

INSTITUTIONAL REVIEW BOARD (IRB) MEDICAL SUBMISSION PREP CHECKLIST

Basic considerations for all parts of the IRB Submission process – before you begin, during the application-writing process, submission, and post-approval.



The Office of Research Integrity (ORI) is the support office for the UK IRB.

BEFORE YOU BEGIN

Plan Ahead!

- Carefully consider any deadlines you have and start early so you can meet those- IRB submission and review take time. See time-to-approval estimates for various review types on the [IRB FAQ webpage](#).
- Review [ORI sample materials](#).
- Consider implications for multi-site research. Make appropriate arrangements for [off-site research](#) and projects that [require reliance agreements](#).
- Plan for the end of your study. Consider what happens if you leave the University of Kentucky (e.g. graduate; transfer to another institution). Will you close the study? Will someone else take over? If so, who?

Mandatory Training

UK policy requires all study personnel who conduct research with human subjects to complete training on protecting human subjects. See our [training FAQ](#) for more information.

- Make sure your own training is up-to-date.
- Ensure all study personnel (including faculty advisors) have current training.

Determine which IRB and Process

Note: E-IRB applications cannot be switched between exempt/other process types or between Medical/Nonmedical. **If you select the wrong type, you may need to create a new application.**

- Whether you submit to the Medical or the Nonmedical IRB is generally determined by which College you are working within. See "[Which IRB will review my research?](#)" for more information.
- Review our [tools and guidance documents](#) to determine which review type applies. Call us if you are unsure!

Other Items

- Contact ORI for help as needed. We want you to succeed!
ORI Main Line: (859) 257-9428 Offsite/Reliance Issues: IRBreliance@uky.edu
General email: IRBsubmissions@uky.edu General Assistance: [Office Hours and Request a Consult](#)
- Log in to the [E-IRB Video Tutorial Library](#) and review the E-IRB video tutorials to learn how to create an application, add attachments, and navigate the system.

WHEN YOU'RE FILLING OUT THE APPLICATION

- Use Chrome or Firefox and SAVE OFTEN. The system will time you out!
- Read through the application sections in order to pull together any materials you will need.
- In the left-hand menu, incomplete sections will have a pencil icon and complete items will have a checkmark icon. Before you can submit, all sections/subsections other than "Submission" must have a checkmark icon in this menu.
- Respond to what applies to your study. Some items may not apply to every study.
- If you are the Principal Investigator (PI), do not list yourself as study personnel. Your information is in the PI Contact Information section and does not need to be repeated.
- If you have a faculty advisor or mentor, select the "contact" and "editor" options when you add him/her to the study personnel list. This will ensure that he/she receives E-IRB system notifications related to your submission and can manage the application in your absence. If you do not have a faculty advisor, it is recommended you have at least one study personnel member listed as a contact and editor.
- Add qualifications for everyone in the study personnel list. This is one tool IRB reviewers use to verify expertise of study personnel.
- Read the **entire instruction block** for each item listed in the Research Description section.
- Clearly describe procedures done specifically for the research, those that will be done regardless of the research (i.e. standard-of-care procedures that will remain unchanged), and if/how standard-of-care procedures will be modified due to the research. Indicate if you are evaluating procedures that will happen regardless of the research. Describe your research activities in terms of who, what, how, why, when, and where.
- Breach of confidentiality is a risk for all studies involving the use of identifiable information or specimens. Address how confidentiality will be maintained in the "Safety Precautions" and "Confidentiality" portions of the Research Description.
- Include all information requested in the E-IRB application and answer each section completely. Do not excessively reference an attached protocol (e.g., sponsored protocol).
- Almost all new studies are open to new subject enrollment (record reviews and data collection count as subject enrollment even if you aren't interacting with subjects).
- Initial applications require signed assurances by a departmental authority and, for student PIs, a Faculty Advisor. The [Department Authorization Signature](#) cannot come from someone listed as study personnel – it's a conflict of interest. This departmental assurance must come from an

independent authority who assumes responsibility for assuring scientific validity, qualifications, subject population, facilities, and mentoring.

- Once all required signatures are obtained, the PI signs his/her responsibilities assurance in the “Signatures” section of the application.
- Lastly, someone with the “editor” role will click the Submission section, enter his/her own linkblue credentials, and click the Submit for Review button.

BEFORE YOU SUBMIT

Check

- that everyone on the study has up-to-date training (you can see training dates in the Study Personnel section – training is good for three years).
- for inconsistencies – number of subjects, the procedures, and study objectives/purpose are common items which you may need to reconcile.
- for copy/paste errors.
- that the informed consent includes all basic and required elements. Use the [consent/assent checklist](#) to verify.
- that all attachments are included, attached in the correct location and as the appropriate document type. For illustrated guidance, see our video tutorials to [Add Attachments \(excluding Informed Consent Docs\)](#) and [Add 'Informed Consent Section' Attachments](#).

Types of documents you may need to attach:

Notes: Each file should only be attached once. Upload it in the first applicable section then refer back as needed. Consent documents must be uploaded as the correct document type (e.g. cover letter, informed consent) so that they receive the approval stamp.

- Consent documents or scripts (e.g., informed consent form, cover letter, phone script)
- Assent documents or scripts (when enrolling minors)
- All applicable data collection tools (e.g., surveys, interview guides, data collection forms, etc.)
- [Advertising materials](#) (e.g., flyers, CCTS resources, planned social media posts, etc.)
- Recruiting messages or scripts (e.g., emails, text messages, phone scripts, etc.)
- Screening questionnaires, surveys, interview questions
- Additional IRB forms, (e.g. [drug](#) or [device](#) form, [impaired consent capacity form](#)), if applicable
- [HIPAA Waiver of Authorization](#) (required when accessing or recording information from charts without patient consent)
- Other committee approvals, (e.g. Nursing Council, [Institution Biosafety Committee](#), [Markey Cancer Center Protocol Review Committee](#), [Graduate Medical Education](#), [Office of Medical Education](#)), if applicable
- Letters of support, if applicable
- Any other relevant documents or forms which should be included

WHEN YOUR SUBMISSION COMES BACK FROM ORI SCREENING OR IRB REVIEW

- Click “All Comments” in the left sidebar to see all of the ORI screening comments. Revisions from the IRB may be inserted as comments or attached as a separate document – to view the list of attachments click “All Attachments” in the left sidebar.
- Respond promptly and fully to requests for more information, or to revisions from the IRB (see the [Respond to Requested Revisions](#) video tutorial for more information). Complete or address all items – if you disagree with a screening comment or revision, add a comment to let us know why.
- If the IRB requests changes to an attachment, please include a version of the document with changes highlighted, tracked, or underlined. For consent documents, attach the highlighted version as the “Informed Consent Highlighted Changes” document type and attach a clean copy of the document with the applicable document type selected (e.g., Cover Letter, Informed Consent/HIPAA Combined Form, Phone Script, etc.).
- Ask for help if you need it! Call the main ORI line (859-257-9428) and ask for staff managing protocol # _____. If a comment is confusing or you’re not sure how to accomplish something, let us know.

POST-APPROVAL RESPONSIBILITIES

- To make a desired change**, submit a modification request for IRB review. Investigators may not make any changes in the research without prior IRB approval, except where necessary to eliminate immediate danger to human subjects.
- Read and comply with** your responsibilities as an investigator as defined in the [PI Responsibilities Guide](#).
- Be aware of deadlines for continuation reviews or annual administrative reviews; submit those in time to get them processed before your approval expires.
- Adhere to reporting requirements. See the [IRB reporting quick guide](#) for more information on reporting requirements.
- Ensure that study personnel who are authorized to obtain consent use the current, stamped version of any consent documents.
- Follow up with your closure plan and all data/record retention requirements.
- To ensure you will receive E-IRB system notifications, set your email filters to accept messages with the subject line "Automated eIRB Message" and check your Spam and Junk folders for messages with that subject line.