**Required Documents Checklist: Uploading Study Documents for an IRB Submission**

The purpose of this guidance is to assist researchers through the uploading of their IRB submission. Uploading your study-related documents in the correct sections of your Research Navigator IRB submission smart-form is a crucial part of ensuring your review moves along quickly. Please use this checklist to ensure you have uploaded the required documentation in the appropriate sections. If you have not already done so, [**click here to view the Request for Clarification video tutorial.**](https://nyumc.sabacloud.com/Saba/Web_spf/NA3P1PRD0091/common/ledetail/0000035044)

**Document Naming**
Please ensure the version date in the document (header, cover, etc.) matches the version date in the file name. Document file should be named without spacing. Use underscore or dash symbols instead of spacing (e.g. Protocol v2). Research Navigator automatically cleans revised word documents—therefore, update the version dates in documents and file names with each draft update and do not label the documents “clean”, “tracked”, etc.

**Replacing Previously Uploaded Documents**Replace the currently uploaded draft in the Documents Tab Section with new revised track-changed draft document using the **UPDATE** button. Do not use the **ADD** button when editing an already-approved document. **NEVER DELETE** a document unless you have been specifically instructed to do so.

|  |
| --- |
| **IRB MODULE: BASIC INFORMATION > ATTACH THE PROTOCOL****Question 10:** Protocol/Protocol summary, Protocol addendum or PI / Sponsor Memo to addend info in the protocol, Questionnaires/surveys/diaries/ subject emergency cards, DSMP/DSMB Charter/Memo/Banking Memo or Protocol/Single patient treatment protocol/Location Management Plan |
| **IRB MODULE: FUNDING SOURCES:****Question 1:**List by Name Upload NIH Grant (under sponsor attachment)\*\* Applicable only for modifications to studies approved under the old Common Rule\*\*  |
| **IRB MODULE: STUDY TEAM MEMBERS****Question 1:**CVs with current NYU Langone Health role listed**Recommended:** to skip this step for future submissions, each team member should upload their CV to their Research Navigator Person Profile. [View OnDemand Video – Adding CV to RNav Person Profile](https://nyulangone-my.sharepoint.com/%3Av%3A/g/personal/royell_sullivan-green_nyulangone_org/EX_csikW5dtWqnxB3H85x9QBj07mwS434UyC9-cf70NXzQ?e=xnN4CQ).  |
| **IRB MODULE: DRUGS > ATTACH FILES(Answering YES to question 1 of the STUDY SCOPE Section opens the Drug page)** **Question 1:** List – Name of drug(s) Upload - Investigator Brochure(s)/Package Inserts**Question 2:** Answer YES if the study is conducted under IND **Question 3:** List - IND# and IND holder, Upload - appendix for IND Exemption, IND Exemption letter**Question 4:** Upload -1571 form, 1572 form, IND letter, 3926 form |
| **IRB MODULE: DEVICE INFO > ATTACH FILES** **(Answering YES to question 2 of the STUDY SCOPE Section opens the Device page)****Section 1:** List the device(s) by their current, official name, Device Manual/Instructions for Use**Section 2:** Answer IDEAnswer “Exempt from IDE requirements” if the device is cleared/approved by FDA and used as indicated –or- if the device is a Class I or Class II 510(k) exempt device.Answer “Abbreviated IDE” if the device is a non-significant risk (NSR) device**Section 3:** List the IDE# and IDE HolderUpload - a memo from the sponsor that provides detailed justification to support point-by-point why the device does not meet each of the 4 criteria for significant risk (SR) device as stated in 21 CFR 812.3(m) (thereby being a NSR device).Upload - the 510k clearance with indication or FDA PMA letter **Section 4**: Upload the IDE letter |
| **IRB MODULE: LOCAL SITE DOCUMENTS > CONSENT FORMS:****Question 1:**Main consent form, Optional/additional consent form, Pregnant Partner consent form, ICF Key Information Sheet, AssentsTelephone verbal scripts, Telephone Consent, Waiver forms, Information sheets, Capacity assessment tools, Research Authorization form, Audio Video consent form**RECRUITMENT MATERIALS**:**Question 2:** Upload- Flyers, Ads/email direct notification language, Web pages with ads, MyChart message, Pregnant Partner Contact Sheet, Recruitment phone scripts, Dear Patient/Physician Letters, Brochures (if they are not consents), Retention materials (i.e. holiday and birthday cards, thank you notes, study newsletters), Postcard, CliniCard Information**OTHER ATTACHMENTS** **Question 3:** Appendices, IRB approval letters from other sitesCurrent medical licenses (PI/Sub-I) if not listed in CV, Department Chair Memo for PI change, eConsent links (i.e. REDCAp), Other documents |
| **IRB MODULE: STUDY-RELATED DOCUMENTS (*Single IRB ONLY*) > CONSENT FORM TEMPLATES:**Participating site templates for the following: Main consent form, Optional/additional consent form, Pregnant Partner consent form, ICF Key Information Sheet, Assents, Telephone verbal scripts, Waiver forms, Information sheets, Capacity assessment tools**RECRUITMENT MATERIAL TEMPLATES:**Participating site templates for the following: Flyers, Ads/email language, Web pages with ads, Pregnant Partner Contact Sheet, Recruitment phone scripts, Dear Patient/Dr. Letters, Brochures (if they are not consents), Retention materials (i.e. holiday and birthday cards, thank you notes, study newsletters), Postcard, CliniCard Information**OTHER ATTACHMENTS:**Any other materials relevant to be sent to participating sites: reliance agreement template, protocol addendum template. |