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| The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment of their research study’s participant file and is indicative of what the Human Subjects Protection Program would expect to see when performing on site monitoring of your research study.  Instructions: Please complete this page for a randomly selected ten percent of enrolled participants; not to exceed 10 participants. If an answer to a question below is “no” or “not applicable”, please justify by typing or writing in additional information as needed in the General Comments Section. For research conducted with a waiver of consent, please complete sections 1 and 4. | | |
| **Participant File** | | |
| Principal Investigator | |  |
| Research Study Title | |  |
| Participant ID | |  |
| List Type of Consent(s) Obtained | |  |
| Version Number or STU Number Reflected in the Document’s Header | |  |
| Name of Person Completing Checklist | |  |
| Date Checklist Completed | |  |
|  | | |
| 1 Participant Information | | |
| Yes  No  N/A | 1. Participant met inclusion/exclusion criteria. | |
| Yes  No  N/A | 1. There is a completed, dated, and signed eligibility checklist. | |
| Yes  No  N/A | 1. Participant consented prior to participation in any research activity with then current version of the consent document. | |
| Yes  No  N/A | 1. The consent process is implemented per the study protocol. | |
| Yes  No  N/A | 1. Participant completed all study related activities as outlined in the consent document. | |
| Yes  No  N/A | 1. Compensation was dispensed to this participant per the protocol. | |
| 2 Written Consent - if n/a check here and move to the next section | | | |
| Yes  No  N/A | 1. The entire original signed consent form(s) or electronic documentation of consent is on file. | |
| Yes  No  N/A | 1. Consent form is signed on or after the IRB approval date and before the study’s expiration date. | |
| Yes  No  N/A | 1. There is an IRB approved stamp on the consent form. | |
| Yes  No  N/A | 1. All yes/no or similar optional elements on the consent form are completed/initialed. If not, then please explain in the comments section. | |
| Yes  No  N/A | 1. The consent form is completed in entirety with printed name, signature and date of both the participant and person obtaining consent. | |
| Yes  No  N/A | 1. At the time that consent was obtained, the person obtaining consent was listed on the IRB Authorized Personnel list and had a role in the consent process. | |
| Yes  No  N/A | 1. Consent form is free of any handwritten changes/corrections. | |
| Yes  No  N/A | 1. Participant was offered a copy of the signed and dated consent form. | |
| Yes  No  N/A | 1. Participant’s receipt or decline of a copy of the signed and dated consent form is documented. | |
| Yes  No  N/A | 1. Applicable for sites that use Rutgers as the IRB of record, participant’s receipt or decline a copy of the signed and dated consent form is documented. | |
| 3 Waiver of Documentation of Consent (Verbal and Online Consent) – if n/a check here and move to the next section | | |
| Yes  No  N/A | 1. Research team is able to confirm participant agreed to participate in the study. | |
| 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 | 4. For research collecting PHI, HIPAA authorization was obtained and documented for each subject, unless waived by the IRB (HIPAA authorization is included in the consent form templates that are provided by the IRB to the investigators). | |
| 4 Data Collection | | |
| Yes  No  N/A | 1. Data is available for this participant. | |
| Yes  No  N/A | 1. For source documentation and case report forms, changes/cross-outs, additional comments (if any) in participant files are initialed and dated. | |
| Yes  No  N/A | 1. For any changes/cross-outs, the original entry is still legible (e.g. scribbling, use of white-out or pencil erased entries are not acceptable). | |
| Yes  No  N/A | 1. Data is collected and maintained in accordance with the IRB approved protocol. | |
| **General Comments** |  | |