**Saint Louis University Institutional Review Board**

**COMMON CONSENT PROCESS ERRORS & CORRECTIVE ACTIONS**

NOTE: References to “Consent form” below includes Assent Forms and HIPAA Authorizations

|  |  |
| --- | --- |
| **CONSENT PROCESS ERROR** | **EXPECTED CORRECTIVE ACTION** |
| Unable to locate a participant’s consent form | * Report1 error to the IRB. * Notify the study sponsor, if applicable. * Re-consent the participant or justify why this cannot practicably be done in the report submitted to the IRB. * Place signed and dated documentation in the file2 with an explanation of the error.   1Errors should be reported to the IRB as a Protocol Violation on the Report Form in eIRB within 7 calendar days of becoming known. Studies using central IRB’s can email the error to irb@slu.edu.  2The approved Protocol Violation can serve as signed and dated documentation.  3If the study team notices a missed signature or date on the day the consent process took place, the person who did not sign or date may correct the form without reporting this to the IRB. Otherwise, the error should be reported. Re-consent of participants may not be required if just study team signatures are missing from the consent document. |
| An unapproved/expired version of the consent form was used |
| The full consent form was not used (i.e., consent form is missing pages) |
| Information in the consent was crossed out or altered in any way not approved by the IRB |
| The person who obtained consent was not approved to do so per IRB-approved protocol |
| A participant was not re-consented when he/she reached the age of 18 |
| All required signatures were not obtained3 (i.e., participant, person obtaining consent, parent, second parent if required, LAR, witness) |
| Not all sections of the consent form were completed (i.e., check boxes unchecked, initials/signatures missing for optional procedures) |
| Signatures were forged |
| The consent process used differed from what was approved in the IRB protocol (e.g. subject gave consent over the phone when protocol stated consent would be obtained in person) |
|  | * Report1 error to the IRB. * Notify the study sponsor, if applicable. * Place signed and dated documentation in the file2 with an explanation of the error.   1Errors should be reported to the IRB as a Protocol Violation on the Report Form in eIRB within 7 calendar days of becoming known. Studies using central IRB’s can email the error to irb@slu.edu.  2The approved Protocol Violation can serve as signed and dated documentation.  3The SLU IRB allows the signed consent form to serve as documentation, but recommends in some studies (e.g., in-patient, decisionally-impaired populations), a consent process note also be written to capture notable details such as time of consent, who was present, etc. Studies using verbal consent can utilize a documentation log. |
| Study procedures occurred before consent was obtained/consent form signed |
| Fake participants and records were created |
| There is no documentation to demonstrate that participant was given a copy of consent materials3 (e.g., given a recruitment statement if consent provided verbally only) |
|  |
| Participant’s printed name missing on the form | Print missing name on the form |
| Participant marked subsection with incorrect notation (i.e. placed an “X” instead of initials) | Document the subject error as a note-to-file |