

**Kansas City University
INSTITUTIONAL REVIEW BOARD (IRB)**

Application Materials Checklist

To reduce the time between application submission and the approval of the protocol, please ensure:

- Forms are fully completed in final format and signed, if applicable
- All required documentation are uploaded to the IRBNet
- The submission package is electronically signed, and then submitted through IRBNet in order for the Research Compliance Office to be notified when the package is locked and ready to be reviewed.

1) NEW STUDY

(Expedited, Full Committee Classifications)

- i. IRB Application
- ii. If applicable, Assent form, Advertising Material, Questionnaire/Survey, Interview Questions, Tests, etc.
- iii. Financial Conflict of Interest Disclosure Form
- iv. CITI Training Completion Report Screenshot of all courses for all research personnel showing name and expiration dates.
- v. Informed Consent Form or Consent Recruitment Statement, if applicable
- vi. Approval Documentation from all Outside Sites, including any external IRB approvals (if applicable)
- vii. Copy of Grant, Contract or Agreement, if research is partially or fully funded through external funds
- viii. Student Data Use Form (This form is required by the registrar if KCU student records will be accessed for research purposes.)
- ix. Any additional documentation that the study has been reviewed and approved by any other committees that might have needed to review your research, if applicable (e.g., IBC, IACUC, etc.).
- x. Request to Use Student Email Distribution Lists Template, if applicable.
- xi. Approved Student Research Activity Application for any COM, CDM or COB student (Except COB Two Year Research Track, Graduate Research Assistant and Anatomy, Summer and OMM Fellows)
(When completed please send it to the Research Compliance Office for processing. When approved, the finalized copy needs to be uploaded to the package submitted)
- xii. Data Sharing Plan, if applicable.
- xiii. Signed Individual Investigator Agreement for external collaborators, if applicable

2) (Exempt Classification)

- i. IRB Application
- ii. IRB Exempt Questions Form
- iii. If applicable, Advertising Material, Questionnaire/Survey, Interview Questions, Tests, etc.
- iv. Financial Conflict of Interest Disclosure Form
- v. CITI Training Completion Report Screenshot of all courses for all research personnel showing name and expiration dates.
- vi. Consent Recruitment Statement
- vii. Approval Documentation from all Outside Sites, including any external IRB approvals (if applicable)

Contact the Research Compliance Office if you have questions.

researchcompliance@kansascity.edu 816-654-7602

- viii. Copy of Grant, Contract or Agreement, if research is partially or fully funded through external funds
- ix. Student Data Use Form (This form is required by the registrar if KCU student records will be accessed for research purposes.)
- x. Any additional documentation that the study has been reviewed and approved by any other committees that might have needed to review your research, if applicable (e.g., IBC, IACUC, etc.).
- xi. Request to Use Student Email Distribution Lists Template, if applicable.
- xii. Approved Student Research Activity Application for any COM, CDM or COB student (Except COB Two Year Research Track, Graduate Research Assistant and Anatomy, Summer and OMM Fellows)
(When completed please send it to the Research Compliance Office for processing. When approved, the finalized copy needs to be uploaded to the package submitted)
- xiii. Data Sharing Plan, if applicable.
- xiv. Signed Individual Investigator Agreement for external collaborators, if applicable

3) CONTINUING REVIEW (For Full Committee Review Studies):

- i. Continuing Review Form
- ii. Updated Financial Conflict of Interest Disclosure Form.
- iii. CITI Training Completion Report of all courses for all research personnel showing name and expiration dates.
- iv. Stamped consent form which have been used, if applicable
- v. Updated Informed Consent Form with changes highlighted, if applicable
- vi. Approval Documentation from Outside Site, including Outside Site's IRB approval (if applicable)
- vii. Any additional documentation that the study has been reviewed and approved by any other committees that might have needed to review your research, if applicable (e.g., IBC, IACUC, etc.).
- viii. Updated & Approved Student Research Activity Application for any COM, CDM or COB student (Except COB Two Year Research Track, Graduate Research Assistant and Anatomy, Summer and OMM Fellows)
(When completed please send it to the Research Compliance Office for processing. When approved, the finalized copy needs to be uploaded to the package submitted)
- ix. Data Sharing Plan, if applicable.
- x. Signed Individual Investigator Agreement for external collaborators, if applicable

4) Annual Report / Renewal Request (For Expedited Studies):

- i. Annual Report / Renewal Request Form
- ii. Updated Financial Conflict of Interest Disclosure Form.
- iii. CITI Training Completion Report of all courses for all research personnel showing name and expiration dates.
- iv. Stamped consent form which have been used, if applicable
- v. Updated Informed Consent Form with changes highlighted, if applicable
- vi. Approval Documentation from Outside Site, including Outside Site's IRB approval (if applicable)
- vii. Any additional documentation that the study has been reviewed and approved by any other committees that might have needed to review your research, if applicable (e.g., IBC, IACUC, etc.).

- viii. Updated & Approved Student Research Activity Application for any COM, CDM or COB student (Except COB Two Year Research Track, Gradate Research Assistant and Anatomy, Summer and OMM Fellows)
(When completed please send it to the Research Compliance Office for processing. When approved, the finalized copy needs to be uploaded to the package submitted)
- ix. Data Sharing Plan, if applicable.
- x. Signed Individual Investigator Agreement for external collaborators, if applicable

5) Exempt Status Report (for Exempt):

- i. Exempt Status Report Form
- ii. Updated Financial Conflict of Interest Disclosure Form, if applicable
- iii. CITI Training Completion Report of all courses for all research personnel showing name and expiration dates.
- iv. Updated Informational sheet with changes highlighted, if applicable
- v. Updated Approval Documentation from Outside Site, including Outside Site's IRB approval (if applicable)
- vi. Any updated additional documentation that the study has been reviewed and approved by any other committees that might have needed to review your research, if applicable (e.g., IBC, IACUC, etc.).
- vii. Updated & Approved Student Research Activity Application for any COM, CDM or COB student (Except COB Two Year Research Track, Gradate Research Assistant and Anatomy, Summer and OMM Fellows)
(When completed please send it to the Research Compliance Office for processing. When approved, the finalized copy needs to be uploaded to the package submitted)
- viii. Data Sharing Plan, if applicable.
- ix. Signed Individual Investigator Agreement for external collaborators, if applicable

6) NOT HUMAN SUBJECTS RESEARCH OR NOT RESEARCH PROJECT:

- i. Human Subjects Research Determination Form.
- ii. HIPAA Approval Documentation, if applicable.
- iii. Approved Student Research Activity Application for any COM, CDM or COB student (Except COB Two Year Research Track, Gradate Research Assistant and Anatomy, Summer and OMM Fellows)
(When completed please send it to the Research Compliance Office for processing. When approved, the finalized copy needs to be uploaded to the package submitted)
- iv. Data Sharing Plan, if applicable.

7) AMENDMENT:

- i. Amendment Submission Form
- ii. Other documents listed under New Study, if applicable to the amendment

8) ADDITION OF PERSONNEL:

- i. KCU IRB Change to Research Team Form
- ii. CITI Training Completion Report Screenshot of all courses for all research personnel showing name and expiration dates.
- iii. Financial Conflict of Interest Disclosure Form
- iv. Approved Student Research Activity Application for any COM, CDM or COB student (Except COB Two Year Research Track, Gradate Research Assistant and Anatomy, Summer and OMM Fellows)



06/13/2024

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v. Signed Individual Investigator Agreement for external collaborators, if applicable

9) REMOVAL OF PERSONNEL:

- KCU IRB Change to Research Team Form

10) ADVERSE EVENT:

- Serious Adverse Event Report

11) CLOSEOUT:

- Study Closure Form