**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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