**IRB Submission Requirements (IRBNet) - (New, First Time Submissions) (Please Note – Residents, Fellows and Students are not permitted to be PI’s. The PI must be a Faculty Member or Physicians on Erlanger Medical Staff)**

**DO NOT SUBMIT THE PACKET UNTIL ALL DOCUMENTS ARE COMPLETE AND UPLOADED AND ALL SIGNATURES ARE OBTAINED**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|   | Exempt Review  | Expedited Review  | Full Review  | Outside IRB used acknowledgement | Hospital QA/QI/Not Human Subject Research**(QA/QI and NHSR projects are submitted in IRBNet)**  |
| Initial Study Application (SmartForm Wizard tab) | x | x | x | x |  |
| Protocol  | X  | X  | X  | x | X  |
| Consent Forms in **Word doc format** \* (A separate HIPAA Consent is required for NCI CIRB approved projects) | X  | X  | X  | x |   |
| Fee Authorization form **(Industry or Grant-Funded Studies only)** \*  |   | X  | X  | x |   |
| HIPAA form/Consent Waiver **(if applicable)** \* | X  | X  | X  | x | x  |
| Surveys, questionnaires, evaluation instruments  | X  | X  | X  | x | x  |
| Recruitment Materials (e.g. email/call scripts, announcements, advertisements, etc)  | X  | X  | X  | x |   |
| Data collection sheets (spreadsheets, key sheet templates, case report forms, etc)  | X  | X  | X  | x | x  |
| Investigator Brochures for Investigational Drugs/Devices **(if applicable)**  |   | X  | X  |  |   |
| Medicare Coverage Analysis\* (if applicable) (REQUIRED for studies involving drugs and devices or when procedures/tests are outside of standard of care) (See Medicare Checklist for documents) |  | x | x | x |  |
| Central IRB approval Letter |  |  |  | x |   |
| UT Medical Student HIPAA and Compliance Training Certificates from UT (if applicable) | x | x | x |  | x |
| Biostatistical Request Form \*(must be completed for all investigator initiated studies)  |  x | x  | x  | x |  |
| CITI Training and CVS for all Research Personnel. (CITI can be linked through IRBNet UserProfile and CV’s added as additional training | X  | X  | X  | x |  |
| Request for Human Subjects Research Determination QA/AI Activity \*  |   |   |   |  | x |
| PI, Co-PI, Key Research Staff and Department Chair Approval (via Ancillary Review) and any other applicable ancillary reviews (Use the Share button to send to research team and outside reviewers.  | X  | X  | X  | x |  x |

 \* Templates for these documents are available in the IRBNet “For Investigators” library

**IRB Submission Requirements (IRBNet)**

**Modifications**

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|  |  |  |
| --- | --- | --- |
|   | **Minor Amendment**  | **Major Amendment**  |
| Revision/Change Form (see “For Investigators” library for form)  | X  | X  |
| CITI Training and CVS for all Research Personnel. (CITI can be linked through IRBNet UserProfile and CV’s added as additional training | X | X |
| Revised documents with changes tracked/noted in Revision/Change Form  | X  | X  |
| PI, Department Chair Approval (via Ancillary Review) and any other applicable ancillary reviews (Use the Share button to send to research team and outside reviewers. | x  | X  |

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**IRB Submission Requirements (IRB NET version) Continuing Review Submissions**

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|  |  |  |  |
| --- | --- | --- | --- |
|   | Expedited Review  | Acknowledged Review for Commercial/NCI CIRBs | Full Review  |
| IRB Form D – Continuing Review Request \*\*  | X  | x | X  |
| Clean, most currently approved, Consent Forms/Permission Forms/Assent Forms in **Word doc format** \*  | X  | x | X  |
| Central IRB Approval Letter |  | x |  |
| Data Safety Monitoring Board Reports  | x  |  | X  |
| Government or sponsor audit/monitoring reports  | x  | x | X  |
| List of subjects enrolled and in follow-up when consent is required | X  | x | X  |
| List of local SAE’s that have occurred **Note**: an adverse event is classified reportable if it meets three criteria: 1) serious, 2) unexpected, and 3) possibly, probably, or clearly caused by the research intervention. | x | x | x |
| PI, Department Chair Approval (via Ancillary Review) and any other applicable ancillary reviews (Use the Share button to send to research team and outside reviewers. | X  | X | X  |

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