**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 has current IRB approval (i.e., received initial approval and has not expired). |  |  |  |  |
| All IRB records not already stored in iMedRIS (e.g., old project documents approved on paper, signed consent forms/statements, data collection spreadsheets, eligibility checklists, questionnaires, etc.) have been retained, in a protected/locked location and accessible only to research personnel. **Note**: *information regarding 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. |  |  |  |  |
| If you were approved for retrospective abstraction, 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 UTHSC IRB prior to use. |  |  |  |  |
| If subjects received any compensation, is there documentation of when they received it or when it was mailed? |  |  |  |  |
| **Informed Consent** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Was the IRB-stamped-approved consent form used to enroll subjects? |  |  |  |  |
| Were all consent forms (stamped-approved & unexpired) signed by subjects prior to any research procedures being conducted, and is this documented in source documents or on the case report forms? |  |  |  |  |
| Do you have a signed & dated consent form on file for every subject enrolled in the project? |  |  |  |  |
| Did only key study personnel listed in Sections 3.0 and listed as obtaining informed consent in Section (415) of your IRB-approved application consent subjects for participation in the project? |  |  |  |  |
| Was surrogate consent for adult subjects approved for use in your project? If so, are the initials & signature lines for the legally authorized representative (LAR) included on your stamped-approved consent form? |  |  |  |  |
| If children were enrolled, did a parent or a court-appointed legal guardian provide permission and sign your stamped-approved consent form?  |  |  |  |  |
| If your research population includes subjects 8-13 years of age, was the assent discussion page of your stamped-approved consent form completed? |  |  |  |  |
| If your research population includes subjects 13-17 years of age, was the assent line on the consent page of your stamped-approved consent form signed by the child subject? |  |  |  |  |
| Did one of your investigators sign the consent form within 72 hours of the subject/LAR and/or parent/legal guardian and the person obtaining consent? |  |  |  |  |
| If your project includes subjects/LARs/parents/legal guardians whose primary language is **not** English, was a non-English stamped-approved consent form used to enroll these subjects? |  |  |  |  |
| If you enrolled a prisoner in your project or any of your research subjects became a prisoner while taking part in the project, did you notify the IRB? *Consult the “Additional Protections: Prisoners” policy on our website.* |  |  |  |  |
| Did your project receive approval for an alteration of consent? |  |  |  |  |
| If an alteration of consent was approved, was the stamped-approved script or survey/consent cover statement used to enroll subjects? |  |  |  |  |
| If you did not obtain informed consent, did your project receive approval for a waiver of informed consent? |  |  |  |  |
| **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 intuitional 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? |  |  |  |  |
| Were all eligibility & ineligibility criteria as listed in the IRB-approved application followed and documented on an eligibility checklist for each subject? If the criteria were not met, were deviations reported to the IRB? |  |  |  |  |
| **Changes/Amendments** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Have there been any changes to the project and/or consent form(s)? |  |  |  |  |
| If so, were the changes submitted to & reviewed by the IRB prior to implementation? **Note**: all changes & revisions to a project must be submitted for IRB review via a *Form 2: Change Request/Amendment*. |  |  |  |  |
| **Continuing Review** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Are you aware of when IRB approval of your project expires? \*NOTE: If your study is expedited and was approved, or approved pending response to administrative provisos, on or after 01/21/2019, you will not receive an expiration date. |  |  |  |  |
| Have there been any lapses in the IRB’s approval of your project? If yes, did you report any research activity that was done during the lapse to the IRB? |  |  |  |  |
| Has your full board project progressed to the point that it involves only one or both of the following:1. Remaining study activities are limited to data analysis, including analysis of identifiable private information or identifiable biospecimens, or
2. Remaining study activities only involve accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

\*NOTE: If yes is checked for this item and your study is DHHS-regulated and it was approved, or approved pending response to administrative provisos, on or after 01/21/2019, then the IRB does not require further review. However, you still must submit a final *Form 3: Continuing Review* to the IRB as a notification of your study status. **If your study is FDA-regulated, you will continue to have an expiration date until the end of the study.** |  |  |  |  |
| Enrollment occurs when the consent form is signed, not when the subject is randomized. Has the total number of subjects enrolled in the project been correctly reported to the IRB via a *Form 3: Continuing Review*? |  |  |  |  |
| Has the gender and racial/ethnic origin of each subject enrolled been collected & reported to the IRB via a *Form 3: Continuing Review*? |  |  |  |  |
| Have there been any adverse events (AEs) or unanticipated problems, complaints, or subject withdrawals while conducting this project? If yes, have all details been reported to the IRB? |  |  |  |  |
| Does your project include the use of a Data and Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC)? If yes, were these reports promptly submitted to the IRB for review? |  |  |  |  |
| Have there been any new findings to change the risk/benefit ratio? |  |  |  |  |
| **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. |  |  |  |  |
| If applicable, are research data on individual subjects coded and the linkage to their names maintained in a separate and secure locations? |  |  |  |  |
| Are hard copies (e.g., 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? |  |  |  |  |
| Was the research data stored & disposed of as described in the IRB-approved application? |  |  |  |  |
| Did your project receive a waiver of the HIPAA authorization? |  |  |  |  |
| **Adverse Events** | **Yes** | **No** | **NA** | **Corrective Actions** |
| Have all reportable problems & adverse events been promptly reported to the IRB? **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 your project is complete (the project is closed to enrollment, all subjects have completed their research interventions & follow-up, and data analysis is complete), has the IRB been notified via a *Form 7: Report of Termination*? |  |  |  |  |

**RESEARCH RECORD-KEEPING INFORMATION:**

Federal regulations (21 CRF 312.62(b)) require the investigator to maintain “case histories,” including the case report forms and supporting documentation. The FDA states that the overall purpose of the source document is “to document the existence of the subjects and to substantiate the integrity of the trial data collected.” In addition, when it is time to publish or present your research, you need to be able to find the data that support your conclusions and analyses. Research records should include:

**Individual Participant Files include items such as:**

1. Original, signed and dated consent forms (IRB-stamped-approved);
2. Verification of the informed consent interview; and
3. Supporting documentation for:

• Inclusion/Exclusion criteria

• Results of tests or procedures

• Communications with participants

• Protocol deviations

• Adverse events

• Deaths

**Study/Project Files include items such as:**

• Participant log and assigned study code;

• IRB-approved protocol;

• IRB approval letters and all other communication with the IRB;

• Other institutional approvals from the study sites;

• Investigator’s Brochure (if applicable);

• All correspondence with sponsors/ federal agencies;

• Sample IRB-approved questionnaires;

• Sample IRB-approved study forms with instructions; and

• Reports of deaths, protocol violations, protocol deviations, and serious adverse events.

**NOTE**: ***If you would like to discuss any aspects of your project with the IRB staff, please call 901.448.4824.***