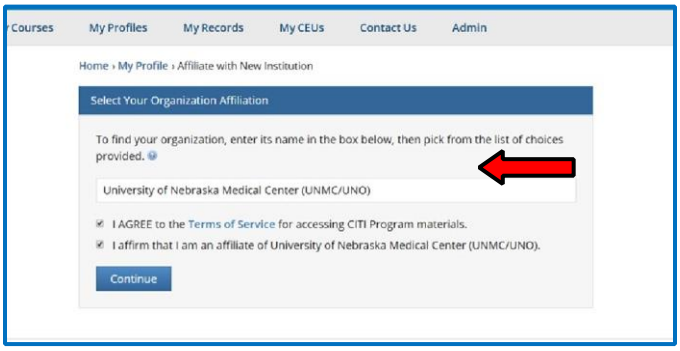
CITI RESEARCH CERTIFICATION INSTRUCTIONS

Faculty, employees, students and other institutional representatives at UNMC/ TNMC/ CH&MC and UNO are required to complete human subjects' research training if they will be working on a research project that involves human subjects via the Collaborative IRB Training Initiative (CITI). The training is done via the internet. The total estimated time to complete the basic course is 1-2 hours and the refresher course will take 30-45 minutes. Please note that you do not have to complete the training in one sitting. The training is presented as several modules with a brief quiz at the end of each module to assess your understanding.

1. Go to CITI website www.citiprogram.org
2. Click "*Register*" if you have not previously logged on (i.e. created an account) to the CITI website.

3. Under Participating Institution, choose "*University of Nebraska Medical Center (UNMC/UNO)*". Click at the bottom on the screen.



4. Create a profile by filling in personal information and creating a username and password.
5. Respond to the questions regarding CEUs and survey participation. Click "*Continue*".

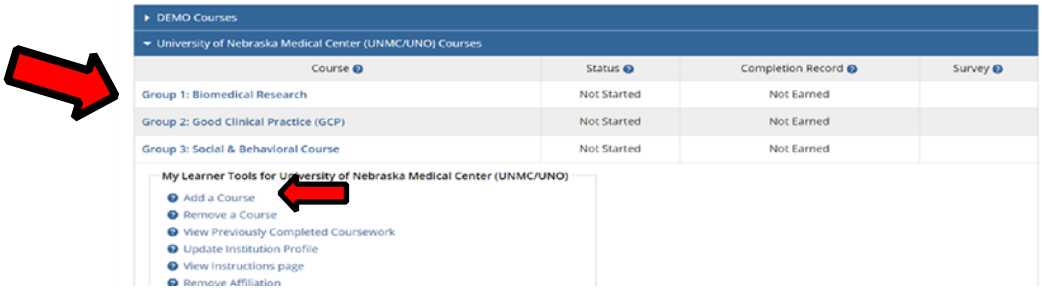
   *NOTE: If you would like to receive CEUs for completing the CITI course, there will be an **additional cost** to you That UNMC/TNMC/CH&MC/UNO does NOT cover.*
6. Complete the profile information ** indicates a required field* Click "*Continue*".
7. Chose "Human Subjects Research". *NOTE: You may take additional groups.*
8. The next screen will ask if you have previously taken the Basic Course in the Protection of Human Research Subjects. If you have never completed CITI training before, you will choose Basic. If you have completed the Basic Course for a different institution or if you are unsure, please contact our office @ 402-559-6463.

NOTE: The RCR course is NOT the same as the Human Subjects Research course.

9. The next screen will ask if you want to affiliate with another institution. You can add affiliations in the future if needed, but do not add others at this time. Click "*Finalize Registration*". CITI will send you an email to activate your account from "citiprogram-noreply@citiprogram.org". Click the link in the email to complete the registration process.

10. Sign in using the username and password that you created.

11. You are now at the Main Menu. Choose the appropriate course:



Group 1: Biomedical

Investigators conducting research about human biological systems and processes, including efficacy and safety of preventative, diagnostic or therapeutic methods must take this course. Biomedical research includes (a) 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, and (b) non-clinical biomedical research to study normal or abnormal physical or physiologic processes (for example, gait and balance testing, biomechanical assessments).

**Investigators conducting research involving Medical Records or Human Biologic Materials must take this course as well.

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"

**Note that investigators conducting these types of trials will probably also need to take the Biomedical course (group 1).

Group 3: Social & Behavioral

Investigators conducting research performed with intent to study behaviors, attitudes and interactions and social processes among and between individuals, groups, and cultures will need to take this course. Generally this category of research has no intent of producing a diagnostic, preventive, or therapeutic benefit to the subject who is not seeking nor expecting a health benefit from the research.

12. Complete each module within the course by clicking the name of the module, reading the information and taking the quiz. You must have obtain a score of 75% to pass the module. You are able to retake the quiz by clicking "View this Module again" at the bottom of the quiz review page.

13. You are able to add additional courses by clicking "Add a Course" under the My Learner Tools.

14. Upon completion, the UNMC IRB automatically receives an email with your completed certificate. You will always have access to log back in and print copies of your certificate as needed. Your certification is valid from UNMC/UNO for 3 years. Call the IRB Office if you have any questions @ 402-559-6463.

NOTE: Other institutions may have different requirements as far as required courses, modules and/or duration of certification.

Current Courses:

Group 1: Biomedical
Group 2: Good Clinical Practice (GCP)
Group 3: Social & Behavioral