RUTGERS UNIVERSITY
Office for Research

CHECKLIST: Post Approval Monitoring Self-Assessment – Participant File		
NUMBER	EFFECTIVE DATE	PAGE
12.103 (HRP-430b)	04.24.2024	Page 1 of 2

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 Research 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	2.	There is a completed, dated, and signed eligibility checklist.
☐ Yes ☐ No ☐ N/A	3.	Participant consented prior to participation in any research activity with then current version of the consent document.
☐ Yes ☐ No ☐ N/A	4.	The consent process is implemented per the study protocol.
☐ Yes ☐ No ☐ N/A	5.	Participant completed all study related activities as outlined in the consent document.
☐ Yes ☐ No ☐ N/A	6.	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	2.	Consent form is signed on or after the IRB approval date and before the study's expiration date.
☐ Yes ☐ No ☐ N/A	3.	There is an IRB approved stamp on the consent form.
☐ Yes ☐ No ☐ N/A	4.	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	5.	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	6.	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	7.	Consent form is free of any handwritten changes/corrections.
☐ Yes ☐ No ☐ N/A	8.	Participant was offered a copy of the signed and dated consent form.
☐ Yes ☐ No ☐ N/A	9.	Participant's receipt or decline of a copy of the signed and dated consent form is documented.
☒ Yes ☐ No ☐ N/A	10.	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	2. An IRB approved verbal consent script is being used to obtain verbal consent.
☐ Yes ☐ No ☐ N/A	3. 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	2. 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	3. 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	4. Data is collected and maintained in accordance with the IRB approved protocol.
General Comments	