**Submitting Amendments to IRB-HSBS**

An amendment to an IRB application is required whenever any modification to an approved study is proposed.[[1]](#footnote-1) The amendment must be reviewed and approved before enacting the proposed changes, except in cases where changes to the study are necessary to alleviate an immediate risk to subjects.

An amendment in eResearch requires a cover sheet and editing of the IRB application. Clear descriptions of the modifications help the review proceed smoothly. Careful document management of new, uploaded materials is also a key aspect to consider. This document addresses issues commonly encountered in the submission of amendments.

**Amendment Cover Sheet**

eResearch automatically creates a title for the amendment that includes the study’s HUM number. Add other descriptive information in the title to describe the amendment.

Example: HUM00012345 Amendment February 10, 2010 New Survey Questions

Provide a summary of the proposed changes in response to question 1.4. Indicate *what* you are going to modify, *why* you need the modification, and *where* in the application the change(s) can be found. If you are providing new or revised documents, include a list of these documents in this summary.

**Editing the eResearch Application**

If you are adding new text to any section, always precede this information with a clearly visible header, such as AMENDMENT FEB 2010, followed by the new details. This should be placed at the end of the existing text. Don’t incorporate significant new details into existing text because it is difficult for reviewers to distinguish new information from what has already been approved.

Review the entire application to be sure that all sections and study documentation (including the research methodology) are revised to reflect necessary modifications. Failure to assure consistency across materials can delay review.

**Document Management**

Use a consistent document naming convention that includes descriptive details in the title. Reference the subject population, the purpose of the document, and the date it was created. See the following page for sample document file names. Click “Add” to upload new documents in the workspace.

In addition to uploading revised documents into the eResearch application, we recommend uploading a duplicate copy of revised documents with track changes turned ‘on’ (or changes highlighted) into Section 44 (Other Supporting Documents) to assist IRB reviewers in easily identifying changes. This is strongly recommended for studies reviewed by the full board.

If conducting your research in a language other than English, provide both English and translated versions.

When uploading a new or revised informed consent or recruitment document, use a blank merge field footer found in Section 10-1 of the eResearch application.

**DO NOT DELETE PREVIOUSLY APPROVED DOCUMENTS!**

**File Naming Samples where Subject Groups and Documents Do Not Vary**

|  |  |
| --- | --- |
| **Type of Document** | **File Naming** |
| Assent for children (for all subjects; no other qualifiers) | Child Assent\_ Amendment Feb 2010 |
| Parental permission (for all subjects; no other qualifiers) | Parent Permission\_Amendment Feb 2010 |
| Debriefing for adults (for all subjects; no other qualifiers) | Debriefing\_Amendment Feb 2010 |
| Recruitment email (for all subjects; no other qualifiers) | Email\_Amendment Feb 2010 |
| An oral consent script for phase 2 (for all subjects; no other qualifiers) | Oral Consent Phase 2\_Amendment Feb 2010 |

**Document File Naming Samples where Study has Different Subject Groups**

|  |  |
| --- | --- |
| **Type of Document** | **File Naming** |
| Assent for Down Syndrome (DS) children (versus children with Autism Spectrum Disorder (ASD) who are also in the study) | Child Assent\_DS\_Amendment Feb 2010Child Assent\_ASD\_Amendment Feb 2010 |
| Parental permission for DS and ASD children in the study | Parent Permission\_DS\_Amendment Feb 2010Parent Permission\_ASD\_Amendment Feb 2010 |
| Debriefing for test group A no information (versus those who receive information who are also in the study) | Test A NO INFO\_Debriefing\_Amendment Feb 2010Test B INFO\_Debriefing\_Amendment Feb 2010 |
| Recruitment email for 9th & 10th grade school teachers (versus 11&12 or versus administrators who are also in the study) | Teacher Email\_9&10\_Amendment Feb 2010Teacher Email\_11&12\_Amendment Feb 2010Administrator Email\_Amendment Feb 2010 |
| An oral consent script for phase 2 used with over 40 who speak Spanish (versus under 40 and English language speakers who are also in the study) | Oral Consent Phase 2\_over 40\_ENG\_Amendment Feb 2010Oral Consent Phase 2\_under 40\_ENG\_Amendment Feb 2010Oral Consent Phase 2\_over 40\_SPN\_Amendment Feb 2010Oral Consent Phase 2\_under 40\_SPN\_Amendment Feb 2010 |

1. Applications that have received an exempt or not regulated determination are excluded from this discussion. [↑](#footnote-ref-1)