RUTGERS UNIVERSITY
Office for Research

CHECKLIST: Post Approval Monitoring Self-Assessment – Social Behavioral Research		
NUMBER	EFFECTIVE DATE	PAGE
12.105 (HRP-430d)	04.24.2024	Page 1 of 6

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 Rutgers HRPP Quality Assurance Team would expect to see when performing on site monitoring or auditing of your Social Behavioral research study.

Instructions: Please complete the section(s) of this checklist that apply to your study. 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.

Social Behavioral Research	
Principal Investigator	
Protocol 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)	☐ Survey ☐ Interview ☐ Educational Research ☐ Behavioral intervention ☐ Reviewed by an External IRB (e.g., Another University or Commerical IRB) ☐ Multi-Site study where the Rutgers IRB serves as the IRB of Record ☐ Other (specify): _____
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)	
Provide Number of Study Participants as of *MM/DD/YYYY*	☐ Number of Enrolled Participants: ☐ Number of Existing Data Reviewed: ☐ Number of *Other* ; Specify Type:
Number of Withdrawn Participants (if applicable)	
Date of Initial IRB Approval	
Date First Participant Consented (or Date Research Procedures Began for Data Review, etc.)	

1. Regulatory Documentation: Indicate whether the following documentation is in your study files; electronic documentation is acceptable. eIRB does not serve as an electronic version of your study file.	
☐ Yes ☐ No ☐ N/A	1. All versions of the IRB approved protocol
☐ Yes ☐ No ☐ N/A	2. All versions of the IRB approved consent document(s) (includes parental permission/assent documents)
☐ Yes ☐ No ☐ N/A	3. All versions of the IRB approved recruitment material(s)
☐ Yes ☐ No ☐ N/A	4. All versions of the IRB approved HIPAA authorization document(s), or HIPAA waiver(s).
☐ Yes ☐ No ☐ N/A	5. All versions of the IRB approved information provided to participants (includes handouts, survey tools, data collection materials, etc.)
☐ Yes ☐ No ☐ N/A	6. 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	7. Delegation of Authority Log (details research staff responsibilities and length of time on study)
☐ Yes ☐ No ☐ N/A	8. 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	9. For studies conducted under a Certificate of Confidentiality (CoC), applicable template language is present in the consent form(s). (Requirement for all NIH Studies after October 1, 2017.)
Section 1 Additional Comments	
2. IRB Documentation on File: Indicate whether the following documentation is in your study files. Electronic documentation is acceptable. Although eIRB contains your study's IRB document history, eIRB does not serve as an electronic version of your study file. If the Rutgers 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	2. All continuing review (CR) approval letters**,** administrative check-in, progress reports **Total on file:** _____
☐ Yes ☐ No ☐ N/A	3. 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	4. All reportable event acknowledgement letters **Total on file:** _____
☒ Yes ☐ No ☐ N/A	5. Documentation of all protocol deviations. **Total on file:**_____
☐ Yes ☐ No ☐ N/A	6. IRB suspension or termination notifications
☐ Yes ☐ No ☐ N/A	7. Copies of email correspondence with the IRB
☐ Yes ☐ No ☐ N/A	8. Documentation of all external/ local/ ethical review approvals
☐ Yes ☐ No ☐ N/A	9. 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 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, provide an explanation in Additional Comments below.
☐ Yes ☐ No ☐ N/A	**2. No** changes were made to the study prior to obtaining IRB approval.

☐ Yes ☐ No ☐ N/A	**3. All** reportable events were reported within the Rutgers University IRB timelines. a. Submit an Unanticipated Problem involving risks to subjects or others, or a death in an interventional study for which a Rutgers IRB is the IRB of record that occurred within 30 days of the intervention or interaction. Unanticipated problems or a death should be reported in accordance to the following timeframe: i. Within 24 hours of discovery – a death in an interventional study for which a Rutgers IRB is the IRB of Record. ii. Within one week of discovery – an unanticipated problem which is a serious adverse event. iii. Within two weeks of discovery – all other unanticipated problems. b. Submit other Reportable Events report required by Rutgers IRB policy within five business days from date of discovery.
Section 3 Additional 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	2. Significant changes were made to the protocol without first obtaining IRB approval. If so, please provide an explanation below.
☐ Yes ☐ No ☐ N/A	3. Modifications received IRB approval prior to implementation.
☐ Yes ☐ No ☐ N/A	4. Data has been shared per the data sharing agreement found in the protocol.
☐ Yes ☐ No ☐ N/A	Research was not conducted during lapses in IRB approval. If so, please provide an explanation below.
Section 4 Additional Comments	
5. 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	2. The investigator retains all research records in accordance with the provisions outlined in the applicable regulations, sponsor requirements, department or agency requirements, and institutional policies. **Please specify the applicable regulations and requirements:** _____
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	2. Recruitment materials in use (e.g., advertisements, telephone scripts, emails, web-postings, etc.) received approval by the IRB.
☐ Yes ☐ No ☐ N/A	3. Mechanisms are in place to verify that each participant meets inclusion/exclusion criteria outlined in the IRB approved protocol.
☐ Yes ☐ No ☐ N/A	4. Participant payment/reimbursement is consistent with IRB approved protocol and consent form(s).
☐ Yes ☐ No ☐ N/A	5. 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 6 Additional Comments	

7. Data Access and Security: Please complete this section as applicable.

☐ Yes ☐ No ☐ N/A	Only IRB approved personnel have had access to the identifiable data.
☐ Yes ☐ No ☐ N/A	Indicate who is responsible for obtaining the data:_____
☐ Yes ☐ No ☐ N/A	List the places data is stored: _____
☐ Yes ☐ No ☐ N/A	Data will be moved off site for analysis. **If yes, please describe:** _____
☐ Yes ☐ No ☐ N/A	HIPAA identifiers are accessed and/or recorded. **If yes, please list the identifiers:** _____
Section 7 Additional Comments	

8. 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 Permission** ☐ **Child Assent** ☐ **Foreign Language Consent** ☐ **Surrogate Consent**

Please indicate whether the following procedures are being followed with respect to the informed consent process.

☐ **Yes** ☐ **No** ☐ **N/A**	1. All participants were enrolled after the effective date of initial IRB approval.
☐ **Yes** ☐ **No** ☐ **N/A**	2. The informed consent process accurately reflects the procedures in the IRB-approved protocol.
	3. Consent is obtained before each participant begins any research procedures.
	4. An investigator seeks consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
	5. Investigators disclose to the subject the information in the consent document.
	6. The consent process and documentation as a whole presents information in sufficient detail and facilitates the perspective participant's or legally authorized representative's understanding.
	7. When the research involves vulnerable populations or participants who have diminished decision-making capacity, the investigators provide additional safeguards to ensure an appropriate consent process.
☐ **Yes** ☐ **No** ☐ **N/A**	8. Participant(s) or the representative(s) was/were provided sufficient time to consider whether or not to participate.
☐ **Yes** ☐ **No** ☐ **N/A**	9. 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**	10. GDPR Language found in Consent Form (When international studies are being conducted in the EEA (European Union) and plan to collect, process, or store identifiable data).
☐ **Yes** ☐ **No** ☐ **N/A**	11. Principal Investigator'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	2. Documentation that participants were consented to the study with a valid consent form (check IRB approval stamp at the bottom of the consent form).
☐ Yes ☐ No ☐ N/A	3. 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	2. Information about the study is made available to participants.
☐ Yes ☐ No ☐ N/A	3. 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	2. 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	2. 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	A short form was used during the conduct of the research study. For short form information: https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/toolkit https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-toolkit
☐ Yes ☐ No ☐ N/A	**Number of Short Forms Used:** **Languages Used:**
☐ Yes ☐ No ☐ N/A	A translated consent form was approved by the IRB.
☐ Yes ☐ No ☐ N/A	**Number of participants enrolled with a foreign language consent: _____**
Surrogate Consent	
☐ Yes ☐ No ☐ N/A	1. A Surrogate consent form was approved by the IRB. For addition surrogate consent process documents and information visit: https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/toolkit https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-toolkit
Section 8 Additional Comments	

9. Clinical Trials: Please complete the following section if the study falls under the definition of a "clinical trial" – if N/A, check here ☐

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, go to https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/clinical-trials https://research.rutgers.edu/researcher-support/research-compliance/human-subjects-protection-program-irbs/clinical-trials

☐ **Yes** ☐ **No** ☐ **Other**	**1.** Did the Principal Investigator write the main study protocol (i.e. is the study investigator-initiated)? If other explain:
☐ **Yes** ☐ **No** ☐ **N/A**	**2.** The consent form(s) contain applicable ClinicalTrials.gov template language.
☐ **Yes** ☐ **No** ☐ **N/A**	**3.** The study is registered on ClinicalTrials.gov. **If yes, provide the NCT#:** _____
☐ **Yes** ☐ **No** ☐ **N/A**	**4.** For completed studies, results are posted on ClinicalTrials.gov.
☐ **Yes** ☐ **No** ☐ **N/A**	**5.** One IRB-approved consent form is posted on a publicly available Federal website after the trial is closed to recruitment, but no later than 60 days after the last study visit.
Section 9 Additional Comments	