Investigator Self-Assessment Checklist for IRB Protocol Post-Approval Monitoring

**INFORMED CONSENT**

Principal Investigator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Project Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please complete all sections applicable to your protocol:**

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| --- | --- | --- | --- | --- | --- |
| **A.** | **FOR ALL SUBJECTS REQUIRING WRITTEN DOCUMENTATION OF CONSENT (SIGNED CONSENT FORM):** | **Y** | **N** | **NA** | **If no, explain (# of deviations, reasons, circumstances - attach additional info. as needed):** |
| 1. | Was **informed consent** obtained from each subject (each person voluntarily agreed and understood)? |  |  |  |  |
| 2. | Is a consent **form** in the research file (or medical record) for each subject consented, (NOTE: a separate consent form must be used for each subject)? |  |  |  |  |
| 3. | Are **all** pages of **each** consent form in the research/medical record for **every** subject? |  |  |  |  |
| 4. | Did the consent form used to consent each subject have the official IRB stamp? |  |  |  |  |
| 5. | Were all of the consent forms used **prior to the expiration** date on the IRB stamp? |  |  |  |  |
| 6. | Was the **correct version** of the consent form used for all subjects (e.g., if there was a subsequently approved amendment, was the later consent used, or if there are multiple arms for a study, was the corresponding correct consent used)? |  |  |  |  |
| 7. | Were all of the consent forms used **free of any changes or handwritten corrections** (e.g., change in contacts, phone numbers, procedures)? |  |  |  |  |
| 8. | Did each **subject** (or their legally authorized representative) **sign and date** the consent form? |  |  |  |  |
| 9. | Was the assent of all minors obtained as approved by the IRB? |  |  |  |  |
| 10. | Did the **PI or a designee** **listed as key personnel** obtain informed consent for all subjects? |  |  |  |  |
| 11. | Did the PI or designee that consented the subject sign and date the consent form for all subjects? |  |  |  |  |
| 12. | Are the dates consistent with the consent process (e.g**.,** consent forms were **not pre-dated or pre-signed-**dates must be inserted at the actual time of consent and before research begins)? |  |  |  |  |
| 13. | If the approved consent forms also included a witness line, were they completed appropriately (e.g., someone other than the designee, dated, etc.? |  |  |  |  |
| 14. | Did all subjects receive a copy of the signed and dated consent form with documentation noted in the research files? |  |  |  |  |
| 15. | Was consent obtained from each subject prior to performing any research-specific screening procedures to determine eligibility? |  |  |  |  |
| 16. | Was consent obtained from each subject **prior** to performing any research procedures (all dates filled in on the consent form must precede the start of any research procedure)? |  |  |  |  |

**Please note that this list is not meant to be all-inclusive. For all “no” answers that are checked, consult with the IRB to determine the appropriate action to be taken. Do not re-consent subjects without IRB approval – a consent addendum is the preferred method for study changes and all other reasons for re-consent must be pre-approved.**

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| **B.** | **FOR ALL SUBJECTS FOR WHOM AN ALTERATION OF CONSENT WAS APPROVED BY THE IRB:** | **Y** | **N** | **NA** | **If no, explain (# of deviations, reasons, circumstances - attach additional info. as needed):** |
| 1. | Describe the alteration of consent that was approved by the IRB (e.g., deception with debriefing) |  |  |  |  |
| 2. | Was **informed consent** obtained from each subject (each person voluntarily agreed and understood)? |  |  |  |  |
| 3. | Do you have documentation in the research files that the process described in B.1. above was followed for every subject? |  |  |  |  |
| 4. | Does the process described in B.1. above include the use of a written consent form? If **yes**, **YOU MUST ALSO COMPLETE A.1. THROUGH A.16.** on page 1. |  |  |  |  |
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| **C.** | **FOR ALL SUBJECTS FOR WHOM A WAIVER OF WRITTEN DOCUMENTATION OF CONSENT WAS APPROVED (no written, signed consent form required):** | **Y** | **N** | **NA** | **If no, explain (# of deviations, reasons, circumstances - attach additional info. as needed):** |
| 1. | Was **informed consent** obtained from each subject (each person voluntarily agreed and understood)? |  |  |  |  |
| 2. | Was use of an Information Sheet approved by the IRB as part of the waiver of documentation? |  |  |  |  |
| 3. | If no, include a description of the consent process below, e.g., note to the research file): |  |  |  |  |
| 4. | Do you have documentation in the research files that the process described in C.2 or C.3 was followed for every subject? |  |  |  |  |
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| **OTHER COMMENTS:** | | | | | |
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