|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment of their research study and is indicative of what the NU IRB compliance team would expect to see when performing on site monitoring of your research study.  **Instructions:** Please complete the section(s) of this checklist that apply to your study. You may print and handwrite answers or you can complete this form electronically. The regulatory binder (where you keep all the documents related to your study) should be centralized and can be maintained within an electronic format (saved pdfs and Word/Excel documents) or within a binder (printed paper copies stored in a three ring binder). If your answers to the questions are "no" please provide a brief explanation in the comments area of each section. Additionally, if "n/a" is indicated and you feel that further clarification is needed, please address them in the comments area as well. Please email [irbcompliance@northwestern.edu](mailto:irbcompliance@northwestern.edu) if you have any questions. | | | | |
| Biomedical Research | | | | |
| Principal Investigator | |  | | |
| STU Number | |  | | |
| Research Study Title | |  | | |
| Sponsor / Funding Agency (if any) | |  | | |
| Name of Person Completing Checklist | |  | | |
| Date Checklist Completed | |  | | |
| Study Information | | | | |
| Type of Study (select all that are applicable) | | **Clinical trial**  **Chart/data review\***  **Registry\***  **Specimen collection\***  **Reviewed by an External IRB^**  **Multi-Site study where the Northwestern IRB serves as the IRB for external site(s)\*\***  **Other (specify):**  *\*If selected, please complete HRP-1405 Registry/Data Review/Specimen Collection Checklist*  *^If selected, please completed HRP-1406 Studies Under External IRB Review Checklist*  *\*\* If selected, please completed HRP-1407 Site File Checklist* | | |
| Study Enrollment Status (select all that are applicable) | | **No enrollment**  **Currently enrolling**  **Closed to enrollment**  **Long term follow-up**  **Data analysis** | | |
| Enrollment Goal | |  | | |
| Number of Screened Participants (if applicable) | |  | | |
| Number of (select from drop-down menu or Other):  Choose an item.  Other (specify): | |  | | |
| Number of Withdrawn Participants (if applicable) | |  | | |
| Date of Initial IRB Approval | |  | | |
| Date First Participant Consented (or Date Research Procedures Began for Data Review, Specimen Collection, etc.) | |  | | |
|  | | | | |
| 1 Regulatory Documentation: Please indicate whether the PI has the following documentation on file; electronic documentation is acceptable. eIRB+ does not serve as an electronic version of your study file. | | | | |
| Yes  No  N/A | 1. Grant application, progress reports and/or correspondence to and from the funding entity | | | |
| Yes  No  N/A | 1. Copy of IRB Roster(s) at the time of study activity are on file (for industry sponsored studies) | | | |
| Yes  No  N/A | 1. All versions of the IRB approved protocol | | | |
| Yes  No  N/A | 1. All versions of the IRB approved consent document(s) (includes parental permission/assent documents) | | | |
| Yes  No  N/A | 1. All versions of the IRB approved recruitment material | | | |
| Yes  No  N/A | 1. All versions of the IRB approved information provided to participants (includes handouts, brochures, survey tools, etc.) | | | |
| Yes  No  N/A | 1. All key research staff have completed their human participants training and valid documentation is on file. If protocol specific training is required, also include documentation of completed training in file. | | | |
| Yes  No  N/A | 1. Delegation of authority log (details research staff responsibilities and length of time on study) | | | |
| Yes  No  N/A | 1. CVs or other relevant documents evidencing qualifications of PI co-investigators, and individuals with a significant research role. It is recommended the CVs are signed, dated and updated at least every other year. | | | |
| Yes  No  N/A | 1. For studies conducted under a Certificate of Confidentiality (CoC), applicable template language is present in the consent form(s). | | | |
|  | **Additional Research Activities** (only address the activities that pertain to your study)**:** | | |
| Yes  No  N/A | 1. Current sample case report forms (CRF) | | |
| Yes  No  N/A | 1. Current CRFs demonstrate adherence to the IRB approved protocol. | | |
| Yes  No  N/A | 1. Record of retained body fluids/ tissue samples | | |
| Yes  No  N/A | 1. Normal lab values | | |
| Yes  No  N/A | 1. Lab certification (e.g. CLIA)? | | |
| Yes  No  N/A | 1. Lab director's CV | | |
| Yes  No  N/A | 1. Data Safety Monitoring Board (DSMB) reports, meeting minutes or indications DSMB review and recommendations. **DSMB meeting frequency:** | | |
| Yes  No  N/A | 1. Have all DSMB reports been submitted to the IRB? **Total number:** | | |
| Section 1  Additional Comments |  | | |
| 2 IRB Documentation on File: Please indicate whether the PI has the following documentation on file. The study’s submission history can be reviewed in eIRB+ and eIRB Legacy (if applicable).  *If the Northwestern IRB has ceded review to an external IRB, the following documentation will be from the external IRB.* | | | |
| Yes  No  N/A | 1. Initial IRB approval letter | | |
| Yes  No  N/A | 1. All continuing review (CR) approval letters.  **Total on file:** | | |
| Yes  No  N/A | 1. All modification and revision approval letters, including documentation of automatic personnel approvals in lieu of an approval letter (such as a system screen shot). **Total on file****:** | | |
| Yes  No  N/A | 1. All reportable new information acknowledgement letters (also called “Safety/Other” reports in eIRB Legacy). **Total on file:** | | |
| Yes  No  N/A | 1. IRB suspension or termination notifications | | |
| Yes  No  N/A | 1. Copies of email correspondence with the IRB | | |
| Yes  No  N/A | 1. Documentation of all external/ local/ ethical review approvals | | |
| Yes  No  N/A | 1. If international research, documentation the proposal was also reviewed and approved within the country’s ethics review/approval infrastructure. | | |
| Section 2  Additional Comments |  | | |
| **3 Protocol Adherence:** Please indicate whether the procedures listed below are followed. | | | |
| Yes  No  N/A | 1. Study procedures are followed as outlined in the current IRB approved protocol. | | |
| Yes  No  N/A | 1. Significant changes were made to the protocol without first obtaining IRB approval. If so, please provide an explanation below. | | |
| Yes  No  N/A | 1. Modifications received IRB approval prior to implementation | | |
| Yes  No  N/A | 1. Data has been shared per the data sharing agreement found in either the protocol or the grant. | | |
| Yes  No  N/A | 1. Research was **not** conducted during lapses in IRB approval. If so, please provide an explanation below. | | |
| Section 3  Additional Comments |  | | |
| 4 Document Retention: Please indicate whether the investigation is compliant with applicable items below. | | | |
| Yes  No  N/A | 1. The method and location of document storage is consistent with the IRB approved protocol. | | |
| Yes  No  N/A | 1. **Sponsored research**: Records are retained until the sponsor authorizes destruction of the records. | | |
| Yes  No  N/A | 1. **General studies**: An investigator retains their Human Subject Research records, including signed and dated consent documents, in accordance with the policies outlined in the [Investigator Manual (HRP-103)](https://irb.northwestern.edu/sites/irb/files/documents/HRP-103%20-%20Investigator%20Manual%20with%20Appendices.pdf) and <http://policies.northwestern.edu/docs/RUR_Appendix_A031815.pdf>. | | |
| Yes  No  N/A | 1. **Federally funded, supported, or regulated studies**: The investigator retains all research records in accordance to the provisions outlined in the applicable regulations. Please select this option if the study falls under the purview of the National Institutes of Health (NIH), Food and Drug Administration, Department of Defense, Department of Justice, Department of Energy or any other federal agency or department that is not listed. **Please specify the department or agency:** | | |
| Section 4  Additional Comments |  | | |
| **5 Participant Recruitment, Selection, and Payment Procedures:** Please indicate whether the procedures below are followed (elaborate if the response is “no”). | | | |
| Yes  No  N/A | 1. Recruitment methods are implemented as described in the IRB approved protocol. | | |
| Yes  No  N/A | 1. Recruitment materials in use (e.g., advertisements, telephone scripts, emails, web-postings, etc.) received approval by the IRB. | | |
| Yes  No  N/A | 1. Screening and enrollment logs are maintained and up to date. | | |
| Yes  No  N/A | 1. Mechanisms are in place to verify participant meets the inclusion/exclusion criteria outlined in the IRB approved protocol. | | |
| Yes  No  N/A | 1. Participant identification list on file. | | |
| Yes  No  N/A | 1. Participant payment/reimbursement is consistent with IRB approved protocol and consent form(s). | | |
| Yes  No  N/A | 1. In cases of withdrawn participants or “dropouts”, the reasons for participant withdrawal are recorded and have been reported to the IRB during continuing review. | | |
| Section 5  Additional Comments |  | | |
| **6 Data Access and Security:** Please complete this section as applicable. | | | |
| **Yes  No  N/A** | 1. Only IRB approved personnel have had access to the data. | | |
|  | 1. Please indicate who is responsible for obtaining the data (e.g., PI, IRB approved personnel, NUCATS EDW analyst, investigator as PowerUser, etc.): | | |
|  | 1. Please list the places data is stored: | | |
| **Yes  No  N/A** | 1. Data will be moved off site for analysis. **If yes, please describe:** | | |
| **Yes  No  N/A** | 1. HIPAA identifiers are accessed and/or recorded. **If yes, please list the identifiers:** | | |
| Section 6  Additional Comments |  | | |
| 7 Informed Consent Process: Please indicate the type(s) of consent used for this study (more than one may apply):  Written Consent Form  Verbal Consent  Online Consent Form  Waiver of Consent  Parental Consent and Child Assent  Foreign Language Consent  Please indicate whether the following procedures followed with respect to the informed consent process. | | | |
| Yes  No  N/A | 1. All participants were enrolled after initial IRB approval was granted. | | |
| Yes  No  N/A | 1. The informed consent form accurately reflects the procedures in the research protocol. | | |
| Yes  No  N/A | 1. Consent is obtained before each participant begins any research procedures. | | |
| Yes  No  N/A | 1. Participant or the representative is provided sufficient time to consider whether or not to participate. | | |
| Yes  No  N/A | 1. Provisions have been made for participants who speak languages other than English. In cases where the short form was not used, an IRB approved translated consent is provided to non-English speaking participants. | | |
| Yes  No  N/A | 1. Consent text does not include exculpatory language, in which the participant or the representative is made to waive or appear to waive any of the participant’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. | | |
| Yes  No  N/A | 1. Researcher’s contact phone number and/or email address listed in the consent document is correct and functional.   Phone number and/or email address listed: | | |
| **For the following sections, please complete those that apply to the type(s) of consent selected above:**  **(**Some studies have different stages and methodologies where the same people are consented to different parts of the study using different consents. Please tally the number enrolled with each consent type, some participants may be counted twice.) | | | |
| **Written Informed Consent** | | | |
| Yes  No  N/A | 1. A copy of the signed and dated consent document is offered to the participant | | |
| Yes  No  N/A | 1. Documentation that participants were consented to the study with a valid consent form (check IRB watermarked approval at the top of the consent form) | | |
| Yes  No  N/A | 1. Documentation of participants who were re-consented and the reason for re-consent | | |
|  | **Number of participants enrolled with Written Consent:** | | |
| **Verbal Consent** | | | |
| **Yes  No  N/A** | 1. An IRB approved verbal consent script is being used to obtain verbal consent | | |
| **Yes  No  N/A** | 1. Information about the study is made available to participants | | |
| **Yes  No  N/A** | 1. Investigator is able to confirm when enrolled participants agreed to participate in the study | | |
|  | **Number of participants enrolled with Verbal Consent:** | | |
| **Online Consent Form** | | | |
| **Yes  No  N/A** | 1. Participant is offered the ability to print the consent form or emailed to them | | |
| **Yes  No  N/A** | 1. Investigator is able to confirm when enrolled participants agreed to participate in the study (does not apply to anonymous studies) | | |
|  | **Number of participants enrolled with Online Consent:** | | |
| **Waiver of Consent** | | | |
| **Yes  No  N/A** | 1. The waiver of consent is still required to conduct the research study | | |
|  | **Number of participants enrolled with Waiver of Consent:** | | |
| **Parental Consent and Child Assent** | | | |
| **Yes  No  N/A** | 1. There is a parental consent form signed for each child participant (select n/a if a waiver of parental consent has been granted) | | |
| **Yes  No  N/A** | 1. There is documentation of child assent for each participant (select n/a if waiver of child assent has been granted) | | |
|  | **Number of parents consented:** | | **Number of children assented:** |
| **Foreign Language Consent** | | | |
| **Yes  No  N/A** | 1. A short form was used during the conduct of the research study. For short form information:   <https://irb.northwestern.edu/process/new-study/informed-consent/short-form-written-consent> | | |
|  | **Number of occurrences:** | | **Languages used:** |
| **Yes  No  N/A** | 1. A translated consent form was approved by the IRB. | | |
|  | **Number of participants enrolled with a foreign language consent:** | | |
| **Section 7**  **Additional Comments** |  | | |
| **8 Clinical Trials:** Please complete the following section if the study falls under the definition of a “clinical trial” – if N/A, check here   * NIH definition of clinical trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. * To determine if your study meets the NIH definition of a clinical trial, the following 4-question survey is provided: <https://grants.nih.gov/ct-decision/index.htm> | | | |
| **Yes  No  N/A** | 1. The consent form(s) contain applicable ClinicalTrials.gov template language. | | |
| **Yes  No  N/A** | 1. The study is registered on ClinicalTrials.gov. **If yes, provide the NCT#:** | | |
| **Yes  No  N/A** | 1. For completed studies, results are posted on ClinicalTrials.gov. | | |
| **Yes  No  N/A** | 1. If NIH-funded, an IRB-approved version of the consent form is posted to a publicly available federal website, such as ClinicalTrials.gov. | | |
| **Section 8**  **Additional Comments** |  | | |