Title: NC State University Researcher's Use of the WCG Private IRB
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Standard Operating Practice: 24

24.1. Executive Summary

This document provides information regarding the NC State University IRB office's unit standard for the use of the private WCG IRB.

24.2. Standard Operating Practice

In accordance with the NC State University IRB office unit standard on Cooperative Research, Reliance Agreements, and Single IRB (sIRB) (Word document), a principal investigator (PI) or designee may submit a study to the WCG IRB if prior approval is obtained from the NC State Institutional Review Board (IRB) office. In addition, the NC State IRB may require the submission of a study to the WCG IRB even if a PI does not submit a request to use the approved external IRB. The types of studies that may qualify for the use of the WCG IRB, the criteria and process for approval, and oversight responsibilities if review is ceded to an external IRB, are summarized in sections 24.3 and 24.4 of this document.

24.3. Operational Procedures

24.3.a. Eligibility Criteria

24.3.a.i. Qualifying Research Types

1. Phase 1, 2, 3, 4, and 5 clinical trials (Word document) for all drugs and any significant risk medical devices

2. Any medical device study that requires a full investigational device exemption (IDE) (opens in a new window) or where the medical device is a significant risk not exempt from the IDE requirement nor eligible for an abbreviated IDE

3. Any drug study that requires an investigational new drug (IND) application (opens in a new window) regardless of the IND exemption status

4. Any study using a drug (opens in a new window) or biologic (opens in a new window) off label or not yet approved by the FDA

5. Any study using invasive measures

6. Any industry sponsored or federally funded research that requires convened full board review, is more than minimal risk to participants, and is biomedical in nature

7. All planned emergency research to be undertaken when the intervention or interaction will be used on subjects unable to provide consent because of the emergency situation

8. Research on surgical techniques or procedures that involve investigational devices

9. Medical device studies where the device is first being used in a human subject

10. Research involving investigational radiological procedures and/or investigational radiologic drugs

11. Research involving gene therapy, gene transfer, or embryonic stem cell therapies

12. Biomedical research involving people who are incarcerated

13. Research on transplant techniques, procedures, or other interventions

14. Federally funded studies where the use of a single IRB is required and the funding agency or lead study team has chosen the WCG IRB to serve as the IRB of Record.

24.3.a.ii. Additional Requirements
If a study fits into one of the categories detailed in 24.3.a.i above, a study may be approved for the use of the WCG IRB only if ALL of the following criteria are met:

1. All required ancillary committee approvals (e.g., Environmental Health and Safety (IBC), Radiation Safety, etc.) are in place and documented in the request for external IRB review unless the ancillary committee must receive IRB approval prior to conducting its review or another exception is noted in the request.

2. No restrictions on the research are imposed by any of the ancillary committees that would prevent the study to be reviewed by an external IRB

3. The principal investigator (PI) received the requisite permission(s) to serve as the PI for the study

4. The PI meets the NC State University IRB office's requirements to serve as a PI on a research protocol

5. There is no legal or regulatory prohibition that prevents the research from being reviewed by the WCG private IRB.

24.3.a.iii. Right of Review
A study may not be submitted to the WCG private IRB without prior written approval by the NC State University IRB office.

24.3.b. Submission and Approval to Use the WCG Private IRB
No study may be submitted to the WCG private IRB without the prior approval of the NC State University IRB office. When submitting a request for approval to use the WCG private IRB, the PI or designee must submit the following to the NC State University IRB office through the electronic submissions system.

24.3.b.i. PI Request to NC State University
The following information should be submitted to the NC State University IRB by the PI for the IRB office to determine if use of the WCG IRB is appropriate:

1. Brief description of the target population, study procedures, and a justification as to why the study requires the use of the WCG private IRB

2. Award information, including:
   a. any information shared with a sponsor (e.g., grant application, etc.); and
   b. the plan for paying WCG private IRB fees

3. Approval letters from all ancillary committees required to review the study (e.g., Environmental Health and Safety (IBC), Radiation Safety, etc.) unless the ancillary committee must receive IRB approval prior to conducting its review or another exception is noted in the request

4. Conflict of interest information and attestations or management plans

5. All required human subjects research training for each member of the research team

6. Description of collaborating researchers or institutions and their role and involvement in the study including funding and activities completed by the researcher.

7. Sponsor obligations must be included if an NC State University PI, group of PIs, or the University is the holder of an investigational new drug (IND) or investigational new device (IDE) determination for the study.

24.3.b.ii. NC State University Referral to Use the WCG Private IRB

1. The NC State IRB office must verify the following:
   a. Eligibility of the study for external IRB review
   b. Ancillary committee approvals
   c. PI and research staff compliance with human subjects' research training required by the University and conflicts of interest (COI) requirements
   d. Whether the study was previously reviewed or is in the process of being reviewed by the NC State IRB office or another IRB
   e. Congruence between the grant proposal and the protocol submitted to the IRB for federally funded studies

2. The NC State University IRB office will consider the following when deciding whether to approve or deny a request to use the WCG private IRB:
   a. internal IRB capacity regarding expertise;
   b. the type and complexity of the study including the category of research and criteria that must be met; and
   c. whether the use of an external IRB is required by contract or is specifically requested by the PI with sound rationale clearly stated.

3. The NC State IRB office may require a study to be submitted to the WCG IRB even if the PI does not submit a request to use an external IRB.

4. No study may be submitted to the WCG IRB without the prior approval of the NC State University IRB office.

5. All studies referred to in 23.3.a.i. require approval from the IRB Director, IRB Chair, or their designee to use the WCG private IRB.

6. Once the verification and approval are complete, the NC State University IRB office will notify the PI regarding whether the request is approved or denied. If approved, the PI may proceed with a submission to WCG private IRB as identified and approved by the NC State IRB office.

24.3.c. WCG IRB Use Processes

1. Even if a study is approved to use the WCG private IRB, the NC State University IRB office may revoke permission to use the WCG private IRB for one or more studies at any time if deemed necessary for the protection of participants or for compliance with federal, sponsor or university policies.

2. When the research is cooperative, all sites must execute their own agreement with the WCG private IRB.

3. When the study is approved by the WCG private IRB, the NC State University researcher will provide the NC State IRB with the approved protocol and documents, and approval letter. This includes any approved materials generated as a part of an amendment or annual approval renewal.

24.4. WCG IRB Usage Fees

The NC State University IRB office is not responsible for any fees associated with review by the WCG private IRB for sponsored research. The NC State IRB suggests discussing research involving human subjects (that falls under the section 24.3 above) with the IRB office at the time of the award application process.

24.4.a. Federally funded research

1. All fees associated with sponsored research studies are expected to be planned for during the award application process. Contact the NC State IRB office for the current WCG standard fee schedule.

2. The standard fee schedule applies to federally funded single site protocols led by NC State researchers only. The NC State IRB will provide the principal investigator (PI) and their departmental business office with the initial communication regarding the requirement for the use of the WCG private IRB including the standard fee schedule.

3. For studies that are cooperative or multi-site research that require single IRB (sIRB), the principal investigator will be required to work with the WCG business development team for study-specific fees and requirements. In these cases, the NC State IRB will provide the PI initial communication regarding the requirement for the use of the WCG private IRB and refer them to the WCG private IRB to determine the fees involved.

24.4.b. Privately funded research

1. All fees associated with privately funded research studies are expected to be planned for during the funding application process.

2. Privately funded single site protocols led by NC State University researchers will use the WCG standard fee schedule. Contact the NC State IRB office for the current WCG standard fee schedule.

3. Privately funded multi-site or cooperative research protocols that require single IRB (sIRB) will use the WCG non-industry fee schedule or the standard fee schedule.

    a. If the entity funding the research pays for the use of the WCG IRB, the standard fee schedule is used.
    b. If NC State University pays for the use of the WCG IRB, the non-industry fee schedule is used.

4. The NC State University IRB office will provide the principal investigator (PI) and their departmental business office with initial communications regarding the requirement for the use of the WCG private IRB and the appropriate fee schedule (standard or non-industry).

24.4.c. Unfunded/unsponsored research

1. NC State University will assume payment responsibility for unfunded/unsponsored human subjects research that requires the use of the WCG private IRB,

2. The NC State IRB office will provide the principal investigator (PI) and their departmental business office with initial communication regarding the requirement for the use of the WCG private IRB including the non-industry fee schedule.

24.5. Reportable Events and Communications

1. Instances of reportable information such as participant complaints, adverse events, unanticipated problems, and issues of noncompliance must be submitted directly to the WCG IRB in accordance with their reporting requirements and to NC State University via their online reporting tools. The NC State University IRB will be notified by the WCG private IRB regarding their determination.

2. The WCG private IRB, the NC State University IRB office, and NC State University Institutional Official (IO) will promptly notify one another of any communications received from a federal agency (FDA, OHRP, etc.), funding agency, or oversight authority in connection with a study.

3. Before a report or communication is sent to a federal agency, oversight authority, or funding agency, the WCG private IRB, the NC State University IRB office, and the NC State University Institutional Official or designee will cooperate regarding any investigations and communications.

4. The WCG private IRB and the NC State University IRB shall determine whether the WCG private IRB and the NC State Institutional Official or designee will jointly report, whether the parties will report separately, or whether one party will make the report. In no event shall the agreement between NC State University and the WCG private IRB prevent the WCG private IRB or the NC State University Institutional Official or designee from reporting directly to a federal agency, oversight authority, or funding agency in order to satisfy its own reporting obligations.

5. If the WCG IRB or NC State University Institutional Official or designee directly reports, the party making the report will copy the other party on the communication.

24.6. Protocol Changes (i.e., Amendments) and Approval Renewals

1. Any subsequent submissions (e.g., amendments, etc.) related to a study under the purview of the external IRB must be sent directly by the principal investigator (PI) or designee to the external IRB in accordance with the applicable external IRB's policies.

2. The PI or designee must notify the NC State University IRB office of the following changes or modifications prior to the WCG IRB submission:

    a. change(s) in the research team (personnel amendments) for verification of compliance with conflict of interest disclosure and human subjects research training requirements;

    b. proposed modifications to the protocol if the modification would require approval from any of the ancillary committees at NC State University (e.g., adding minors to the protocol, increasing the levels of radiation for research purposes only); and

    c. any changes to the grant proposal or protocol that may require a congruency review before the WCG IRB can review the study.

24.7. NC State IRB Office Processes for WCG IRB Protocols

24.7.a. Obligations and Oversight

1. NC State University maintains overall responsibility for conduct of the research regardless of which IRB reviews the study. That responsibility is shared among multiple entities within NC State University, including the PI, the PI's department, the NC State University IRB, the NC State University Institutional Official, and the compliance and monitoring groups within the NC State University.

2. Other obligations and oversight responsibilities and the entities typically charged with ensuring compliance with these obligations include:

    a. conducting ancillary committee reviews as applicable and informing the WCG IRB of the reviews that will affect the study (HRPP);

    b. informing the WCG IRB of any local context issues as requested by the external IRB (PI; HRPP);

    c. promptly reporting to the WCG IRB any serious or continuing noncompliance in connection with a study in accordance with the WCG IRB's reporting requirements (PI, PI's Department);

    d. promptly reporting to the WCG IRB any unanticipated problems involving risks to participants or others in connection with a study in accordance with the WCG IRB's reporting requirements (PI, PI's Department)

    e. promptly reporting other events or issues in accordance with the WCG IRB's reporting requirements (PI, PI's Department);

f. maintaining a system for receiving and addressing participant complaints about the study and providing this information to the WCG IRB via the NC State current reporting practices

24.7.b. Record Keeping

1. The NC State University IRB will maintain a record of the study in an electronic system maintained by the IRB office.

2. The NC State University IRB office will retain a record of any authorized changes and any modifications that would require approval from any of the NC State University ancillary committees or departments.

3. Per the agreement with the WCG private IRB, the NC State University IRB office will ensure that it is provided access to the study records and reviews conducted by the WCG private IRB upon request.

24.7.c. Independent Auditing

The NC State University IRB office will perform periodic random audits of each study completed by the WCG private IRB in order to ensure compliance with all applicable laws, regulations, guidance, University policies, and contractual requirements.