Version 3/29/24

Columbia University Local Context & Protocol-Specific Form

Purpose: If an **external IRB* that will serve as the Reviewing IRB** for Columbia University ("Columbia") research **has not provided a local context form,** completion of this form is required. It should initially be completed by the Columbia research team and then reviewed and finalized by Columbia Human Research Protection Office ("HRPO") staff before being provided to the Reviewing IRB**.**

Instructions: To facilitate the review by the Reviewing IRB, please respond to the following questions as relevant, to provide information about Columbia, i.e., "local", requirements that pertain to this research. **Please attach the completed and signed form in your Rascal IRB submission. A Rascal IRB submission is required for tracking and administrative review purposes. HRPO staff will review the form for completeness and accuracy, and will also sign the form. The fully executed form will need to be provided to the Reviewing IRB with your submission.**

In the Rascal IRB application:

- designate the non-Columbia IRB as the Reviewing IRB in the "Attributes" section
- if there is a standalone protocol or grant application, complete all fields in the application except for the areas for which "abbreviated submission" can be checked to indicate that the requested information is in the attached standalone protocol or grant application
- if there is NO standalone protocol or grant application, complete all fields in the application
- attach applicable HazMat appendices (e.g. Appendix A (infectious materials); Appendix H (radiation), etc.);
- attach all study-related material provided by the sponsor (i.e., master protocol approved by the Reviewing IRB, template consent forms, questionnaires, documentation of approval by the Reviewing IRB for the lead site)
- attach Columbia-specific study documents and consent forms. In these situations, consent forms should not be developed or submitted via the Consent Form Module in Rascal

If the Rascal application is incomplete (i.e., above listed information is missing or not appropriately addressed), the administrative review conducted by HRPO staff may be delayed, which will in turn delay submission to the Reviewing IRB.

Submission to the Reviewing IRB may only occur after the HRPO administrative review is complete and the Columbia research team is notified through RASCAL correspondence that submission to the external IRB may proceed.

***External IRB**: Any non-Columbia IRB that has been authorized to conduct review of Columbia research.

Please use the Cover Page for WCG Reliance if the WCG IRB (formerly "WIRB") will be the Reviewing IRB, including for Phase III oncology protocols or for NIH funded protocols for which Columbia has designated WCG to be the Single IRB as per the grant application.

Protocol Title:

Rascal Protocol Number:

Reviewing IRB (i.e., name of External IRB):

Please check below each item that is relevant to your study:

☐ **One or more Columbia ancillary reviews are required for the research**:
☐ PRMC ☐ JRSC ☐ IBC ☐ Pathology ☐ Other: identify

Institutional Policies that apply to this research (complete secondary questions if a policy/guidance applies):

☐ **Recruitment of CUIMC/NYPH patients based on information in CUIMC/NYPH medical records**

☐ The recruitment process is consistent with CU policy - IRB SOPs.

(Initial contact should be made by the treating physician to provide the patient with the researcher's contact information, or to obtain the patients' permission to provide their contact information to the Researcher. If the latter, the treating physician should document in the medical record that permission was obtained. For certain units where patients may not have an established relationship with the physician of record, such as the Emergency Department, the medical director may introduce the study to patients, e.g., through a letter mailed to the patient.)

☐ The Columbia Epic Consent to Contact registry will be utilized.

☐ A HIPAA form D (preparatory for research) was attached to the protocol in Rascal.

(This form does not need to be submitted to the reviewing IRB.)

☐ **Genetic Testing as defined in NYS 79-l will be conducted.** (Genetic Testing Policy)

(This policy would generally NOT apply when genotyping will be performed to answer a question other that the identification of a genetic variation linked to a predisposition, and/or subjects are symptomatic of the condition being tested. The policy applies when samples are collected in New York State.)

☐ **The Columbia** Incidental Findings from Imaging Procedures Conducted for Research Studies Policy applies.

Will high-density scans performed for the study read by a CUIMC credentialed radiologist? ☐ No ☐ Yes
If no, select the following:

☐ Plans for managing incidental findings that are consistent with the Policy requirements are included in the protocol

Note that language related to incidental findings should be included in the consent form.

☒ **CU consent form language was included in the CU specific consent form** as relevant (Consent form language):

- Confidentiality section: the list of entities that may access and review research records, includes CUIMC/NYP and the Office of Human Research Protection (OHRP), and the Epic language for applicable studies
- Research-Related Injury section, for greater than minimal risk research: One of the approved CUIMC statements or equivalent
- Risks section: radiation risks statement approved by JRSC
- Contact information for the Columbia research team for questions
- HRPO contact information for questions about subject rights

- SSN will be disclosed outside of Columbia
- Genetic Testing requirements per NY 79-l
- Incidental findings
- Audio/video/photo recording
- Mandatory test results report to NY State Health Authorities (e.g. HIV+/Hepatitis B & C positive test results)
- Compensation/reimbursement of subjects: information that SSN will be collected if payment by check
- Recommended terminology: "fetus" should be used instead of "unborn baby"

☐ **Surrogate Consent is proposed for some or all subjects.** (Informed Consent Policy)

1. The study presents greater than minimal risk to subjects lacking capacity ☐ Yes ☐ No
2. Does the protocol hold the prospect of direct benefit to subjects? ☐ Yes ☐ No

If yes to question 1 and no to question 2, enrollment of subjects lacking capacity is not acceptable per CU policy

3. Are plans to assess capacity provided in the protocol? ☐ Yes ☐ No
4. Is an exception to allow the Principal Investigator or a member of the study team to assess capacity being requested?

☐ No

☐ Yes, and the protocol includes a specific request for such an exception that includes a justification and written plan or assessment of capacity

☐ **E-Consent is proposed.** (Electronic Informed Consent guidance)

☒ The protocol describes the consent process in sufficient detail as per CU guidance.

☐ **Informed consent on the same day as an elective clinical procedure is proposed.** (Same Day Consent Policy)

(Same day consent is generally allowable only when the research poses minimal risks or a minor increment above minimal risk and consent cannot be obtained in advance.)

☐ **Sensitive Data in electronic format will be collected, generated, stored and/or transmitted.** (CU policy Data Security Plan - Sensitive data)

Are there plans to generate, collect and/or maintain Sensitive Data on a Columbia multi-user system?

☐ No

☐ Yes, and the Columbia multi-user system has been certified by CUIMC IT for storage of Sensitive Data

Are there plans to maintain and/or transmit sensitive data to a non-Columbia multi-user system?

☐ No

☐ Yes, and there is an existing contract for services with the entity that controls/owns the system, and Columbia requirements are met.

☐ **Enrollment of non-English speaking subjects is anticipated.** (Enrollment of Non- English Speaking Subjects Policy)
(Local community has a predominant Spanish-speaking population: If the research offers the prospect of direct benefit and recruitment occurs in the local community, Spanish translation of consent form and study-related documents is required.)

Will study related materials be translated by a study team member or other Columbia affiliate?

☐ No, the Columbia Spanish Translation Center, a commercial entity, or the sponsor will translate study related material

☒ Yes, and a back translation has been/will be provided (if required)

☐ **Enrollment of children is proposed.**

☐ The protocol includes plans to obtain assent that meet the requirements of Children as Subjects of Research CUMC Policy

☐ **Enrollment of women in labor is proposed.**

☐ The protocol includes plans to enroll laboring women in accordance with our Clinical Research Involving Pregnant Women guidance.

☐ **Use of an investigational laboratory test (i.e. not FDA-cleared, approved for different indication or exempt test) is proposed and** New York Article 5, Title V, Section 574 applies:

(If patient-specific results will be reported, a NYS clinical laboratory permit and test-specific approval by State of New York Wadsworth Laboratory is required prior to reporting. The Clinical Laboratory Evaluation Program (CLEP) administers this process.)

☐ **Research procedures performed by a Home Health Care Agency are proposed.**

☐ The Home Visit Checklist was completed and attached.

☐ CU/NYPH Employees/Residents/Fellows/Interns/Students will be recruited as research subjects.
There is a justification for the use of this population and there is a plan to minimize elements of coercion or undue influence

☐ **None of the above institutional policies or requirements apply to this research.**

Section for HRPO staff to complete:

☐ There is an individual or institutional financial interest that may constitute an individual or institutional **conflict of interest (COI)** as described in the University Financial Conflict of Interest policies for this protocol. Conflict of Interest Policy and Policy on Institutional Conflict of Interest

If checked, indicate the review status by the Research Compliance COI committee:
☐ Pending ☐ Complete

☐ **HIPAA:** This study involves the collection or use of Protected Health Information (PHI)

☐ Reviewing IRB serves as the Privacy Board (common scenario)

☐ CU serves as the Privacy Board (only applicable to NCI CIRB studies at this time)

Signatures:

Principal Investigator or Designee _____ Date _____

HRPO Reviewer _____ Date _____

All Columbia University policies and guidance, not limited to those noted above, have been provided to the Reviewing IRB and should be referenced during regulatory review (see Human Research Policy Guide)

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