Required and Optional Components for NEW Expedited/Full Board IRB Submissions

Required:

- IRB-1 or IRB-9 online application eform
- IRB-1 or IRB-9 Word document study protocol form (always download current version from IRB website)
- Appendix A (list of key personnel) online eform
- Data Security Assessment Form (always download current version from IRB website)

Other essential documents for IRB submission that may be relevant to your research

- Consent form(s)
- Information Sheet(s)
- Parental Permission Form
- Parental Notification Form
- Photo/Video Release Form
- Assent Form
- Incomplete Disclosure/Deception Debriefing Statement
- Survey/Measures including those created by researchers (e.g. demographic forms)
- Interview/Focus Group Questions
- Screening, medical history, data collection forms and checklists
- Screen shots of computer games, films, apps., etc.
- Recruitment flyers, website postings, social media postings, etc.
- Recordings of recruitment radio/television advertisements
- Screen shots of recruitment websites
- Photographs/illustrations of any investigator designed devices
- Grant application (if not yet submitted to Sponsored Programs Services)
- Other IRB approval or site permission letters (email permission ok)
- Communication with FDA regarding drug and devices
- Investigator brochure (common with clinical trial submissions)

Instructions for routing your submission after you click the submit icon in InfoEd (Submit):

Faculty initiated research:

- Review InfoEd "How To" guides.
- IRB protocols not funded by an internal funding program or by an external source do not have to be routed to the person designated in each Department/School to approve IRB submissions. IRB protocols funded by Department/School sources must be routed for Department/School approval.
- Only new protocol submissions require Department/School review. Amendments and re-approvals do not.

For Student initiated research:

- ***ALL*** student research submissions (of any kind) require the faculty PI be inserted in the InfoEd route for approval. Amendments, Re-Approvals, Protocol Deviations do not require Department/School approval unless Department/School's own policy requires this.

Special Instructions for use of school records (UConn, Other Higher Education Institutions, K-12 institutions, etc.)

Family Educational Records Privacy Act (FERPA)

- Contact Rachel Krinsky-Rudnick, JD, CIPP/US, Associate Vice President and Chief Privacy Officer prior to protocol submission if during the course of your research you are accessing UConn or Non-UConn academic records governed under the FERPA for research purposes Contact mailto:rachel%20at%20Rachel.rudnick@uconn.edu.

Required and Optional Components of a NEW Exempt or Limited IRB Review Submission

Required:

- IRB-5 or IRB-7online application eform
- IRB-5 or IRB-7 Word document study protocol form (obtain download current version from IRB website)
- Appendix A (list of key personnel)
- Data Security Assessment Form (always download current version from IRB website)

Other essential documents for IRB submission that may be relevant to your research:

- Information Sheet
- Survey/Measures
- Interview/Focus Group Questions
- Recruitment flyers, website postings, social media postings, etc.
- Screen shots of computer games, films, etc.
- Grant Application (if not yet submitted to Sponsored Programs Services)
- Site Permission Letters

Required and Optional Components of Amendments to a New Exempt, Expedited, Limited IRB Review, or Full-Board Protocol Submission

Required:

- IRB-3 Request to Amend online application eform

Other essential documents for IRB submission that may be relevant to your research

- Track-Change and Un-tracked (clean) versions of any Word documents amended.
- Any new added document not previously reviewed to the IRB (e.g. new recruitment flyer).
- Note changes to online eforms cannot be tracked. Still make the required change to the eform as part of the amendment submission and submit. IRB staff will review.
- Site Permission Letters
- New or revised Surveys/Measures
- New or Revised Interview or Focus Group Measures
- New or Revised Debriefing Statement

Required and Optional Components for Re-Approval or Closure of an Expedited or Full-Board Protocol Submission

Required:

- IRB-2 Request to Re-approve/Close online eform
- NIH Cumulative Enrollment Report – only if NIH funded. Obtain from IRB website and upload to InfoEd

If Enrollment is Ongoing:

- Clean, unvalidated copies of consent, assent, parental permission forms. Clean, unvalidated copies of recruitment. Note these are only required if recruitment continues.

Required and Optional Components for a Protocol Deviation Submission (all levels of review)

Required:

- IRB-6 Protocol Deviation Report eForm

Other essential documents for IRB submission that may be relevant to the protocol deviation

- Any relevant supporting material.
- Copies of reports of the deviation to sponsor, other IRB, etc.

Other important information and tips:

Do not include the names of participants. Refer to participants only by study ID number. Redact participant name from ***all*** documents provided with submission.

Required and Optional Components of an Adverse Event Submission (all levels of review)

Required:

- IRB-4 Adverse Event Report online eform

Other essential documents for IRB submission that may be relevant to the adverse event:

- Physician Notes
- Research Key Personnel Staff Statements
- Copies of reports of the event to sponsor, other IRB, etc.
- Any relevant supporting material

Other important information and tips:

Do not include the names of participants. Refer to participants only by study ID number. Redact participant name from ***all*** documents provided with submission.

Questions

Contact IRB staff at (860) 486-8802/0986 if you have any questions regarding what to submit or if you would like to discuss your submission with IRB staff.