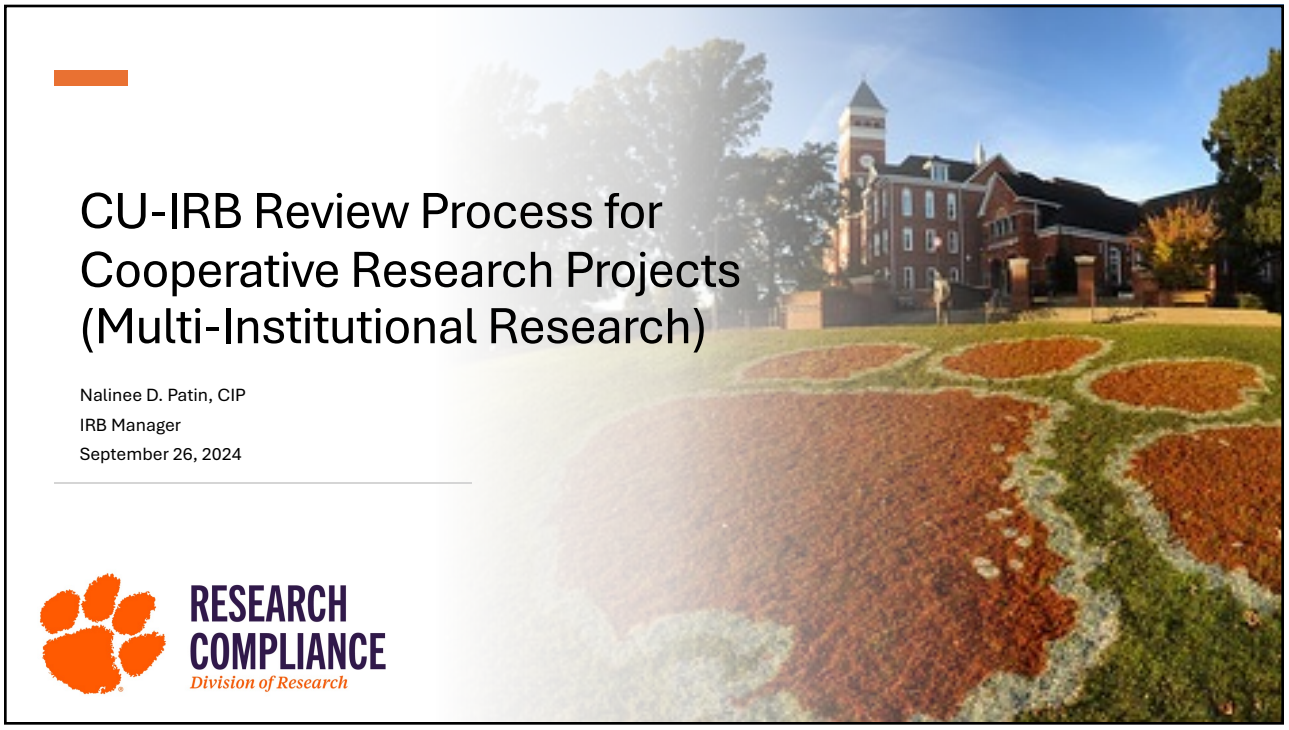

CU-IRB Review Process for Cooperative Research Projects (Multi-Institutional Research)

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IRB Manager
September 26, 2024

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Definitions/Common Terms

- **Cooperative Research**: Research projects that involve more than one institution.
- **sIRB**: Federal regulations' single IRB mandate requiring institutions located in the United States (US) that is engaged in cooperative research to rely upon another US institution's IRB approval for that portion of the research that is conducted in the US. **Purpose is to avoid duplication of effort.**
- **Reviewing IRB**: The IRB office designated to review the IRB protocol for all the research sites involved with the project. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research. **There are some exceptions to the requirement.**

Reference: 45 CFR 46.114 Cooperative Research (federal human subjects research regulations)

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Definitions/Common Terms Cont'd

- **IRB Protocol**: Project description of the research activities involving human subjects; includes research methods, recruiting process/documents, informed consent process/documents, data collection instruments, and other supplemental documents required by the IRB office.
- **Local Context Review**: Administrative review by the local IRB office relying on the designated reviewing IRB.
- **IRB Authorization Agreement (IAA)**: Commonly referred to as a reliance agreement. Agreement outlining the terms of the joint review arrangement with institutions participating in a cooperative research project. Documents the local IRB office relying on the review IRB.
- **Engaged in Research**: An institution is "engaged in research" if it (or its employees, staff, or agents) has a key role in designing the research, conducting the research, analyzing and interpreting the results, or gaining informed consent from human subjects; may include some recruiting procedures. (Reference: 2022 SACHRP Recommendations: New Interpretation of the "Engaged in Research" Standard)

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IRB Office Review Levels

Administrative Review: Review conducted by the IRB Office/IRB Manager.

Exempt Level Review: Studies involving low risk research activities **and** meet one of the Exempt categories identified in the federal regulations.

Expedited Level Review: Studies involving low risk research activities that **do not meet one of the Exempt categories**.

Full Board Level Review: Studies involving **more than minimal risk** research activities, as defined by the federal regulations. IRB protocol reviewed by all the IRB members at a scheduled IRB meeting with quorum (convened IRB). Majority votes determine approval/disapproval of the study.

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When and Why to Register a Cooperative Research with CU-IRB Office

When to register?

- All studies when CU researchers (employees and students) are "engaged" in the research. Funded and unfunded studies.
- There are some exceptions for the School of Nursing (SON) Doctor of Nursing Practice (DNP) projects. Outlined in a guidance document developed by SON and CU-IRB Office.

Why is registration required?

- CU-IRB Office is the registered IRB for CU researchers and ultimately responsible for the conduct of CU researchers on the project.
- CU-IRB Office is required to keep a record of all human subjects research involving CU researchers.
- Each institution is still responsible for safeguarding the rights and welfare of human subjects and for complying with the federal regulations.

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When is a Reliance Agreement required?

Required for all federally sponsored cooperative research projects, including projects with Prisma Health, MUSC, UofSC and other SC institutions.

Institutions may elect to enter into a reliance agreement for unfunded cooperative research projects to avoid duplication of effort.

Only required for Expedited or Full Board review studies.

CU-IRB Office do not enter into reliance agreements for Exempt level review studies.

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CU-IRB Office Application Type

In the current InfoEd online submission system, use the **Deferral Application** type.

Upcoming Changes!!

New IRB application eForms will be rolled out in December.

More information to come in October 2024.

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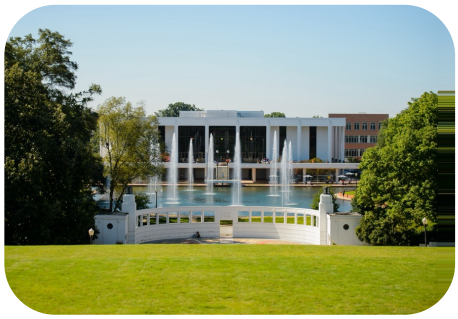
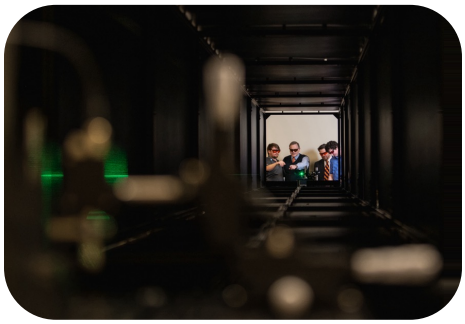
What documentation is required?



Collecting data at a CU campus?

- All documents reviewed by the reviewing IRB.



Not collecting data at a CU campus?

- Reviewing IRB determination letter and approved application.
- Data management plan (DMP) if data will be stored on CU servers or devices.
- CU personnel training documents.

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What is involved with a local context review at CU?

Determine if any local policy or state laws apply to the study. For example, SC mandatory reporting law if data collection will occur in SC, any CU policy for recruiting employees or students, etc.

Determine if CU ancillary reviews are required (other compliance offices, CCIT, privacy officer, etc.).

Review conflict of interests (COI) of researchers and verify that COI is on file.

Verify CU-IRB and sponsor required training.

Required information is shared with the reviewing IRB.

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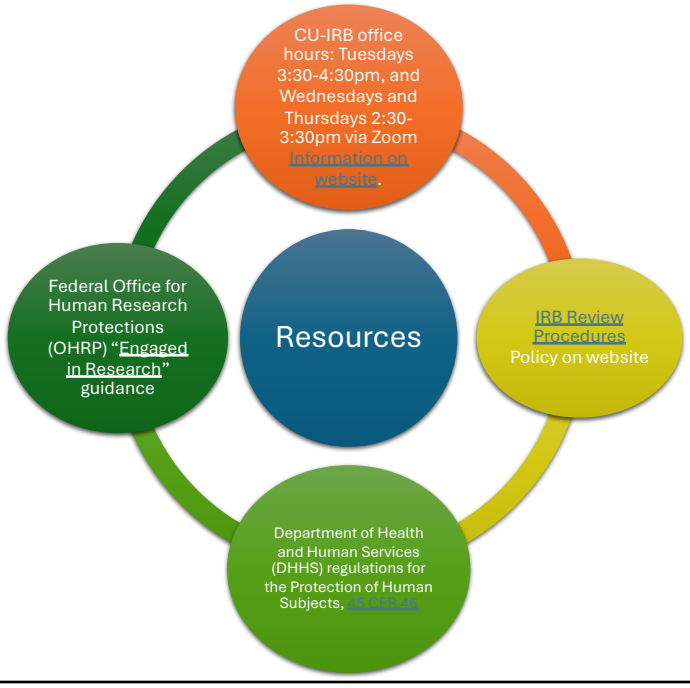

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