

The University of North Carolina at Greensboro

IRB Quality Improvement Cayuse Submission Guide



UNCG

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How to Determine if IRB Approval is Required

Any individual or group of individuals collecting data (questionnaires, surveys, interviews) on other individuals must determine if IRB approval is required. This process provides the individual(s) and participant(s) with protection regarding federal laws.

UNCG uses three screening questions in the Cayuse IRB application to decide if IRB review is required. If you are affiliated with UNCG, a Cayuse IRB application is needed to work on a project involving human subjects. Examples include sending a survey to students, faculty, staff, or non-university affiliated persons. Even if you are working with another institution, an IRB application must be completed with UNCG.

Not Human Subjects Research (NHSR)

Per federal regulations, the UNCG IRB is required to review and approve all human subjects research. An online form was designed to help faculty/students/staff decide whether an activity meets the federal definition of human subjects research. If you believe your project does NOT meet the definition of human subjects research, you can complete this [NHSR Self-Determination form](#).

- There are related limitations to this process that should be reviewed carefully before continuing.
 - Externally funded projects cannot use the application and must be submitted thru the [Cayuse Human Ethics System](#).
 - Journals and/or publications may require an official determination from the IRB. The online form is **not a determination**. If you anticipate publishing in a journal that may require an official determination letter, you should submit an application thru the [Cayuse Human Ethics System](#).
 - If you use this form, you are unable to use language referencing IRB approval in your study documents or materials.

Please note: UNCG School of Nursing requires all DNP students to submit their (NHSR) Quality Improvement projects through Cayuse to receive an official IRB NHSR determination. DNP students may NOT use the NHSR self-determination form linked above.

CITI Training

- Quality Improvement projects are not considered to be human subjects research, so they do not require any Citi training modules to be completed.

Logging into the System

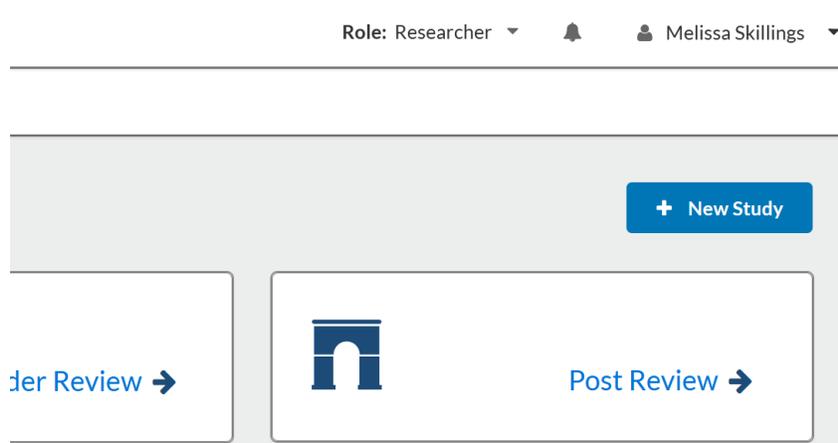
UNCG uses the Cayuse Human Ethics System (Cayuse) for submission of studies requiring review. Cayuse requires a Single Sign On.

To log in:

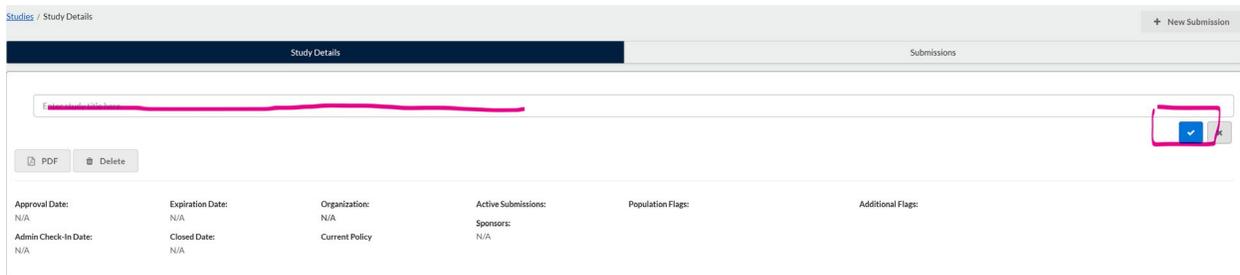
1. Navigate to <https://uncg.cayuse424.com/>
2. Select Cayuse IRB (Human Studies Compliance)

Creating a New Study

1. Upon entering Cayuse, you will click “New Study” in the upper right corner.



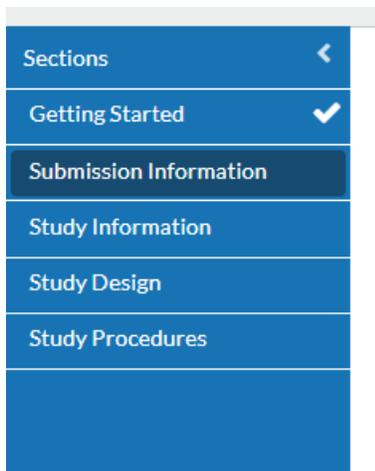
2. Next, you will enter the study title and approve the record. This will bring you into the main application.



Additional instructions and details can be found here: <https://cayuse.uncg.edu/wp-content/uploads/2024/03/New-Study.pdf>

Completing the Study Submission

When you enter the main application, you will see a menu on the left-hand side of the screen. This will help guide you thru each section of your submission. When completing a quality improvement application, you will see a shortened menu as shown below. There is information in each section of the application that is important to read and include when completing your application. The below is information in addition to what is already explained and provided in the Cayuse application.



1. Submission Information

Multi-Institutional Study

This is a study that involves more than one institution. IRB approval may have been obtained elsewhere. Multiple sites may have the same funding. Data may be collected at more than one institution.

Most quality improvement projects would not be considered “multi-institutional” since they are not considered research projects, but if the other IRB involved with the project requires review there as well, then you would select “yes” and that each institution is conducting their own IRB review.

Questions #1 - #3

1) Does your project involve a systematic investigation, including research development, testing and evaluation, which is designed to develop or contribute to generalizable knowledge?

- The above question is the federal definition of research. If your submission meets the federal definition of research, please respond "yes"
- You should only answer yes if your activity meets all the above

Generalizable Knowledge – Question #1

While regulations do not define "generalizable knowledge", one way to think about it is the information is expected to expand the knowledge base of a scientific discipline or other scholarly field of study and yield one or both of the following:

- Results that apply to a larger population beyond the site of data collection, or the specific subjects studied
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study. Also, please clarify if you plan on further analyzing the outcome data for research purposes.

Quality improvement projects are not intended to contribute to generalizable knowledge; they are only intended to improve an existing practice for the benefit of the institution that the data goes back to. If you intend to analyze data gathered from a quality improvement project for research purposes, then it would be considered research at that point and no longer be QI.

Researchers who intend to only complete their project for quality improvement purposes should answer NO to this question, since the project would not meet the federal definition of research.

Please note: UNCG School of Nursing requests that DNP students only complete quality improvement projects and not research. If you are a DNP student who feels your project also meets the federal definition of research, please discuss this with your faculty advisor.

Interaction or Intervention – Question #2

Interaction or Intervention includes in person and remote collection. If you are collecting information from a person but the information is not about them, this question should be answered no.

Private Identifiable Information – Question #3

Are you using identifiable private information or biospecimens for your project that you are retrieving in a way other than direct interaction? Ex. Secondary data

What type of Activity is this Submission For?

- Quality Improvement Project: Please provide information on the following questions:
 - Is this activity based on existing practice and is trying to improve it? **QI projects should be able to answer yes to this question.**
 - Is this data going back to the institution for quality improvement practices? **QI projects should be able to answer yes to this question.**
 - Please confirm you will **not** be re-analyzing this data for research purposes. **QI projects should be able to answer yes to this question. If the answer is no, then your project may be research.**

Is this a community-engaged project?

Answer this question “yes” if your project is defined as a collaborative and reciprocal partnership between the university and its communities for mutually beneficial knowledge exchange and positive, sustainable transformation.

QI projects would typically answer “no” to this question.

2. Study Information

Principal Investigator Status

- Faculty should only be selected if you are a current active faculty member at UNCG.
- Student should only be selected if you are completing this project for course or degree requirements at UNCG.
- Staff should only be selected if you are a current active faculty member at UNCG.

Personnel

- Names in this section must match all other names in the documents attached.
- Student PI’s, please list your faculty advisor in the faculty advisor section as well as a Co-PI.
- PI’s typically list themselves as the primary contact.

External Researchers

This section typically does not apply to QI projects since external researchers are not engaged in research, because QI projects are not research.

Select yes if you are working with someone who is not affiliated with UNCG but works at a different institution. When you select yes, a request for more information about this researcher will open.

Community Co-Researchers

This section typically does not apply to QI projects since community co-researchers are not engaged in research, because QI projects are not research.

Select yes if you will be working with someone that is not affiliated with UNCG and does not work at another institution with an IRB.

- Community co-researchers may need community partners training. A form is sent to ORI for each co-researcher to determine if training is needed. [This form](#) can be found on the UNCG Scholar training Page and should be sent to ori@uncg.edu as soon as possible.
- Please note that community researchers will not have access to human subjects Citi training and would need to complete an alternative human subjects training. Once the IRB decides that your community researcher is an eligible community partner then additional instructions will be given to you, that will outline next steps to

complete the required human subjects research training. Information about community co-researcher training is found on our [training page](#).

Will this study be funded?

Include any funding you will be receiving for this project. If this changes during the application or project, this section must be updated.

If you have not already done so, you must link your application to the grant proposal in Cayuse SP. The instructions to do so can be found here: <https://cayuse.uncg.edu/wp-content/uploads/2024/03/To-Link-an-IRB-Application-to-a-Cayuse-SP-Proposal.pdf>

Are there any study team members funded by a different source?

Include any funding members of your team will be receiving for this project. If this changes during the application or project, this section must be updated.

Signed Agreements

Include any agreement related to this research. Ex: Data Use

Study Site

- Most QI projects take place at an outside location (i.e., a clinic or hospital). If so, select “external site” and provide the name of the location.
- International Research includes online studies that will be open to participants across the world. If you are conducting international research, added assessment and information is required.
 - If you are obtaining data within the EU, a GDPR assessment is needed.

Study Dates

- Make sure the study date is not already past. It will need to be updated to reflect the current review.

3. Study Design

Please note: when submitting an application for a QI (or any NHR) project, you should not refer to the project as research or as a study (which indicates research). Also, you will not reference IRB approval, since the IRB does not approve NHR projects; we only provide a determination.

Is this study a clinical trial?

QI projects should answer no to this question. If you feel that your project meets the definition of a clinical trial, it may be considered research.

- Clinical Trial means research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to reevaluate the effects of interventions on biomedical or behavioral health related outcomes. (NIH Decision Tool: <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/definition>)

Study Background

- Provide a clear and concise rationale about why the project is needed. The information in this section should be easily translated to the information included in the rest of your study submission.

Hypothesis

- QI projects typically do not have a hypothesis; you may answer this as n/a.

Study Purpose/Research Questions

- The overall purpose of the project.

Outcome Measures

- QI projects should list outcome measures. Outcome measures for QI are the before-and-after indicators that show whether your process change made things better.

Inclusion and Exclusion Criteria

- If participants must be employed at a specific site or part of a specific group to be included in the QI project, that should be listed.
- Please include if participants will be eighteen or older, located in the US, and can read/speak English.
- For Exclusion Criteria, if anyone in the inclusion criteria can take part in this study, this can be answered no.

4. Study Procedures

- General Questions that must be answered in the rest of this application - the who, what, when, where, and how of the entire project. Use these questions to guide your application. For example:
 - Where will the project take place? (online, in the classroom, hospital, etc.)
 - What will the participants do?
 - Where will data be stored and who will you share it with?

Describe all study procedures.

- This section must clearly describe only the study procedures for the project. Please do not include detailed information about recruitment, incentives, risks, or consent in this section. Proofread your document and make sure the information contained in this section is consistent throughout your application.

Audio and Video Recording

- Please follow the ITS Audio/Video Recording Guidelines: <https://scholar.uncg.edu/policies/>
- If using Teams, use the secure platform and follow the instructions to set up a secure environment.

Follow-Up

- If you are following up with participants after the first part of your project, your participants are no longer non-identifiable.
- Include in study procedures how you will follow up with participants and how second events will be scheduled. Make sure any follow-up scripts are included in the recruitment scripts section.

Forced or Required Responses

- Forced (required) responses are not recommended as the participant should be able to choose whether they want to respond to a certain question.

Observations

- Where will the observation take place? Will you observe participants in a public space or in a private space? Is there an expectation of privacy even though the participant is in a public space?
- How long will you observe participants?
- What information will you collect about participants?
- How will you document the data you will gather? Video, audio, notes?
- Will you gather information about a participant that could be embarrassing, risky, or document illegal behaviors?
- Will you be observing children?

Qualtrics

- Please confirm the anonymized responses will be turned on. For more information please see: <https://www.qualtrics.com/support/survey-platform/survey-module/survey-options/survey-protection/>

Research in Private Homes

- Two researchers are required when people do visits in the participant's home.

Software

- All software and apps must be approved thru the UNCG software process. Please confirm you have received or will receive that approval before beginning work on this project. <https://software.uncg.edu/>
- If using Teams, use the secure platform and follow the instructions to set up a secure environment https://uncg.service-now.com/kb?id=kb_article_view&sysparm_article=KB0012260

Tools used with permission

- If something being used with permission (like research tool) include whether this person will also receive data.

Describe your recruitment procedures

This section should clearly describe only the recruitment procedures for your project. When and how will each piece of your recruitment procedures happen. Include who will be completing the recruitment on your project. If you have included any recruitment information in the study procedures section, it must match what is included in this section.

For example, in study procedures you state you will be emailing participants. In this section, you cannot say that you are both emailing and calling participants.

Listserv

- What listserv are you planning to use?
- How will you gain access to this listserv?
- Do you have permission to email members from the listserv administrator?
- Who will be sending the emails to the listserv population?

Number of Contacts

- How many contacts do you propose?

Public Flyers

- Please be clear that you will be posting flyers only publicly and with permission.

Recruiting in a Public Space

- Be clear about how recruitment will occur. It is preferred that PIs not approach potential participants but allow potential participants to approach them. Example: A table setup with study information.

Recruiting from UNCG Classrooms

- If the study team will recruit in the classroom, the Department chairs unaffiliated with the research project must provide approval in writing. The approval can be documented in a letter or email.

Social Media

- Which sites are you using (Facebook, Twitter, etc.)? If you are posting on any group pages, please clarify you will obtain any needed permissions. Please also clarify you will not post on other individuals' pages.
- Are you posting on your own social media, groups, or other pages?
- How will you be corresponding with participants (e.g., what script will you be using).
- Will the PI post study advertisements on social media in a way that keeps digital privacy (for example, by setting default settings to block individual posts in response to the ads)?

Word of Mouth

- Word of mouth should be defined. Is there a script, what does this mean, etc.

Are you affiliated with the study site (if outside of UNCG)? (ex. you are employed by the study site)

- DNP students who complete QI projects are often employed by the QI site and would answer yes to this question.

Has site approval been obtained?

No study activities can occur until a site approval letter is received. If a letter is not yet received it will need to be submitted with a modification after the study is approved.

Agency Letter

- **QI projects that take place off the UNCG campus must submit a site approval (agency letter) to complete their project at that site.**
- NOTE: Agency letters are not needed when an agency, school, organization, or individual will be made aware of the project and asked to refer potential participants to the investigator to be provided more information regarding participation.
- The UNCG IRB requires that agency letters be included with IRB applications under either of the following two circumstances:
 - Under circumstances involving UNCG being “either a) the primary awardee under a federal grant, contract, or cooperative agreement supporting research to which the FWA applies, or b) the coordinating center for federally-conducted or –supported research to which the FWA applies, the Institution is responsible for ensuring that all collaborating institutions engaged in such research operate under an appropriate OHRP-approved or other federally-approved assurance for the protection of human subjects.” Under such circumstances, the UNCG investigator must attach to the IRB application, evidence which may take the form of an agency letter.
 - Under circumstances involving an agency, school, organization, or individual providing the researcher access to potential research participants or authorizing data collection at the agency, school, or organization's location. Consistent with this requirement:

Directories and Mailing Lists

- When access to potential research participants involves use of organizational directories, mailing lists, etc., the agency letter is not needed if the contact information is publicly available or can be bought for the purpose of contacting potential research participants.

Listservs

- In the case of listservs, agency letters are not needed when an individual managing the listserv sends out the recruitment information (as such an action implies agreement of the managing individual/organization). If an individual who does not manage the listserv sends out the information (e.g., a listserv member), an agency letter or documentation explicitly saying that the listserv is available for recruitment of research participants must be attached to the application.

Classroom

- Recruitment of participants from a UNCG class needs an agency letter from an instructor or department chair unaffiliated with the project.

Secondary Data

- If using secondary data, require a letter from the site explaining what they will provide PI for study.

Recruitment Materials and Documents

Please note: Since QI is not considered research, please do not refer to “research” or “study” in any of these documents or the application.

Documents

- Please explain how each document in the recruitment materials and documents section will be used for recruitment.
- Make sure recruitment documents are consistent with study design tab inclusion criteria.
- If you are using a survey, please include the link (Qualtrics, etc.).

Photographs

- Please confirm you have permission to use the photograph.

QR Codes

- Please confirm this will lead to the attached recruitment documents or upload the document tied to the QR Code.

Required components of a recruitment document

- The principal investigator’s name
- A contact name with either a phone number or email address
 - Also consider:
 - What will the participant be expected to do
 - Time or other commitment required by participants.
 - Location of project and name and contact information of a person to be contacted about the study (if other than already provided)

Describe Payment/Incentives

Explain how participants will receive their payment/incentives. If this amount will be prorated, this must be described. Explain why the payment/incentive being provided is appropriate (example: the time commitment needed).

Descriptions that cannot be used

- Free
 - Participants must complete the study to receive the incentive. This could be considered misrepresentation.
- Raffles
 - The State of NC does not allow raffles. Please use drawing.

Equipment Return

- Incentives should not be withheld for equipment return. Can use the assignment of an equipment agreement as mentioned previously.

Extra Credit

- Clarify whether participants are receiving points for participation or receiving the points as part of course requirements outlined in the course syllabus. If the points are given as part of the course, not extra credit for the research, then the points should not be listed as an incentive.

Describe the duration of study participation...

- Please show the timetable for study completion including the duration of data analysis.

Timeline Dates

- For Start Date use 'upon IRB **determination**'
- For other dates use spring, fall and year or fall term, spring term. If you use specific dates and deviate at all, a modification will be needed.

Describe the information to be gathered...

Typically, this section is brief. You can list below and do not have to provide details on each as it was previously included in sections of the application.

- Include what applications will be used for collection, transcription, and analysis.
- If using previously collected data, explain how this data will be used.
- If collecting, data include how this will be done.

Software on UNCG Devices

Confirm that you will receive approval for all software and apps being used for your research. This is done thru the UNCG software process. You will also find a list of previously approved and available software. <https://software.uncg.edu/>

Software on personal devices

- If you are asking participants to download software on their personal device then you must include the following language in your consent form: This study asks you to use [name of third-party software]. Third party software is outside of our control. Your information could get out or be used by [name of third-party software] for other purposes that are not related to the study. Your computer could be corrupted. Please carefully read and think about the [name of third-party software] Terms of Service and Privacy Policies before agreeing to give them any of your information. If you do not want to share your data with [name of third-party software], that is completely acceptable, but you will not be able to enroll in this study.

Data Management Plan

If you have a data management plan for your project, it should be attached under the "Attachments" tab in the section labeled "Other." The language in this plan should match the information being provided in the Participant Protection, Safeguarding Participant's Identity section.

Data management plans are not common for QI projects.

Will the data be transmitted or shared outside of UNCG?

Explain how you will share the data with others. If you will not share the data, this should be answered N/A.

QI data is typically shared back to the institution the project is being completed to improve.

Study Instruments

Attach all study instruments in their final version. They should not have edits, redlines, comments, etc. The IRB must see/hear/view all documents that the participants will. Please provide links **AND** pdf versions of documents.

Please note: Since QI is not considered research, please do not refer to “research” or “study” in any of these documents or the application.

Participant Data, Specimens, and Records

Answer Yes if you are using data or biospecimens that have not been collected thru direct interaction and could identify the individual. Remember that audio recording/voice is identifiable.

Will any of the above Study Instruments or Participant Data, Specimens...

Answer Yes if you are collecting identifiable information. Ex: you are emailing participants, or you are recording participants’ voice.

Genetic Testing

Answer Yes if you will be using genetic testing.

Drugs, Devices, Biologics

Confirm if device being used this a commercially available. If not, please clarify whether the device being used for this study may be used for diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

Will Protected Health Information held by a Covered Entity be used...

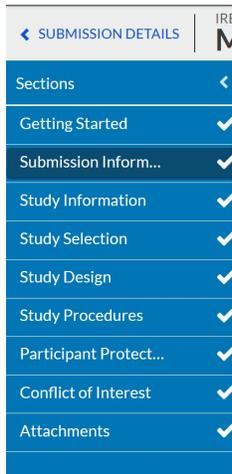
If PHI from a covered entity is being used, more questions will open about the types of identifiers that will be received.

HIPPA Data

- HIPPA data retention for PHI is six years.

Submitting a Study for Review

Once you have completed all sections successfully, checkmarks should appear next to each item in the left-hand menu. You will see directly below this menu a choice to complete the submission.



Responding to Stipulations

Once your IRB protocol is complete and submitted, it will be reviewed by an IRB Analyst. As part of this process, there will be questions about your submission. These will be received, and you will respond in the Cayuse system.

To learn how to respond to stipulations, follow the instructions here:

<https://cayuse.uncg.edu/wp-content/uploads/2024/03/Responding-to-Stipulations.pdf>

Changing the Principal Investigator

There are instances when a PI change is needed. Those could include:

- PI leaving UNCG and turning research over to a new PI.
- Students graduating must change their PI to their student advisor.

To complete a PI change, a modification must be submitted thru the Cayuse system.

Completing a Modification

A modification should be submitted when a previously approved item from your protocol requires a change. All changes must be submitted via the modification process.

To submit a modification follow the instructions here: <https://cayuse.uncg.edu/wp-content/uploads/2024/03/Submitting-a-Modification-1.pdf>

Closing a Study

Studies may be closed when the involvement of human subject's ceases. **Do not** file a study closure report if any of the following six conditions apply. Such studies must remain active and continue to receive ongoing IRB review and approval:

- Enrollment at the UNCG approved site is ongoing.
- Research-related interventions and/or follow-up at the UNCG-approved site is ongoing.
- Participant follow-up at the UNCG -approved site is ongoing.
- Biological specimens containing personally identifiable information are being kept in a repository that has been approved as part of this study or upon which analysis or research is ongoing. If, however, specimens were transferred to a separate repository that has ongoing IRB approval, the study may be closed.
- Data analysis or manuscript preparation that involves the use or access to personally identifiable information is ongoing.
- If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.

To submit a closure follow the instructions here: <https://cayuse.uncg.edu/wp-content/uploads/2024/03/Submitting-a-Closure.pdf>