

KU-Lawrence Human Research Protection Program New IRB Submission Checklist

New Study Checklist

- Complete [Human Research Protocol](#)

- Create/gather needed documents (check only that apply for your study - not all are required)
 - [Consent Forms](#)
 - [Assent Forms \(minors\)](#)
 - [Recruitment Materials](#)
 - Interview questions/ survey questions/ focus group questions
 - Tests/assessments
 - Debriefing statement (deception or omission studies)
 - External site approval letter
 - KU Environmental Health & Safety (EHS) approval
 - [HIPAA Documents](#)
 - Award/contract materials
 - Other relevant forms

- Students Only: Receive approval of documents from faculty supervisor

- Complete human research [training in CITI](#)
 - Note: need to complete once every 3 years.
 - Faculty supervisors need to have current human research training for student projects (all study team members need to have training).
 - Contact irb@ku.edu with any external study team members to receive further assistance.

Determine if your study is a [Single-Site or Multi-Site Study](#)

[Create a New Study](#) in eCompliance

- Upload all relevant documents.
- Add study team members (including faculty supervisor).
- Submit using the "Submit" button on Study home page.
- Students only: have faculty supervisor complete ancillary review.

Checklist of Documents in eCompliance	
eCompliance Page	Documents to Prepare and Upload
Basic Information	* Human Research Protocol
Funding Sources	Grant Applications; Award Letter; Contract (If Applicable)
Study Team Members	<p>Anyone involved in the following:</p> <ul style="list-style-type: none"> • Obtaining Consent for research purposes • Interacting/Intervening with participants for research purposes • Has access to identifiable data for research purposes • Serving as a faculty supervisor for a student project <p>For Non-KU affiliates, email irb@ku.edu for more information.</p>
Study Scope	N/A
Research Locations (if checked in Study Scope)	<p>If research is being conducted offsite at another institution/company/university/school, etc.</p> <p>IRB reliance letter (if available). Letter of Support (if applicable)</p>
Consent Forms and Recruitment Materials	Consent Documents and Recruitment Materials
Supporting Documents	<p>If Applicable:</p> <ul style="list-style-type: none"> • Surveys, instruments • Data collection sheet • Subjects instructions, diaries, etc. • Debriefing statements • EHS approval • External site approval • HIPAA waiver request • Other relevant documents
	*Required on all new studies