Required and Optional Components for
NEW Expedited/Full Board UConn 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 reapprovals 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 Rachel.rudnick@uconn.edu.

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

Required:
- IRB-5 or IRB-7 online 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)

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.