

## 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

<input type="checkbox"/>	Principal Investigator (PI)	<input type="checkbox"/> Study Personnel Smartform <input type="checkbox"/> eIRB Communication Contact Smartform <input type="checkbox"/> Conflict of Interest (COI) Smartform <input type="checkbox"/> Protocol (if applicable) <ul style="list-style-type: none"> <li><input type="checkbox"/> Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace)</li> </ul> <input type="checkbox"/> ICF (if “Enrolling Subjects,” “Subjects receiving treatment/intervention,” or “Subjects in follow-up”) <ul style="list-style-type: none"> <li><input type="checkbox"/> Section A – Purpose</li> <li><input type="checkbox"/> Volunteers Statement</li> <li><input type="checkbox"/> Search ICF for other mentions of PI (MS Word Hint: Use CTRL + F to search)</li> <li><input type="checkbox"/> Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace)</li> </ul> <input type="checkbox"/> HIPAA (if separate from ICF) <ul style="list-style-type: none"> <li><input type="checkbox"/> HIPAA Smartform – Upload HIPAA Clean copy (tracked changes go in Amendment Workspace)</li> </ul> <input type="checkbox"/> Recruitment Materials (if “Enrolling Subjects”) <input type="checkbox"/> Search study application for other mention of PI (Hint: Use CTRL + F to search the printer version of the application) <input type="checkbox"/> Add new PI’s CV and check off Statement of Assurance
<input type="checkbox"/>	Study Title	<input type="checkbox"/> Study Identification Smartform – Question 1.0 <input type="checkbox"/> ICF <ul style="list-style-type: none"> <li><input type="checkbox"/> Consent Smartform – Upload ICF Clean copy (tracked changes go in Amendment Workspace)</li> </ul> <input type="checkbox"/> Protocol <ul style="list-style-type: none"> <li><input type="checkbox"/> Protocol Smartform – Upload Protocol Clean copy and update Question 3.1 (tracked changes go in Amendment Workspace)</li> </ul> <input type="checkbox"/> HIPAA (if separate from ICF) <ul style="list-style-type: none"> <li><input type="checkbox"/> HIPAA Smartform – Upload HIPAA Clean copy (tracked changes go in Amendment Workspace)</li> </ul> <input type="checkbox"/> Recruitment Materials/other documents (if study title included)
<input type="checkbox"/>	Number of Subjects	<input type="checkbox"/> Study Subjects Smartform – Questions 1.0 & 2.0 <input type="checkbox"/> ICF <ul style="list-style-type: none"> <li><input type="checkbox"/> Section A – Purpose</li> </ul>

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

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

<input type="checkbox"/>	ICF Specific Sections: MUSC Standard Paragraphs and Volunteers Statement	<input type="checkbox"/> No changes made to this section, other than PI information, without prior approval from MUSC Legal Counsel. <input type="checkbox"/> If changes other than PI information are made, MUSC Legal Counsel's documented approval uploaded to General Comments Smartform.
<input type="checkbox"/>	Study Personnel Changes	<input type="checkbox"/> Adding Personnel <input type="checkbox"/> Names and roles listed in Amendment workspace description. <input type="checkbox"/> CITI Training completed and valid. <input type="checkbox"/> Study Personnel Smartform <input type="checkbox"/> Removing Personnel*(see note) <input type="checkbox"/> Names are listed in Amendment workspace description. * <input type="checkbox"/> 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. <input type="checkbox"/> eIRB Communication Smartform, if applicable

### Tips for Amendments

<input type="checkbox"/>	If updating the Protocol, update Questions 3.1 & 3.2 on Protocol Smartform to match Protocol version and date.
<input type="checkbox"/>	If updating the ICF/HIPAA, update the version and date.
<input type="checkbox"/>	Clean copy(ies) of revised documents uploaded into smartforms using "Upload Revision" button.
<input type="checkbox"/>	Only use "Add" button if adding a brand new document to the study.
<input type="checkbox"/>	<u>External IRB amendment</u> – Update any applicable documents on the External Documents Smartform.
<input type="checkbox"/>	<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. <input type="checkbox"/> Lead study documents use the MUSC watermark. <input type="checkbox"/> RSDs (relying site documents) use the MUSC watermark for remote/relying site documents.
<input type="checkbox"/>	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.
<input type="checkbox"/>	<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.