

# Training

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The topics found below will provide various learning resources for common IRB items.

If there is a topic that you would like to learn more about but do not see it listed below, please contact us at 402-559-6463 or at [irbora@unmc.edu](mailto:irbora@unmc.edu).

- [CITI Training](#)
- [Community Partners](#)
- [Consent Forms](#)
- [E-Signature Instructions](#)
- [IRB Training Videos](#)
- [RSS Training](#)
- [Virtual Training/Office Hours](#)

# CITI Training

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## What is CITI?

Collaborative Institutional Training Initiative (CITI) certification is an institutional requirement for all personnel engaging in Human Subject Research (HSR). It includes three primary modules that are required by the institution to participate in conducting various types of research: Group 1: Biomedical Research, Group 2: Good Clinical Practice (GCP), and Group 3: Social & Behavioral Research.

Faculty, employees, students and other institutional representatives at UNMC, Nebraska Medicine, CHMC, and UNO are required to complete the Human Subjects Research (HSR) course via CITI if they will be working on a research project that involves human subjects. It takes approximately 1-2 hours to complete a Basic course. The training does not have to be completed in one sitting, but can be spread out over time if needed.

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## Instructions

A PDF with instructions for how to navigate CITI can be found [here](#).

### Basic or Refresher?

The Basic course is designed to establish certification and should be taken when:

- No previous CITI training has been completed, or:
- Prior CITI certification has been expired for a period greater than three years

The Refresher course is designed to re-establish certification for three years and should be taken when:

- The Basic course of a particular group has already been taken, and:
- Recertification is required, but has not been expired for a period of three or more years

Course required based on type of research:

**Group 1: Biomedical Research** – Investigators conducting research about human biological systems and processes, including efficacy and safety of preventative, diagnostic or therapeutic methods must take this course. Types of research:

- Clinical trial using a drug, medical device, technique or other intervention or strategy (including non-physical means, like diet, cognitive therapy, etc.) to diagnose, treat or otherwise study a particular condition or disease.
- Non-clinical biomedical research to study normal or abnormal physical or physiologic processes (for example: gait and balance testing, biomechanical assessments, etc.).
- Research involving medical records or data registries.
- Research involving human biologic materials.

**Group 2: Good Clinical Practice (GCP)** – Investigators conducting clinical trials funded by NIH, or utilizing an FDA regulated drug, device, or biologic must take this course. A clinical trial is defined as “a research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes”.

Investigators conducting these types of trials must also take the Biomedical course (Group 1).

*This GCP course meets the minimum criteria for training identified by some sponsors. (Check to see if your sponsor is listed.) If so, your CITI completion report can be supplied to the sponsor to meet their GCP training requirement.*

**Group 3: Social & Behavioral** – Investigators conducting research performed with intent to study:

- Behaviors, attitudes, and interactions/social processes among and between individuals, groups, and cultures.
- Generally, this category of research has no intent of producing a diagnostic, preventative, or therapeutic benefit to the subject who is not seeking nor expecting a health benefit from the research.
- This course is primarily taken by students at UNO, although it is common for Nursing Program students to be required to take this as well.

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## Researchers/Students transferring from other institutions:

Please email all completion reports for previously completed CITI training courses to [irbora@unmc.edu](mailto:irbora@unmc.edu). CITI courses are unique from institution to institution and transcript comparison will be required. Only the completion report shows the modules required for transcript comparison. Once previous training has been updated, the IRB will determine if any additional training or Refresher courses will be required.

It is highly recommended that you email the Completion Report prior to beginning the Refresher course. Please do not send completion certificates.

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## Collaborators with UNMC:

Any independent entity collaborating with UNMC for the purposes of research must also complete CITI training as required by the institution. When registering for CITI, please affiliate with UNMC/UNO and do not register as an independent learner.

If you need assistance with your username and/or password from an institution other than UNMC/UNO, you can contact:

**CITI Support:** 888-529-5929 (9:00 a.m. to 7:00 p.m. EST/Monday – Friday).

If you have more than one CITI account, you can request that they be merged by calling CITI Support. Once merged, all training completed will be available under one account.

For all questions regarding CITI training, please contact the IRB Office at 402-559-6463 or email [irbora@unmc.edu](mailto:irbora@unmc.edu).

# Community Partners

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All individuals that work on human subject research projects must complete **human subject research training**. Faculty, students, or employees of UNMC, NM, CHMC, UNO, BMC, or another academic partner institution are required to take CITI training. **Community partners who collaborate on research projects may complete the CIRTification program as an alternative to the CITI Program.**

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## Who are Community Partners?

Community partners are non-academic personnel (e.g. community leaders, representatives from supporting community organizations) engaged in research requiring IRB approval. This program is specifically and only for community members collaborating on human subject research studies.

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## Who is NOT considered a Community Partner?

Students or staff affiliated with UNMC, NM, CHMC, UNO, BMC, or research staff affiliated with other private entities directly engaging in human subject research.

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## What is CIRTification?

CIRTification is a training program in human research protections created by the University of Illinois Chicago CCTS that is tailored to the unique roles of community research partners. It is interactive and relevant to the roles and responsibilities that community partners have in research projects. The program considers community partners' limited experience with research, discusses key concepts in research ethics and responsible conduct of research in plain language, and focuses on applying knowledge to real-life scenarios. Ideally, CIRTification Online will not only teach community partners about the importance of protecting research participants, it will also empower them to be active contributors to their respective research teams.

CIRTification introduces learners to the basics of the research - the terminology, people, and methods. It reviews the history of research abuses that have informed current ethical principles,

rules, and regulations.

The training program also covers standard and best practices for:

- Recruitment and informed consent
- Collecting and protecting data
- Handling changes that may arise during participant interactions
- Reviews the role of the Institutional Review Board in protecting the right and safety of human research participants

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## What can I expect?

The program takes about 3-4 hours total to complete and can be completed in multiple sessions. The course is currently available in English, Spanish, and Haitian Creole. The course includes audio, video, text, and interactive activities.

Learners will complete a knowledge quiz at the end of the program and receive a date-stamped certificate of completion. Please save a copy of this certificate for your records and email a copy to [IRBORA@unmc.edu](mailto:IRBORA@unmc.edu).

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## Online Training Instructions:

Please follow the instructions below to enroll in CIRTification. Please select **University of Nebraska Medical Center** only from the list.

1. Go to <https://training.ccts.uic.edu/>
2. Click “Register” in the top right-hand corner.
3. Select “I am not from UIC”.
4. Complete the registration form. Under “Site”, select “University of Nebraska Medical Center”.
5. Once the form is filled in, click “Register” at the bottom of the form.
6. Visit the Course Catalog. Information about CIRTification will appear. Click “Learn More”.
7. Click “Enroll” to start the CIRTification course.

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## Frequently Asked Questions (FAQ):

<b>Who can I contact for help?</b>
For assistance, please contact: Megan Berger at <a href="mailto:mberger@unmc.edu">mberger@unmc.edu</a>

**How long is this training valid?**

The training is valid for three years.

**How do I access my completion certificate?**

After completing the quiz at the end of the training, the option to print and save a date-stamped certificate of completion is available. If for some reason you missed this or are unable to complete this step, Megan Berger can access the completed training certificate. Email her at [mberger@unmc.edu](mailto:mberger@unmc.edu).

*CIRTification is funded through the University of Illinois at Chicago Center for Clinical and Translational Science and supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through Grant UL1TR002003. We encourage mention and citation of CIRTification Online in grant proposals, conference presentations, published manuscripts, and other reporting. Suggested citation: CIRTification Online: Community Involvement in Research Training. University of Illinois at Chicago, Center for Clinical and Translational Science.*

# Consent Forms

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## Capacity to consent

- Assessment of capacity to consent to participate in research
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## Consent Form Readability

Recent changes to the Federal Regulations governing human subject research (the “Common Rule”) have included a focus on improving the readability of consent forms and include regulations requiring understandable language, and organization and presentation of information that facilitates understanding.

In response to these requirements, beginning October 31, 2019, consent forms must satisfy minimum readability standards. **We are working on a way to receive proof of PRISM training. Therefore, until further notice, we are not requiring physical proof, but written assurance.**

Though we expect to extend the standard to other sections, initially only the readability of the **Invitation and Summary section** will be assessed.

This section must have Flesch Kincaid reading level  $\geq 8$  and Flesch Reading Ease  $\geq 60$ . Readability may be scored within the RSS application by clicking on the “Readability” button.

CFs not meeting these minimum readability measures will be returned to the investigator for modification.

To assist investigators and their staff in developing necessary skills to write effective consent forms, the PI and the person responsible for writing the consent form, **must complete online training through PRISM** (Program for Readability in Science and Medicine). The hour-long training covers health literacy and readability, plain language strategies and examples, and interactive editing examples and exercises.

*For more information on process, readability standards, and readability tips, see below.*

**Readability Assessment Process:**



- Readability can be assessed within the RSS application by clicking on the “Readability” button. This will open a new page with assessments of Flesch-Kincaid reading level and Flesch Reading Ease for the invitation and summary section.
- In computing reading levels, technical terms (especially drug names and names of medical procedures) may unavoidably adversely affect the score. You may choose to use the name once, and then say "the test drug" or "the operation" subsequently. However, in all cases, an effort should be made to use a simpler word or phrase.
- The IRB recognizes that sections of some consent forms may be of such a technical nature that it may not be possible to keep to an 8th grade reading level. In these situations, the invitation and summary at least must meet the standard described above, and the investigator must describe what additional tactics will be used to assure and assess comprehension.

### Readability Standards:

- The Flesch–Kincaid readability tests are readability tests designed to indicate how difficult a passage in English is to understand. There are two tests, the Flesch Reading Ease, and the Flesch–Kincaid Grade Level. Although they use the same core measures (word length and sentence length), they have different weighting factors.
- The results of the two tests correlate inversely: a text with a comparatively high score on the Reading Ease test should have a lower score on the Grade-Level test.
- Many other measures of readability exist. SMOG (Simple Measure Of Gobbledygook) is a more exacting measure of readability, and accurately scores for the grade level required for complete text comprehension. (The Flesch-Kincaid formula grades for less than complete comprehension). SMOG demonstrates strong correlation with the required reading level in validation studies. The SMOG formula is based on the number of words consisting of three or more syllables. The SMOG score is commonly used to assess readability of healthcare information.

### Tips for writing readable Consent Forms:

- PRISM online training is a web-based plain language tutorial for research professionals, including scientists, research staff, Institutional Review Boards (IRBs), or communications staff. The hour-long training covers health literacy and readability, plain language strategies and examples, and interactive editing examples and exercises.
- There are a variety of tools available to assist investigators in improving readability of CFs. PRISM online training addresses some tactics. [The PRISM Readability Toolkit is available here.](#)
- The Readability Toolkit is a plain language handbook illustrating how to improve the readability of research consent forms and other materials for study participants. The Toolkit includes plain language principles and strategies, quick reference guide and editing checklist, Plain language alternatives to complex terms, easy-to-read template language for consent forms and links to readability resources.

<b>Do</b>	<b>Do Not</b>
Use short sentences and use words familiar to the non-medical reader.	Use medical terminology without explaining it, or use words that an 8th grader would not understand.

<b><i>Do</i></b>	<b><i>Do Not</i></b>
Refer to thesauruses and medical glossaries made for children to find alternative ways to refer to medical terminology.	Use medical “jargon” or words longer than three syllables, when another word is also appropriate.
Use the second person (“you”) and note that they are asked to participate in a research study. Be personal.	Use the third person (“the subject”), and avoid writing “invite” to refer to their participation.
Use pictures and graphs wherever possible.	Provide information solely in large blocks of text, with long sentences.
Say “for example” or “so forth.”	Say e.g. or etc.
Use tablespoons or teaspoons to refer to the measurement of bodily fluids, and spell them out.	Use ml or cc to refer to volumes of bodily fluids, or abbreviate teaspoons/tablespoons.
Say “greater than” or “less than”.	Use “>” or “<” or other symbols that an 8th grader might have trouble understanding at first glance.
Describe study terminology such as “randomized”, “placebo”, or “double blind”; such as “like the flip of a coin”.	Use medical or study terminology without explaining it in lay terms.
Use the words “study drug” or “study regimen”.	Use the terms “therapy” or “treatment” to describe drugs, devices, or procedures.
Refer to investigational drugs or devices as “experimental” or “investigational”, and that it means the FDA has not yet approved it.	Refer to investigational drugs or devices as “new.”

### Readability Examples and Templates:

- [Invitation and Summary Template](#)
- [Invitation and Summary Sample 1 \(Phase I Oncology Drug\)](#)
- [Invitation and Summary Sample 2 \(QOL Oncology\)](#)
- [Invitation and Summary Sample 3 \(Phase III Drug\)](#)
- [Invitation and Summary Sample 4 \(Knee Replacement\)](#)

## Consent Teach-Back Tool

UNMC is recommending that study teams utilize the "teach-back" method during the informed consent process for their clinical studies. This method will enhance the informed consent process, ensuring participants are well-prepared before consenting and enrolling in clinical studies.

Our aim is to empower clinical research investigators and coordinators with the tools and knowledge to ensure that research study participants are fully informed and understand all aspects of the informed consent form.

### Teach-Back Tool

### Ethical Responsibility in Research

- Disclosure: It's our duty to provide all necessary information to potential research participants.
- Decision-making: We must ensure that participants can make informed decisions based on the information provided.

## **The Importance of Health Literacy**

"Health literacy plays a crucial role in maintaining a healthy lifestyle and making informed decisions about our health care. Yet, a report from the HHS Surgeon General in 2019 highlighted that *only 12% of Americans possess proficient health literacy skills*. This underscores the importance of clear communication in the informed consent process."

*Reference: HHS Surgeon General Reports and Publications, 2019*

## **Consent Teach Back: A Strategy for Clarity**

- A strategy to improve the researcher's ability to explain the ICD content in a way that is clear and understandable.
- An opportunity to facilitate understanding of why a participant may or may not want to participate.
- A tool to assure that the participant is provided with sufficient opportunity to discuss the information given to them and to consider whether or not to participate

## **The 5 T's of Teach Back**

1. Triage: Concentrate on one topic at a time.
2. Tools: Utilize models, written tools, posters, graphics, etc., to aid in explaining the desired information.
3. Take Responsibility: Phrase it as, "I want to make sure I did a good job explaining..."
4. Tell Me: Encourage the participant to express their understanding in their own words. Be specific about what you expect them to relay back.
5. Try Again: If the participant's understanding isn't clear, revisit the topic.

*Reference: Anderson, Leister and DeRego, Health Literacy Research and Practice, 2020*

## **Evaluating Understanding with Teach-Back**

- Participant's Understanding of the Study:
  - Purpose
  - Procedures
  - Risks
- Appreciating the Consequences of Participation:
  - Recognizing it's a research study
  - Potential benefits (or lack thereof)
  - Impact on current or future treatments
  - Confidentiality and data access
- Participant's Reasoning/Decision Process:
  - Awareness of other options
  - Understanding that participation is VOLUNTARY

- Participant's Ability to Make a Choice.

# E-Signature Instructions

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The e-signature function in RSS is a way to electronically sign consent forms. It can be used if the consent process is conducted in person (face to face) or remotely (telephone or video as approved by the IRB). RSS e-signature can only be used for certain studies, outlined in the table below.

*E-signature can only be used on newly created Narrative Consent Forms.*

**When can RSS e-signature be used? (as of 2/20/2024)**

Study Types	
FDA-regulated (drug/device) studies	Yes
Non-FDA-regulated studies	Yes
Commercially funded studies	Yes
Federally funded studies	Yes
CIRB (studies relying on an external IRB)	No
Multi-site studies where UNMC is the IRB of record	No

Consent forms that are electronically signed in RSS are maintained in the RSS application, so paper forms do not need to be printed and stored. See the links below for instructions on in person or remote e-signatures:

- [E-signature for in person consent](#)
- [E-signature for remote consent](#)

If you have any questions or would like to schedule a training session, please contact Sue Logsdon at [slogsdon@unmc.edu](mailto:slogsdon@unmc.edu).

# IRB Training Videos

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Below are training topics related to the IRB, its history, and its function. Please let these videos serve as a training tool for those new to the IRB and research fields. If you need individual assistance with specific issues, or for general information, please contact us at [irbora@unmc.edu](mailto:irbora@unmc.edu) or through the RSS Message Portal.

## **UNMC IRB Basics: Introduction to the Institutional Review Board**

## **Getting Approved by the IRB: Everything You Need to Know**

## **Informed Consent**

## **Ethical Access to Patients as Human Subjects of Research**

## **IRB Considerations in Research Involving Drugs and Devices**

## **Use of the IRB Short Form**

# RSS Training

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Guides to assist with RSS procedures:

If there is a topic that does not appear below, please contact [irbora@unmc.edu](mailto:irbora@unmc.edu)

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**Adding Personnel**

**Adding Documents to an Application**

**Consent Forms 101**

**Creating and navigating a New Application**

**Deleting Personnel**

**Functions within a Consent Form**

**How to submit an Incident Report**

**Navigating the RSS Dashboard**

**Signatures on a Consent Form**

**Submitting a Change Request**

**Using the in-person RSS E-Signature**

**Using the remote RSS E-Signature**

**Working within an Application 101**

# Virtual Training/Office Hours

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## IRB Office Hours

We can be reached by phone (402-559-6463) or by email ([irbora@unmc.edu](mailto:irbora@unmc.edu)) Mon-Fri 7am-5pm.

The IRB offers two virtual learning/training sessions each month.

- 2nd Monday of every month 9-10 AM ([Zoom link](#))
- 4th Thursday of every month 2-3 PM ([Zoom link](#))

Please direct questions regarding virtual training hours to the IRB Education Coordinator: Megan Berger [mberger@unmc.edu](mailto:mberger@unmc.edu) or 402-559-6044