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.
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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 |
| **Research Locations (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* |