**This is only a quick-reference sheet and policies are subject to change. You should always consult *all* of our current policies, *in full*, at** [**http://www.uthsc.edu/research/compliance/irb/researchers/standard-operating-procedures.php**](http://www.uthsc.edu/research/compliance/irb/researchers/standard-operating-procedures.php) **.**

**If you have any questions, please call 901.448.4824.**

**Principal Investigator**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **IRB #**\_\_\_\_\_\_\_\_\_\_\_

**Project Title**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Approval & Record Keeping** | **Yes** | **No** | **NA** | **Corrective Actions** |
| The project was determined to be exempt by the UTHSC IRB. |  |  |  |  |
| All IRB records not already stored in iMedRIS (e.g., old project documents approved on paper, signed consent statements, data collection spreadsheets, questionnaires, etc.) have been retained, in a protected/locked location and accessible only to research personnel. **Note**: *information regarding length of record retention is located in the Study Closure and Record Retention policy on our website. In addition, see the end of this checklist for more record-keeping information.* |  |  |  |  |
| All key study personnel listed on the IRB application are currently certified in human subjects protection training (CITI or NIH). |  |  |  |  |
| The project conducted is consistent with the project description & procedures outlined in the IRB-approved application. |  |  |  |  |
| For each subject, did you record the inclusive dates for the period that the information you abstracted was entered into the medical record? (The dates should be within the range of retrospective dates listed in your application.) |  |  |  |  |
| All data collection instruments used were reviewed & approved by the IRB prior to use. |  |  |  |  |
| **Informed Consent** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Did your project receive approval for an alteration of consent? |  |  |  |  |
| If an alteration of consent was approved, was the IRB-stamped-approved (and unexpired) script or survey/consent cover statement used to enroll subjects prior to any research procedures being conducted, and is this documented in source documents or on the case report forms? |  |  |  |  |
| If you did not obtain informed consent, did your project receive approval for a waiver of informed consent? |  |  |  |  |
| If your project did not receive a waiver or alteration of consent, did you use your stamped-approved consent form/statement when consenting? |  |  |  |  |
| **Institutional Requirements** | **Yes** | **No** | **NA** | **Corrective Actions** |
| If you are conducting the project at Le Bonheur Children’s Hospital, Methodist Healthcare, or Regional One Health, have you received appropriate institutional approval? |  |  |  |  |
| If there have been any changes in the investigator’s situation (privileges, license, etc.) or institutional commitments (facilities or personnel/financial resources) for your project, have these been reported to the IRB? |  |  |  |  |
| If applicable, was a copy of the signed consent form/statement placed in the medical record, and the original kept in the research record? |  |  |  |  |
| Was documentation regarding the informed consent discussion included in the medical record and research record? |  |  |  |  |
| **Recruitment** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Were subjects identified & recruited according to the methods outlined in the IRB-approved application? |  |  |  |  |
| Were any advertising/recruitment materials which were used to recruit subjects reviewed & approved by the IRB prior to use? |  |  |  |  |
| **Changes/Amendments** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Have there been any changes to the project? |  |  |  |  |
| If so, were the changes reviewed & approved by the UTHSC IRB prior to implementation? **Note**: all changes & revisions to a project must be submitted for IRB review via a *Form 2: Change Request/Amendment*. |  |  |  |  |
| **Privacy, Data Storage & Confidentiality** | **Yes** | **No** | **NA** | **Corrective Actions** |
| The subjects’ privacy was protected, and safeguards are in place as outlined in the IRB-approved application. |  |  |  |  |
| Are hard copies (i.e., paper data collection instruments) stored in a secure & locked location? |  |  |  |  |
| Is electronic data on a secure & protected computer?  |  |  |  |  |
| Is access to computer, electronic files, and/or physical files limited to the key study personnel who were listed as having access in the IRB-approved application? |  |  |  |  |
| Did your project receive a waiver of the HIPAA authorization? |  |  |  |  |
| **Unanticipated Problems** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Have all reportable problems & adverse events been promptly reported to the IRB (e.g., stolen laptop containing private information)? **Note**: *information regarding adverse event reporting requirements is located in the Adverse Event Reporting policy on our website.* |  |  |  |  |
| **Closure** | **Yes** | **No** | **NA** | **Corrective Actions** |
| If the project is complete, has the IRB been notified via a *Form 7: Report of Termination*? |  |  |  |  |

**NOTE**: ***If you would like to discuss any aspects of your project with the IRB staff, please call 901.448.4824 or email at*** ***irb@uthsc.edu***