studies specifically (industry-sponsored studies)</u> – when making changes that affects the contract with the sponsor (i.e., increasing number of subjects, PI change, study title change, sponsor commitment, etc.) notify ORSP for possible contract changes.