INSTITUTIONAL REVIEW BOARD (IRB) AUTHORIZATION AGREEMENT

This Institutional Review Board (IRB) Authorization Agreement (“Agreement”) establishes the ability for the *INSTITUTE/ORGANIZATION IRB* to serve as the IRB of record (“IRB of Record”) for research with human subjects conducted at *Weill Cornell Medical College* (“Research”):

**Relying IRB: Weill Cornell Medical College (WCMC)**

Federalwide Assurance (FWA): FWA00000093

IORG: 0000617

IRB Registration: 00009417 (G1); 00009418 (G2); 00009419 (Expedited IRB); 00009420 (Cancer 1 IRB); 00009421 (Cancer 2 IRB)

**IRB of Record: INSTITUTE/ORGANIZATION (XXX)**

Federalwide Assurance (FWA): FWA########

IORG: #######

IRB Registration: #######

This agreement is limited to the following research:

**STUDY TITLE (Study Abbreviated Title)**

Funding Information: e.g. Industry, Federal, Institutional,Consortium, etc.

WCMC Principal Investigator: NAME, DEGREES

INSTITUTE/ORGANIZATIONPrincipal Investigator: NAME, DEGREES

The review performed by the IRB of Record will serve to meet the human subject protection requirements of the OHRP-approved FWA of the participating institution/organization that is relying on the IRB of Record hereunder (“Relying Institution”). The specific roles and responsibilities of the principal investigator and collaborating investigators at each participating institution/organization must be clearly detailed in the IRB approved protocol. In addition, the roles and responsibilities of the institution serving as the IRB of Record and the Relying Institution(s) are outlined in sections A and B below.

# Responsibilities of the IRB of Record are to:

* 1. Maintain registration with OHRP;
  2. Maintain a Board membership that satisfies the requirements of 45 CFR 46 and 21 CRF 56;
  3. Perform initial reviews, continuing reviews, reviews of submitted reportable events for the ceded Research that involve risks to subjects or others, amendments, incidents of serious or continuing noncompliance, and any other documents as needed to be consistent with the applicable regulations;
  4. Maintain and make accessible to the Relying Institution(s) the IRB of Record application, protocol reviews, letters to principal investigators, approvals and disapprovals, and minutes of the IRB of Record meetings relevant to the protocol;
  5. Notify the Relying Institution(s) immediately in the event of a suspension or restriction of the IRB of Record’s authorization to review studies; and
  6. Provide the Relying Institution(s) approved informed consent form(s), including relevant language translations. The consent form will indicate areas where the Relying Institution(s) may add language or otherwise customize the consent form for its own institution(s). The changes are generally limited to the following areas: privacy and confidentiality, HIPAA, payment for research related injury, site-specific norms, and local contacts. Any modifications will be subject to approval by the IRB of Record, which will then provide a final approval consent form to the Relying Institution(s) for use;
  7. Receive and review all conflict of interest determinations, including management plans, which may include appropriate redactions, made by the Relying Institution(s). The IRB of Record will require that any management plans are incorporated into its deliberations and that any mandated disclosures to subjects are included in the approved informed consent form. If the IRB of Record determines that a management plan requires modifications in order to protect Research participants, the IRB of Record will promptly notify the Relying Institution(s). If the Relying Institution(s) is(are) not willing or able to modify its management plan consistent with the IRB of Record’s request, then the Research will not be eligible for review under this Agreement. The IRB of Record will not disapprove prohibitions or management plans that are more stringent or restrictive than what the IRB of Record would require. If the IRB of Record is unable to implement the Relying Institutions’ prohibitions or management plans, the Research will not be eligible for review under this Agreement; and
  8. Notify the Relying Institution of any IRB of Record policy decisions or regulatory matters that might affect the institution’s reliance on IRB of Record reviews or performance of the Research at the Relying Institution.

# Responsibilities of the Relying Institution(s) are to:

1. Maintain an FWA;
2. Provide the IRB of Record with the current names and addresses of local contact persons who have the authority to communicate for the specific human research activity at the Relying Institution;
3. Require that the principal investigators and other research personnel at the Relying Institution(s) who are involved in the Research are appropriately qualified and meet the Relying Institutions’ standards for eligibility to conduct Research. This includes, but is not limited to, having the required professional staff appointments, credentialing, insurance coverage, and background checks for their assigned role in the Research;
4. Perform local analysis of any specific requirements of state or local laws, regulations, policies, standards (social or cultural) or other factors applicable to the Research, and notify the IRB of Record of any relevant requirements or results of the analysis that would affect its conduct of the Research. Provide the applicable information to the IRB of Record as appropriate for consideration;
5. Perform local review by other local ancillary committee reviews (e.g. Privacy, Radiation Safety, Institutional Biosafety Committee, etc.) when required by the Relying Institutions’ policies. The determinations should be provided to the IRB of Record when pertinent to its review and determinations;
6. Provide the IRB of Record with all specific wording needed to complete the identified site-specific sections, as enumerated in A.6 above, of the study consent form(s) approved by the IRB of Record;
7. Maintain policies regarding the disclosure and management of conflicts of interest related to Research and share those policies with the IRB of Record when requested. Require that Relying Institution(s) investigators and other research personnel involved in the Research disclose financial interests as required under the Relying Institution(s) policies. Require that conflicts of interest are reviewed and a management plan is implemented, if and as required under Relying Institution(s) policies. Provide all management plans to the IRB of Record for its review and consider modifications from the IRB of Record (as described in A.7 above). The Relying Institution(s) will require compliance of all management plans related to the Research.
8. Notify the IRB of Record immediately if there is ever a suspension or restriction of the local IRB’s authorization to review studies;
9. Notify the IRB of Record immediately if there is a suspension or restriction of the principal investigator at the Relying Institution;
10. Require the safe and appropriate performance of the Research at the Relying Institution. This includes, but is not limited to: monitoring study compliance; reviewing material protocol deviations and any unanticipated problem involving risk to subjects and others that occur at the institution; ensuring a mechanism exists by which complaints about the Research can be made by local study participants or others. Any action taken as a result of problems that are identified in these areas should be shared with the IRB of Record and the principal investigator of the lead institution(s);
11. Require the principal investigator at the Relying Institution(s) to maintain appropriate copies of all approvals, and other correspondence documenting the review and approval of the Research as required by the regulations;
12. Maintain compliance with any additional state, local, or institutional requirements related to the protection of human subjects;
13. The Relying Institution may, at any time, choose to change its decision to cede review and continuing oversight of its human subject research to the IRB of Record for the Research conducted pursuant to this Agreement. In such cases the IRB of Record and Relying Institution(s) will work together to facilitate the transfer of IRB oversight with the goal of limiting the potential disruption to the Research. Until the IRB oversight is transferred, the IRB of Record will continue to assume oversight responsibility.

The Officials signing below agree that each participating institution/organization may rely on the IRB of Record for review and continuing oversight of its human subject research.

The point(s) of contact for each institution with reference to this agreement, including all inquiries and notifications:

Weill Cornell Medical College

Point of Contact: Lauren Blumberg, Assistant Director of Regulatory Compliance

Telephone: 646-369-3751

Email: lab7018@med.cornell.edu

INSTITUTE/ORGANIZATION Institutional Review Board

Point of Contact: NAME, DEGREES, TITLE

Telephone: ###-###-####

Email: [XXXXX@XXX.XXX](mailto:XXXXX@XXX.XXX)

Signature of Signatory/Institutional Official: *Weill Cornell Medical College*

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Timothy Wilkin, MD, MPH

Assistant Dean, Clinical Research Compliance

Signature of Signatory Official/Institutional Official: INSTITUTE/ORGANIZATION *Institutional Review Board*

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NAME, DEGREES

TITLE