RUTGERS UNIVERSITY
Office for Research

CHECKLIST: Post Approval Monitoring Self-Assessment – Biomedical Research		
NUMBER	EFFECTIVE DATE	PAGE
12.104 (HRP-430c)	04.24.2024	

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 Human Research Protection Program would expect to see when performing on site monitoring of your biomedical research study.

Instructions: Please complete the section(s) of this checklist that apply to your study. The regulatory binder (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 as well.

Biomedical 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)	☐ Clinical Trial*. ☐ Chart / Data Review. ☐ Registry. ☐ Specimen Collection. ☐ Reviewed by an External IRB (e.g., Another University or Commercial IRB). ☐ Multi-Site study where the Rutgers IRB serves as the IRB of Record. ☐ Other (specify): _____. **If selected for a clinical trial of a drug or device, also complete 12.102 (HRP-430a) Drug or Device Clinical Trial Checklist.*
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 Collected Specimens: . ☐ Number of Existing Data Reviewed: . ☐ Number of Registrations for Registry: . ☐ Number of **Other (Specify Type:):** .

Number of Withdrawn Participants by the PI (if applicable)	.
Number of Subjects who Dropped out of the Study (if applicable)	.
Date of Initial IRB Approval	.
Date First Participant Consented (or Date Research Procedures Began for Data Review, Specimen Collection, 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, brochures, 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).
Additional Research Activities (only address the activities that pertain to your IRB-Approved Protocol**:**	
☐ Yes ☐ No ☐ N/A	10. Current sample case report forms (CRF).
☐ Yes ☐ No ☐ N/A	11. Current CRFs demonstrate adherence to the IRB approved protocol.
☐ Yes ☐ No ☐ N/A	12. Record of retained biospecimens.
☐ Yes ☐ No ☐ N/A	13. Normal lab values.
☐ Yes ☐ No ☐ N/A	14. Lab certification (e.g., CLIA).
☐ Yes ☐ No ☐ N/A	15. Lab director's CV.
☐ Yes ☐ No ☐ N/A	16. Data Safety Monitoring Board (DSMB) reports, meeting minutes or indications DSMB review and recommendations. **DSMB meeting frequency: _____.**
☐ Yes ☐ No ☐ N/A	17. Have all DSMB reports been submitted to the IRB? **Total number: _____.**
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. **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: _____.**
	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 investigator/research team 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	5. 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. Screening and enrollment logs are maintained and up to date.
☐ Yes ☐ No ☐ N/A	4. Mechanisms are in place to verify participant meets the inclusion/exclusion criteria outlined in the IRB approved protocol.
☐ Yes ☐ No ☐ N/A	5. Participant identification list on file.
☐ Yes ☐ No ☐ N/A	6. Participant payment/reimbursement is consistent with IRB approved protocol and consent form(s).
☐ Yes ☐ No ☐ N/A	7. 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	1. Only IRB approved personnel have had access to the identifiable data.
☐ Yes ☐ No ☐ N/A	2. Indicate who is responsible for obtaining the data:_____.
☐ Yes ☐ No ☐ N/A	3. List the places data is stored: _____.
☐ Yes ☐ No ☐ N/A	4. Data will be moved off site for analysis. **If yes, please describe:** _____.
☐ Yes ☐ No ☐ N/A	5. HIPAA identifiers are accessed and/or recorded. _____.
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 followed with respect to the informed consent process.

☐ Yes ☐ No ☐ N/A	1. All participants were enrolled after effective date of initial IRB approval.
☐ Yes ☐ No ☐ N/A	2. The informed consent process accurately reflects the procedures in the IRB-approved protocol.
☐ Yes ☐ No ☐ N/A	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 the 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 being 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. A waiver of consent is 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	1. A short form was used during the conduct of the research study. For short form information: Human Research Protection Program Toolkit | Rutgers Research	
	Number of Short Forms used: _____.	**Languages used:_____.**
☐ Yes ☐ No ☐ N/A	2. A translated consent form was approved by the IRB.	
	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: Human Research Protection Program Toolkit | Rutgers Research.	
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 visit: Clinical Trials Registration and Results Reporting | Rutgers Research.

☐ **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	