|  |
| --- |
| 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 Northwestern IRB compliance team would expect to see when performing on-site monitoring or auditing 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 research record (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 found in each section. You do not have to include documentation with the completed checklist unless requested. Please email irbcompliance@northwestern.edu if you have any questions. |
| Social Behavioral 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) | [ ]  **Questionnaire or Survey**[ ]  **Interview**[ ]  **Clinical trial** *(see definitions in section 9)*[ ]  **Chart/data review\*** [ ]  **Registry\***[ ]  **Reviewed by an External IRB^**[ ]  **Multi-Site study where the Northwestern IRB serves as the IRB for external site(s)\*\***[ ]  **Other (specify):***\*If selected, also complete HRP-1405 Registry/Data Review/Specimen Collection Checklist**^If selected, also complete HRP-1406 Studies Under External IRB Review Checklist**\*\* If selected, also complete HRP-1407 Site File Checklist* |
| Study Enrollment Status (select all that are applicable)*NOTE: For chart review/specimen analysis studies, each chart/specimen analyzed is equivalent to an enrolled human participant. Please complete participant enrollment questions using this definition.* | [ ]  **No enrollment**[ ]  **Currently enrolling**[ ]  **Closed to enrollment**[ ]  **Long term follow-up**[ ]  **Data analysis** |
| Enrollment Goal or Sample Size |  |
| Number of Screened Participants (if applicable) |  |
| Number of (select all that apply):[ ]  **Enrolled participants**[ ]  **Collected specimens**[ ]  **Data Reviewed**[ ]  **Registrations for registry**[ ]  Other (specify): Choose an item. |  |
| Number of Withdrawn Participants (if applicable) |  |
| Date of Initial IRB Approval*(If relying on an external IRB for review, provide the date the external IRB approved the Northwestern affiliated site)* |  |
| Date First Participant Consented (or Date Research Procedures Began for Data Review, etc.) |  |
| Brief summary of current study status *(for example: study is currently closed to enrollment and undergoing data analysis – anticipate study closure within 1 year)* |  |
|  |
| 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 correspondence to and from the funding entity
 |
| [ ]  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(s)
 |
| [ ]  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. Records of investigator and staff human participants training and/or protocol specific training
 |
| [ ]  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), a CoC has been obtained and filed, and the applicable template language is present in the consent form(s).
 |
| [ ]  Yes [ ]  No [ ]  N/A | 1. Documentation of previous audit(s) or post-approval monitoring (by any entity, such as the IRB, NIH, OHRP, sponsor, etc.) is on file, and all identified issues are addressed.
 |
| Section 1Additional 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 place of an approval letter (such as a system screenshot). **Total on file****:**
 |
| [ ]  Yes [ ]  No [ ]  N/A | 1. All reportable new information acknowledgment letters (previously called "Safety/Other" reports)

**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 IRB Policy Adherence:** Please indicate whether the investigation is compliant with the applicable items below. |
| [ ]  **Yes** [ ]  **No** [ ]  **N/A** | 1. Research was **not** conducted prior to initial IRB approval or during lapses in IRB approval. If so, explain below.
 |
| [ ]  **Yes** [ ]  **No** [ ]  **N/A** | 1. **No** changes were made to the study prior to obtaining IRB approval.
 |
| [ ]  **Yes** [ ]  **No** [ ]  **N/A** | 1. **All** reportable events were reported within the Northwestern University IRB timelines.
	1. **Death** of an NU/NU Affiliated participant, or a participant at a site that has ceded IRB review to the NU IRB that is unanticipated and related to the research must be reported within **24 hours of knowledge or notification**.
	2. **Other Reportable New Information** pertaining to an NU/NU Affiliate, or at a site that has ceded IRB review to the NU IRB, must be reported within **5 business days of knowledge or notification.**
 |
| Section 3Additional Comments |  |
| **4 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. Modifications are implemented promptly after receiving IRB approval.
 |
| [ ]  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. If deception is used, participants are fully debriefed after all research procedures when required.
 |
| Section 4Additional Comments |  |
| 5 Document Retention: Please indicate whether the investigation is compliant with the 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 the destruction of the records.
 |
| [ ]  Yes [ ]  No [ ]  N/A | 1. **A**l**l Studies**: An investigator retains their Human Participant Research records (including but not limited to IRB-approved versions of protocols, other study instruments such as surveys, questionnaires, and recruitment materials, data sets and analyses of data, etc.) following the policies outlined in [the Investigator Manual (HRP-103)](https://irb.northwestern.edu/resources-guidance/policies-guidance/index.html), the IRB Office's Research Records Retention Page, and the **Retention of University Records: Appendix A - Records Retention Schedule**, which may be found on the NU webpage: <https://policies.northwestern.edu/all-policies/university.html>.
 |
| [ ]  Yes [ ]  No [ ]  N/A | 1. If **HIPAA** applies (there is a HIPAA authorization or the IRB approved a waiver of HIPAA authorization for your study): An investigator retains their Human Participant Research records (including signed and dated consent and authorization documents, documentation of verbal authorization, and/or record of IRB determination of a waiver of HIPAA) following NU policy[: Retention of University Records: Appendix A - Records Retention Schedule](https://policies.northwestern.edu/all-policies/university.html), for at least 6 years after completion of the research.
 |
| [ ]  Yes [ ]  No [ ]  N/A | 1. **Federally funded, supported, or regulated studies**: The investigator retains all research records following the provisions outlined in the applicable regulations. Please select this option if the study falls under the purview of the National Institute of Health, 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 5 Additional Comments |  |
| 6 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. Mechanisms are in place to verify that each participant meets the inclusion/exclusion criteria outlined in the IRB approved protocol.
 |
| [ ]  Yes [ ]  No [ ]  N/A | 1. Participant payment/reimbursement is consistent with IRB approved protocol and consent form(s).
 |
| [ ]  Yes [ ]  No [ ]  N/A | 1. Earned course credit for student participant pools 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 6Additional Comments |  |
| **7 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 7Additional Comments |  |
| 8 Informed Consent Process: Please indicate the type(s) of consent used for this study (more than one may apply):*Written Documentation of Consent may be a wet ink signature on a paper consent form or a valid electronic signature on an "eConsent" form. To use Verbal Consent or Online Consent, the IRB must have approved a waiver of the requirement to obtain a signed informed consent document.*[ ]  Written Documentation of Consent (including eConsent) [ ]  Verbal Consent [ ]  Online Consent[ ]  Waiver of Consent [ ]  Parental Consent and Child Assent [ ]  Foreign Language ConsentPlease indicate whether the following procedures have been 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(s) accurately reflect 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 a 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 Documentation of Consent (including eConsent)** |
| [ ]  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 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** |
| [ ]  **Yes** [ ]  **No** [ ]  **N/A** | 1. Participant is offered the ability to print the consent form or the study team emails a copy 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. The translated consent form was approved by the IRB.
 |
|  | **Number of participants enrolled with a foreign language consent:** |
| **Section 8****Additional Comments** |  |
| **9 Clinical Trials:** Please complete the following section if the study falls under the definition of a "clinical trial."* NIH definition of a 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. Use the 4-question survey at the link to determine if your study meets the NIH definition of a clinical trial: <https://grants.nih.gov/ct-decision/index.htm>
* Did the Principal Investigator write the main study protocol (i.e., is the study investigator-initiated)?

[ ]  **Yes**[ ]  **No**[ ]  **Other (specify):**      **If this section is N/A, check here and skip this section** [ ]  |
| [ ]  **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 9****Additional Comments** |  |