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)
  o Consent Forms
  o Assent Forms (minors)
  o Recruitment Materials
  o Interview questions/ survey questions/ focus group questions
  o Tests/assessments
  o Debriefing statement (deception or omission studies)
  o External site approval letter
  o KU Environmental Health & Safety (EHS) approval
  o HIPAA Documents
  o Award/contract materials
  o Other relevant forms

☐ Students Only: Receive approval of documents from faculty supervisor

☐ Complete human research training in CITI
  o Note: need to complete once every 3 years.
  o Faculty supervisors need to have current human research training for student projects (all study team members need to have training).
  o 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
  o Upload all relevant documents.
  o Add study team members (including faculty supervisor).
  o Submit using the "Submit" button on Study home page.
  o Students only: have faculty supervisor complete ancillary review.
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<td><em>Human Research Protocol</em></td>
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<td><strong>Funding Sources</strong></td>
<td>Grant Applications; Award Letter; Contract (If Applicable)</td>
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| **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*