SUNY Downstate IRB & Privacy Board
FORM 21-1: Quality Assessment Form
(Version 06.01.2021)
Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.
Note: Free Adobe Reader available at: www.adobe.com

Section 1: General Information:

A. Principal Investigator:

B. Project Title:

C. IRBNet#:

D. Funding Source:

E. Type of Study:

☐ Drug/Biologic ☐ Device ☐ Repository ☐ Genetics ☐ Vaccine

☐ Survey/Focus Group ☐ Chart or Data Review

☐ Other (describe):

F. Name of Reviewing (External) IRB, for multi-site study, if applicable:

G. Is written (signed) informed consent required for this study?

YES ◯ NO ◯

H. Initial Approval Date:

I. Period of Assessment: Start date: End date:

J. Assessment Type: ◯ Preliminary ◯ Follow-Up ◯ Final

K. Reason for Assessment:

- (●) Routine Assessment by IRB
- ( ) For-Cause Assessment by IRB
- ( ) Quality Assessment of IRB Documentation Only by IRB
- ( ) Clinical Trials Office Assessment
- ( ) OCAS Assessment
- ( ) Other, describe:

L. List any concerns that prompted the need for this assessment:

M. If applicable, list any documents or information that a reviewing (external) IRB requests be reviewed in order to decide non-compliance. *Include relevant participant IDs, and or percentage of records to be reviewed, where appropriate.*

Section 2: Participant Numbers:

***SINCE STUDY STARTUP:**
**CAUTION: For multi-site studies overseen by an External (Reviewing) IRB, ONLY include Downstate data*

A. *Number approved to be in the research
(include screening):

B. *Number enrolled
(i.e., via consent/authorization, surveys, focus groups):

C. *Number included, not otherwise enrolled
(i.e., via charts, data):

D. *Number of screening failures
(Enter 0 if protocol does not involve screening):

E. *Number who withdrew/stopped participation on their own
(do not count screen failures):

F. *Number of participants withdrawn
by the PI before reaching the study end point:

G. *Summarize the reasons the participants withdrew and/or were withdrawn:

H. Comments regarding above numbers (optional):

Section 3: General Assessment:

A. Confirm all of the following are correct, as applicable for the study:

	Y	N	N/A	Not Evaluated
1. **Regulatory Documentation:**				
a. The project has current IRB approval (no lapse in current continuing review period).	◉	○	○	○
b. All source documentation and data collection are accurate, complete, and appropriately transcribed.	◉	○	○	○
c. All investigators listed on this project are up to date on all required training.	◉	○	○	○
d. All implemented changes to the project have been approved by the IRB.	◉	○	○	○
e. All Reviewing (External) IRB determinations have been submitted to the Downstate IRB.	◉	○	○	○
f. All new findings that change the risk benefit ratio have yet been reported to the IRB.	◉	○	○	○
g. The IRB approved stamped versions of the Consent Form and related materials are used to enroll participants as indicated below :				
i. Consent Form with HIPAA Authorization	◉	○	○	○
ii. Stand Alone Consent Form	○	○	◉	○
iii. Supplemental Consent Form	○	○	◉	○
iv. Pregnancy Follow-Up consent	○	○	◉	○
v. Stand-Alone HIPAA Authorization	○	○	◉	○
vi. Information Sheet	○	○	◉	○
vii. Information Sheet with HIPAA Authorization	○	○	◉	○
viii. Assent Form	○	○	◉	○
ix. Short Form	○	○	◉	○
x. SUNY RF Payment Consent	○	○	◉	○
xi. Research Recruitment Authorization Form(s)	○	○	◉	○
xii. Medical Release Form	○	○	◉	○

	Y	N	N/A	Not Evaluated
xiii. Translated consent forms	○	○	◉	○
xiv. Certificates of translations	○	○	◉	○
h. The following materials are used in accordance with IRB approval:				
i. Recruitment materials	◉	○	○	○
ii. Questionnaires or surveys	◉	○	○	○
iii. Data collection tools (or list of data to be collected)	◉	○	○	○
i. All versions of research records listed below have been retained, are readily accessible, and are up to date and accurate:				
i. Protocol	◉	○	○	○
ii. IRB Documentation (submission materials, including the IRB application, approval or determination letters, approved master consent forms, approved advertising and recruitment materials, correspondence)	◉	○	○	○
iii. Study Manuals	○	○	◉	○
iv. Policies	○	○	◉	○
v. Revocation/Withdrawal notices	◉	○	○	○
vi. Enrollment Logs	◉	○	○	○
vii. Signed Delegation of Responsibility	◉	○	○	○
viii. Source Documentation	◉	○	○	○
ix. Copy of normal lab values	◉	○	○	○
x. Copy of lab certification	◉	○	○	○
xi. Documentation of review of all lab results	◉	○	○	○
xii. Documentation to support study team qualifications (Signed and dated CV, medical/clinical licensure)	◉	○	○	○
xiii. Study team training documentation/logs	◉	○	○	○
xiv. Sponsor correspondence	◉	○	○	○
xv. Monitoring log	◉	○	○	○

	Y	N	N/A	Not Evaluated
xvi. Notes to Files	◉	○	○	○
xvii. Adverse Events	◉	○	○	○
xviii. Deviation Logs	◉	○	○	○
xix. Documentation of data and safety monitoring, including log of monitoring activities, meeting agendas, minutes and reports of the data monitory committee.	◉	○	○	○
xx. Research participants files (i.e., consent forms, eligibility, protocol compliance, AEs, Events requiring IRB reporting, etc.)	◉	○	○	○
j. Other (describe):	○	○	◉	○

2. For an **FDA regulated Clinical Investigation (IND/IDE study)**, all versions of research records listed below have been retained, are readily accessible, and are up to date and accurate:

a. FDA Form 1572	◉	○	○	○
b. Confirmation that all labs are listed on the 1572 form	◉	○	○	○
c. IND Letter from FDA or Sponsor	◉	○	○	○
d. Investigator Brochures	◉	○	○	○
e. Published literature or information about previous human/animal experience	◉	○	○	○
f. Device Package Inserts	○	◉	○	○
g. Device Manual	○	◉	○	○
h. IDE Letter or SR/NSR determination from FDA, Sponsor, or IRB	○	◉	○	○
i. Financial disclosures of investigators	◉	○	○	○
j. Copies of monitoring reports, monitor visiting logs, and correspondence with sponsor to items that require remedies.	◉	○	○	○
k. Complete list of SAEs	◉	○	○	○
l. Organizational chart on file	◉	○	○	○

	Y	N	N/A	Not Evaluated
m. Abnormal lab values reviewed, dated, and signed or initialed by responsible party.	◉	○	○	○
n. Other (describe):	○	○	◉	○

3. **Process for Recruitment, Selection, Enrollment, and Data Collection:**

a. Only eligible participants been enrolled into the study.	◉	○	○	○
b. Participants were identified and recruited according to the methods approved by the IRB and institution policy.	◉	○	○	○
c. All advertising or recruitment materials used to recruit research participants were approved by the IRB and on file.	◉	○	○	○
d. All inclusion and exclusion requirements were followed as approved by the IRB.	◉	○	○	○
e. There is documentation of participant eligibility.	◉	○	○	○
f. Any deviations with the IRB approved inclusion or exclusion requirements were reported to the IRB.	◉	○	○	○
g. Only investigators approved by the IRB recruited and enrolled research participants.	◉	○	○	○
h. All applicable consent/authorization forms were signed and dated by all those required to sign (participant, LAR, investigator, witness, consent monitor, etc.) the form(s) prior to study participation in the IRB approved research procedures.	◉	○	○	○
i. All study participants received a copy of the signed and dated informed consent/authorization forms.	◉	○	○	○

	Y	N	N/A	Not Evaluated
j. Copies of the signed informed consent/authorization forms were sent to medical records when applicable for a study (i.e., clinical trials with IND or IDE, NIH funded studies, studies with a Certificate of Confidentiality).	◉	○	○	○
k. Any changes made to any consent/authorization forms were approved by the IRB before they were used.	◉	○	○	○
l. If consent/authorization form was revised, participants consent was re-obtained, and/or they were notified as required by IRB and/or sponsor.	◉	○	○	○
m. Other (describe):	○	○	◉	○

4. **Research Activities:**

a. All research procedures comply with the protocol or project description, IRB application materials, study intervals, and procedures as approved by the IRB.	◉	○	○	○
b. All data collection instruments, or data elements were approved by the IRB.	◉	○	○	○
c. Changes were only implemented after IRB approval was obtained.	◉	○	○	○
d. Confirm study procedures were not conducted during a period of expiration, closure, termination, or suspension.	◉	○	○	○
e. All required reportable events were reported to the IRB prior to the required deadline.	◉	○	○	○
f. Site(s) where research is conducted is adequate.	◉	○	○	○
g. Other (describe):	○	○	◉	○

	Y	N	N/A	Not Evaluated
5. **Privacy, Security, Data Storage, Confidentiality, and Data Management:**				
a. The participants' privacy and confidentiality are protected with appropriate safeguards in place as approved by the IRB.	◉	○	○	○
b. Source documentation and data collection are accurate, complete and appropriately transcribed.	◉	○	○	○
c. Hard copies of consent forms and data forms are stored in a secure, locked location.	◉	○	○	○
d. All data are stored and transmitted securely.	◉	○	○	○
e. Data Safety Monitoring Plan (DSMP) is followed and safety/data reviews are occurring according to plan.	◉	○	○	○
f. Participant records include:				
i. Consent forms	◉	○	○	○
ii. Eligibility	◉	○	○	○
iii. Protocol compliance	◉	○	○	○
iv. AEs	◉	○	○	○
v. Events requiring IRB reporting	◉	○	○	○
g. Other (describe):	○	○	○	○
6. **All required ancillary approvals are documented in IRBNet and/or the research records, as applicable**	◉	○	○	○
7. **IRB Records**				
a. Ancillary reviews that are required to be completed prior to IRB approval were completed.	○	○	◉	○
b. CMRC certification, when required.	○	○	◉	○
c. IRB records are accurate and complete.	○	○	◉	○

	Y	N	N/A	Not Evaluated
d. IRB letters include the correct and appropriate documentation, including IRB determinations.	○	○	◉	○
e. IRB minutes for this study include the correct and appropriate documentation, including any IRB determinations.	○	○	◉	○
f. Other (describe):	○	○	◉	○

8. **Other (describe):**

a.	○	○	◉	○
b.	○	○	◉	○
c.	○	○	◉	○
d.	○	○	◉	○

B. Describe any discrepancies, including any concerns with the recruitment process and/or the informed consent process:

Section 3: Research Participant Study Record Assessment:

A. Describe informed consent forms below:

Title	Approval Date	Expiration Date	Master copy of IRB approved version on file? Y N N/A
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉
			○ ○ ◉

B. Randomly select participants' study records based on the target number described in the IRB guidance and list their ID code below:
(Do not list names)

C. Confirm all of the following are correct:

	Y	N	N/A	Not Evaluated
1. All of the original signed copies of informed consent forms (and/or related materials) are securely stored.	◉	○	○	○
2. The investigators who obtained informed consent were approved by the IRB to conduct the research.	◉	○	○	○
3. All required individuals signed and dated the forms prior to the research procedures.	◉	○	○	○
4. The consent process is documented in the research record.	◉	○	○	○
5. If the IRB or sponsor required that informed consent be re-obtained from study participants, informed consent was re-obtained, documented, and conducted in the appropriate and timely manner.	◉	○	○	○
6. Research participants meet all eligibility criteria and is appropriately documented in the research records.	◉	○	○	○
7. The correct versions of all forms were used.	◉	○	○	○
8. Each document is properly completed with initials/signatures.	◉	○	○	○
9. There is documentation that the participant received a copy of all of the forms used to obtain informed consent.	◉	○	○	○
10. Abnormal lab values reviewed, dated, and signed or initialed by responsible party.	◉	○	○	○
11. All copies of informed consent/authorization forms documents were sent to medical records when applicable for a study (i.e., clinical trials with IND or IDE, NIH funded studies, studies with Certificate of Confidentiality).	◉	○	○	○
12. Other (describe):	◉	○	○	○

D. Description of any discrepancies:

Section 4: Informed Consent Process Observation:

Describe what went well and report any concerns below. Indicate NA or Not Evaluated, if applicable.

Section 5: Interviews:

A. Names of Study Staff who were interviewed:

B. Summary of interview findings:

Note: Do not attribute findings to any specific study staff.

Section 6: Reports to the IRB:

A. Indicate whether a CAPA is required or a reportable event must be reported to the IRB:

- ◯ CAPA required and will be reported to the Downstate IRB
- ◯ Reportable events must be reported to the IRB.
- ◯ Both CAPA and Reportable events must be reported to the IRB
- ◯ N/A – Neither CAPA nor Reportable events are required to be reported to IRB

Section 7: Acknowledgements:

The QAP Assessor and PI must sign below. Please e-sign using Adobe software:

1) Open form in Adobe software.
2) Use Fill & Sign tool to complete.
3) Confirm all responses are correct.
4) Click on Red Signature tab to sign.
5) Save file.

Note: Free Adobe Reader available at: www.adobe.com

Assessor (print name above)

_____ _____

Signature of Assessor Date

Principal Investigator (print name above)

_____ _____

Signature of Principal Investigator Date