Request for NC State University Researcher to Use the WCG Private IRB

The researcher will complete and submit this form to the NC State IRB office via the eIRB system. In the eIRB system itself, the PI should only complete the "title" and "description" tabs. This completed form and required information from this completed form must be uploaded as supplemental documents to the eIRB application before submission.

Study Name: Click or tap here to enter text.
NC State Protocol Number: Click or tap here to enter text.

NC State University PI Name(s): Click or tap here to enter text.
Non-NC State University Collaborator(s): Click or tap here to enter text.
Justification as to why Collaborating PI's IRB cannot serve as IRB of record: Click or tap here to enter text.
Sponsor Name: Click or tap here to enter text.

Brief description of study including target population and procedures: Click or tap here to enter text.

This study qualifies for the use of the Private WCG IRB because it is:

☐ A Clinical Trial in Phase I, II, III, and IV for all drugs and any significant risk devices.
☐ A Device Study that requires a Full IDE or significant risk device (not exempt from the IDE requirement nor eligible for an Abbreviated IDE)
☐ A Drug Study that requires an IND (regardless if IND Exemption Status)
☐ A study that is using a drug or biologic.
☐ A study that is using invasive measures.
☐ Industry sponsored or federally funded research that requires full board review, is biomedical in nature, and involves more than three sites or centers.
☐ A planned emergency research
☐ Research on surgical techniques or procedures that do not involve investigational devices
☐ A device studies that are first in human
☐ Research involving investigational radiologic procedures and/or investigational radiologic drugs
☐ Research involving gene therapy, gene transfer, or embryonic stem cell therapies
☐ Biomedical Research involving people who are incarcerated
☐ Research on transplant techniques, procedures, or other interventions
☐ Other: Click or tap here to enter text.

Ancillary Reviews, Approvals, and Requirements
Ancillary Reviews are reviews of human research projects by compliance groups or individuals and happen in addition to the IRB review. These reviews vary, depending on the grant requirements and type of research performed and may be required by federal or state regulations, IRB policy, or institutional requirements. A satisfactory approval from the appropriate ancillary review group must be obtained prior to the IRB issuing their initial review approval.

☐ Institutional Biosafety Committee (IBC) Click or tap here to enter text.
☐ Tribal IRB Review Click or tap here to enter text.
☐ Radiation Safety Click or tap here to enter text.
☐ Export Control Click or tap here to enter text.
☐ There are no restrictions on the research imposed by any of the ancillary committees that would prevent the study to be reviewed by an external IRB
☐ There is no legal or regulatory prohibition that prevents the research from being reviewed by the WCG Private IRB.
☐ Approval letters from ancillary reviews are provided to the NC State IRB

General Information

Description of how the WCG IRB will be paid (funding source):
Click or tap here to enter text.

Provide Necessary information for Conflicts of Interest (COI) including Attestations, or Management Plans
Click or tap here to enter text.

Proof of Completion for Required Human Subjects Training for all research team members and collaborators has been uploaded with this request form.
☐ Yes

If the study involves an IND or IDE, the IND/IDE information has been provided to the NC State IRB including sponsorship requirements.
☐ Yes
☐ No

Email addresses of research team members who need access to the electronic application system used by the WCG IRB
Click or tap here to enter text.

Name and email address of NC State University Departmental Business Office Contact:
Click or tap here to enter text.