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	Anyone involved in the following: • 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 For Non-KU affiliates, email irb@ku.edu for more information.
Study Scope	N/A
External Sites (if checked in Study Scope)	If research is being conducted offsite at another institution/company/university/school, etc. IRB reliance letter (if available). Letter of Support (if applicable)
Consent Forms and Recruitment Materials	Consent Documents and Recruitment Materials
Supporting Documents	If Applicable: • 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**