Cover Page for Reliance on WCG IRB

This form is to be completed by the research team for all requests for the WCG IRB (formerly Western Institutional Review Board (WIRB)) to serve as the Reviewing IRB for Phase III oncology protocols or for NIH funded protocols for which Columbia University has designated WCG to be the Single IRB as per the grant application.

To facilitate WCG review, please respond to **all** of the following questions, each of which solicits information about Columbia University, i.e., "local", requirements that pertain to the research. **Please submit this cover page with your Rascal IRB Protocol submission, which is required for tracking and administrative review purposes. **Please also provide this form to WCG with your WCG submission.**

In the Rascal IRB application, designate WCG as the reviewing IRB in the "Attributes" section. All fields in the application must be completed except for the areas for which "abbreviated submission" is checked to indicate that the information is in the attached standalone protocol or grant application. In addition, all study-related material provided by the sponsor (i.e. template consent forms, questionnaires, etc.) must be attached to the Protocol submission and revised to meet all requirements of Columbia University policies and guidance. Please be advised that if the Rascal application is incomplete, the administrative review process that will be conducted by Columbia University Human Research Protection Office (HRPO) staff may be delayed. Submission to WCG may only occur after the HRPO administrative review is completed.

Protocol Title:

Rascal Protocol Number:

Is this protocol a Phase III industry sponsored protocol? No Yes If yes, is this study managed by the Cancer Center Clinical Protocol Data Management Compliance Core (CPDM)? Yes No

Is this protocol being submitted to WCG because Columbia University has designated WCG as the Single IRB per your grant application? Yes No

Ancillary Reviews required for the research:

PRMC JRSC IBC N/A No Ancillary Reviews Needed

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

Genetic Testing (Genetic Testing Policy)

Appropriate language according to local policy has been added to the consent

Incidental Findings (Incidental Findings from Imaging Procedures Conducted for Research Studies Policy)

Plans for managing Incidental findings are included in the protocol

Consent form includes language related to incidental findings

Informed Consent Policy, Surrogate Consent (Informed Consent Policy)

Does the protocol hold the prospect of direct benefit to subjects? Yes No

Are plans to assess capacity are provided in the protocol? Yes No

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 for assessment of capacity

E-Consent guidance (Electronic Informed Consent)

Does the protocol describe the consent process in sufficient detail as per CU guidance? Yes No

Do you propose to obtain consent on the same day as the elective procedure? (Same Day Consent Policy)

Yes No

Do you anticipate enrollment of non-English speaking subjects? (Enrollment of Non English Speaking Subjects Policy)

No

Yes. If yes, will study related materials be translated by a study team member?

No, a commercial entity will translate study related material

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

Do you anticipate enrollment of subjects under the age of consent?

No

Yes, and the protocol includes plans to obtain assent that meet the requirements of Children as Subjects of Research CUMC Policy

Do you anticipate enrollment of women in labor?

No

Yes, and the protocol includes plans to enroll laboring women according to the Clinical Research Involving Pregnant Women guidance

Does this study involve the collection or use of PHI?

Yes No

None of the above institutional policies apply to this research

Other:

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 WCG and should be referenced during regulatory review (see Human Research Policy Guide).