HUMAN SUBJECTS RESEARCH & THE IRB

IRB CHAIR, NMHU (LARA HEFLIN)

2023

YOUR NMHU IRB COMMITTEE MEMBERS – SPRING 2023

- Thomas Brooks –Department of Psychology
- Lara Heflin – (Chair) Department of Psychology
- Robert Karaba – School of Education
- Chelsea Lucero – Community Member
- Rey Martinez – School of Social Work
- Christian Montaño – Community Member
- PJ Sedillo – School of Education

IS IT RESEARCH?

- Research – “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (HHS,45 CFR 46. 102(d))
  - University-wide surveys of staff and faculty?
  - Classroom demonstrations of science?
  - Class-based research project that planning to submit to conference or journal?

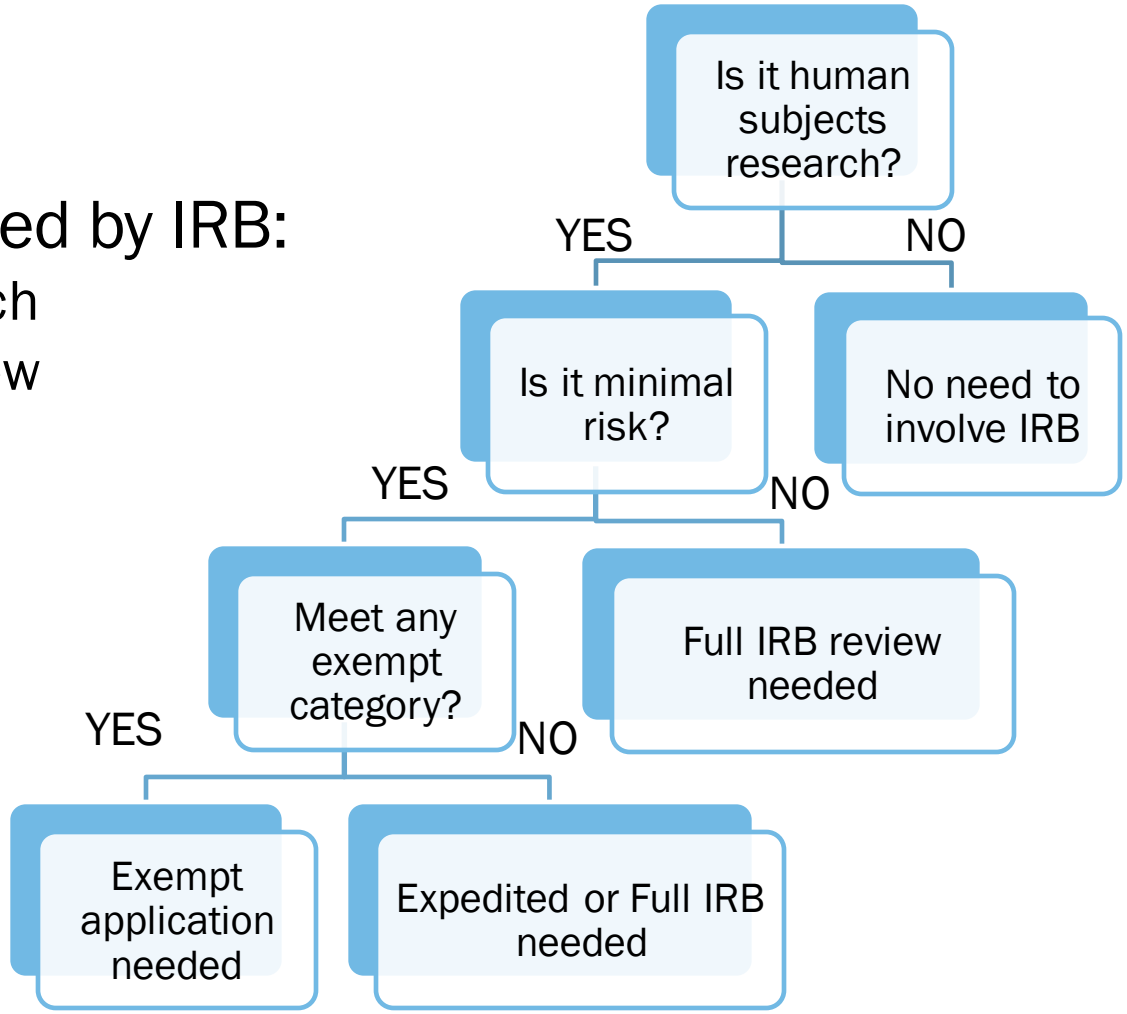
IS IT *HUMAN SUBJECTS* RESEARCH?

- Human subject –"a living individual about whom an investigator (whether professional or student) conducting research:
  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.“

DECISION TREE

3 categories reviewed by IRB:

1. Exempt research
2. Expedited review
3. Full IRB review



EXEMPT RESEARCH: CRITERIA

1. Minimal risk & no protected participants (see part III of exempt form)
2. Meets 1 of following categories (summarized—see form for full details):
    1. Research involving normal educational practices
    2. Research involving educational tests, survey or interview procedures, or observation of public behavior (* additional requirements apply)
    3. Research involving benign behavioral interventions (* additional requirements apply)
    4. Secondary research for which consent is not required
    5. Federal research to study, evaluate, improve, or examine public benefit or service programs
    6. Taste & food quality evaluation & consumer acceptance studies
    7. Storage or maintenance for secondary research for which broad consent is required
    8. Secondary research for which broad consent is required (* additional requirements apply)

EXEMPT RESEARCH: TO APPLY

1. Complete “exempt review form” at: https://its.nmhu.edu/IntranetUploads/006479-NMHU-IRB-Exe-924201925300.pdf
2. Write abstract with:
    1. Purpose(s) of research
    2. What subjects will do (if applicable)
    3. The nature of the data to be obtained
    4. How anonymity or confidentiality will be maintained
    5. Copies of *ALL* questionnaires/instruments/surveys/recruitment materials to be used
3. Submit to IRB Chair (currently Lara Heflin – lheflin@nmhu.edu)

EXPEDITED REVIEW: CRITERIA

- No more than minimal risk to participants
- Does not include protected populations
- Does not involve use of medical, academic, or other personal (e.g., psychiatric) records without consent
- Does not involve tissue obtained at autopsy
- Does not involve Native Americans

EXPEDITED REVIEW: TO APPLY

- Materials needed:
  - IRB application completed (https://its.nmhu.edu/IntranetUploads/005931-NMHUIRB-P-21201944423.pdf)
  - Informed Consent form (template at: https://its.nmhu.edu/includes/onlinedocs/display.html?quicklink=5961)
  - Human subjects training certificate
  - Copies of *ALL* questionnaires/instruments/surveys planned to be used
- Submit to IRB Chair (currently Lara Heflin – lheflin@nmhu.edu)

FULL IRB REVIEW: CRITERIA

- If any of the following apply, *must* apply for Full Committee IRB review:
  - Potentially more than minimal risk
  - Deception involved (unless proactively consented to be deceived!)
  - Protected populations involved
  - Involves use of medical, academic, or other personal (e.g., psychiatric) records without consent
  - Involves tissue obtained at autopsy
  - Involves Native Americans

FULL IRB REVIEW: TO APPLY

- Materials needed:
  - IRB application completed (https://its.nmhu.edu/IntranetUploads/005931-NMHUIRB-P-21201944423.pdf)
  - Informed Consent form (template at: https://its.nmhu.edu/includes/onlinedocs/display.html?quicklink=5961)
  - Human subjects training certificate
  - Copies of *ALL* questionnaires/instruments/surveys planned to be used
- **Submit at least 2 weeks before an IRB meeting** to IRB Chair (currently Lara Heflin – lheflin@nmhu.edu)

SPRING 2023 IRB MEETINGS

- 1st Wednesday of every month
  - Feb 1, 2023
  - March 1, 2023
  - April 5, 2023
  - May 3, 2023

INFORMED CONSENT ELEMENTS (MUST INCLUDE ALL)

- “a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental
- a description of any reasonably foreseeable risks or discomforts to the subject
- a description of any benefits to the subject or to others which may reasonably be expected from the research
- a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
- for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained
- an explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject
- a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled”

From: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#4132

ADDITIONAL INFORMED CONSENT ELEMENTS (IRB CAN REQUEST)

- “a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
- anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent
- any additional costs to the subject that may result from participation in the research
- the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject
- a statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject
- the approximate number of subjects involved in the study”

From: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html#4132

CONTINUING REVIEW

- Required for research that involves more than minimal risk or required Full IRB Review for approval
- Annual basis while research is ongoing
- 1-page form: https://its.nmhu.edu/IntranetUploads/005212-NMHUIRB-C-11142017115147.pdf

Continuing Review Questions

- # of participants enrolled
- Unanticipated problems/risks as a result of research?
- Did you ask any participants to withdraw?
- Did any participants choose to withdraw?
- Complaints about perceived harm or unfairness?
- Changes to potential risks or benefits?
- Any addenda, amendments, modifications?
- Any findings so far?

IRB AMENDMENTS

- Need to make changes to your research after you've received IRB approval?
  - Email IRB Chair (currently Lara Heflin – lheflin@nmhu.edu) describing proposed amendments
  - Include:
    - The original study approval # (e.g., #007-2028)
    - Any new materials, changes to informed consent, etc.
    - As needed, the revised IRB research proposal form with changes highlighted

HUMAN SUBJECTS TRAINING

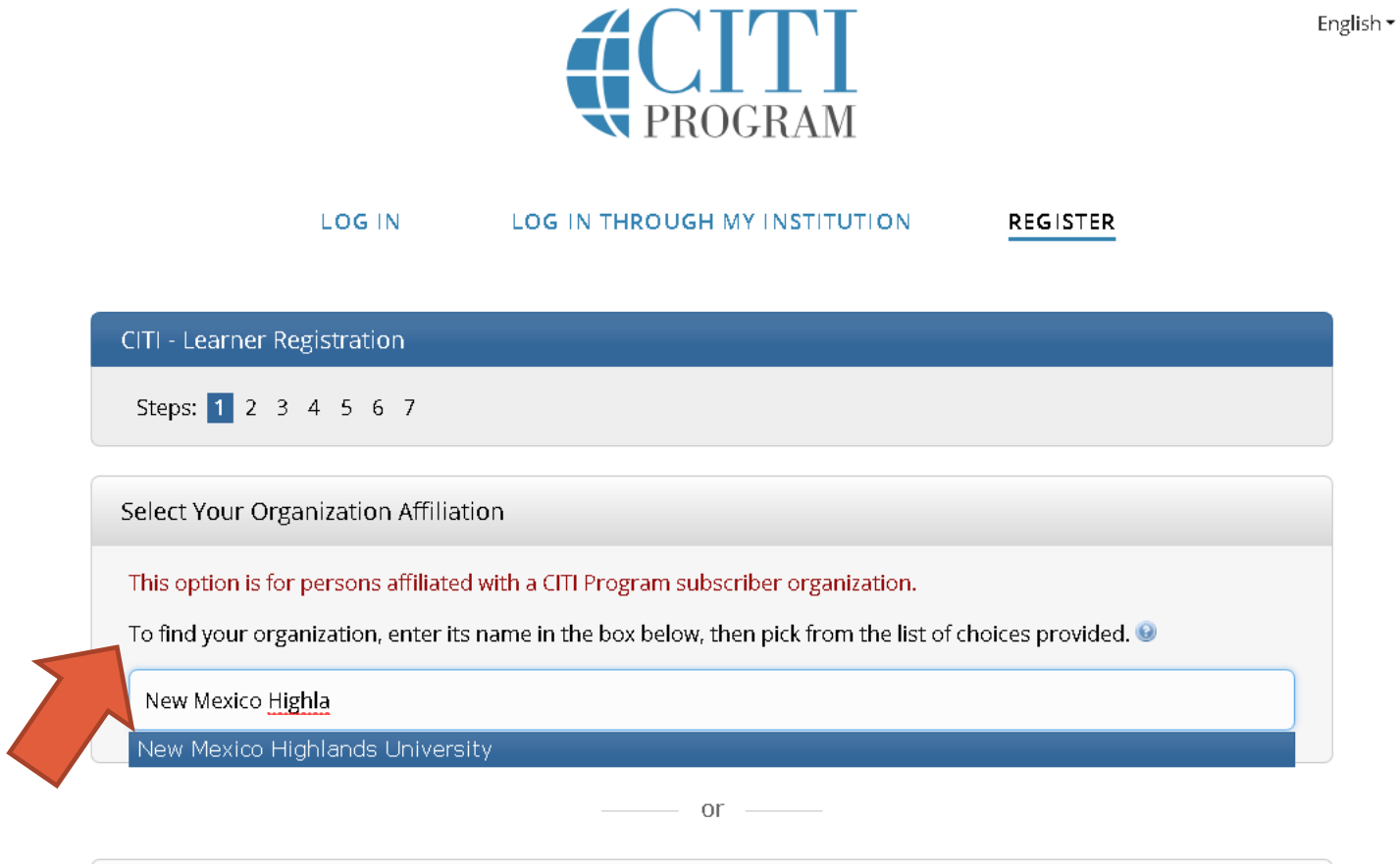
- For Full or Expedited IRB Review, need to include Human Subjects Training Certificate
- NMHU contracts with CITI to provide this training
- Prior IRB Chair David Pan created the following slides to show how to access and complete the training

GO TO
HTTPS://ABOUT.CITIPROGRAM.ORG/EN/HOMEPAGE/

and click on the “Register” button and enter New Mexico Highlands University under Organization Affliation.

Follow the steps to register.

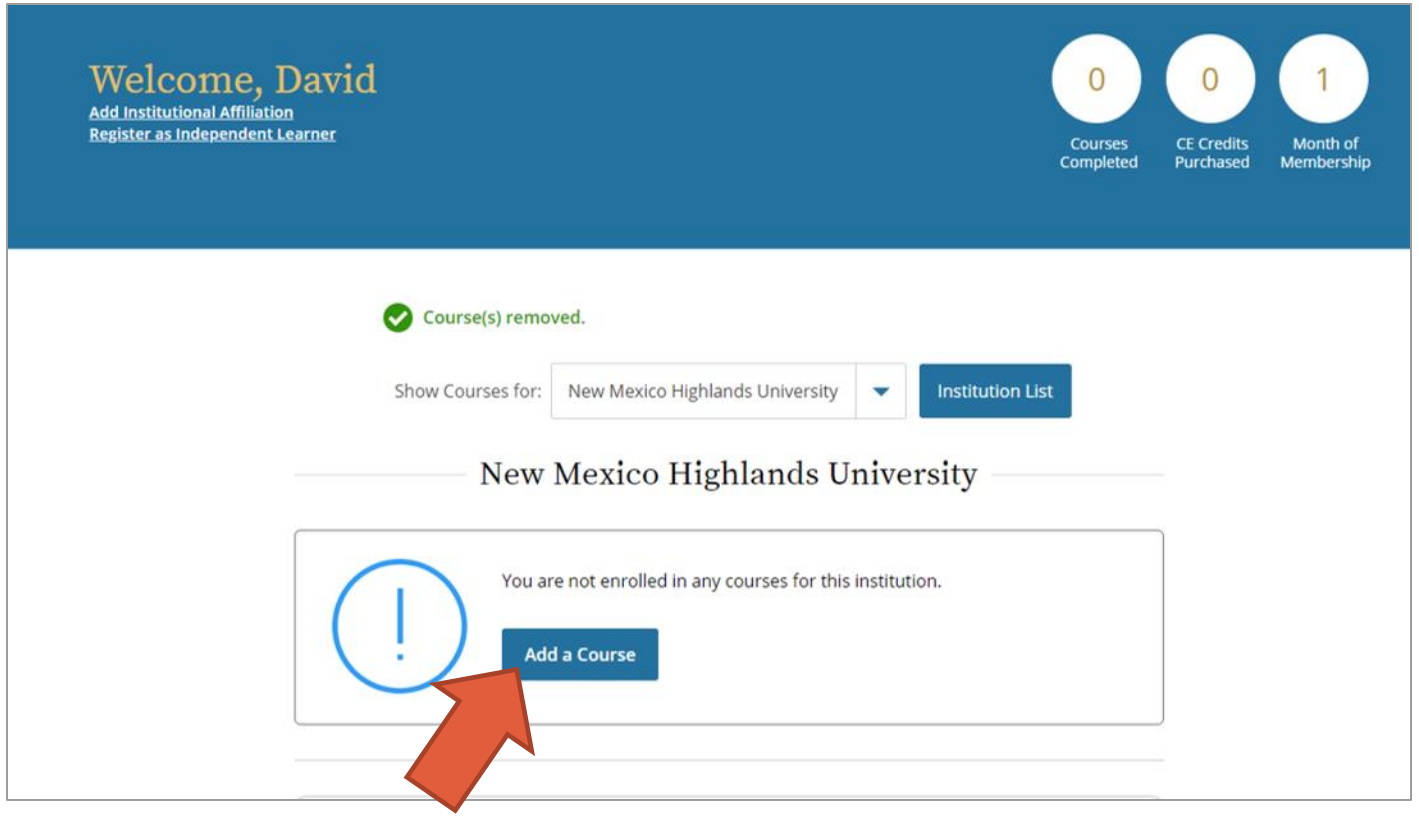
Register using your NM Highlands email address.



Select Curriculum

New Mexico Highlands University

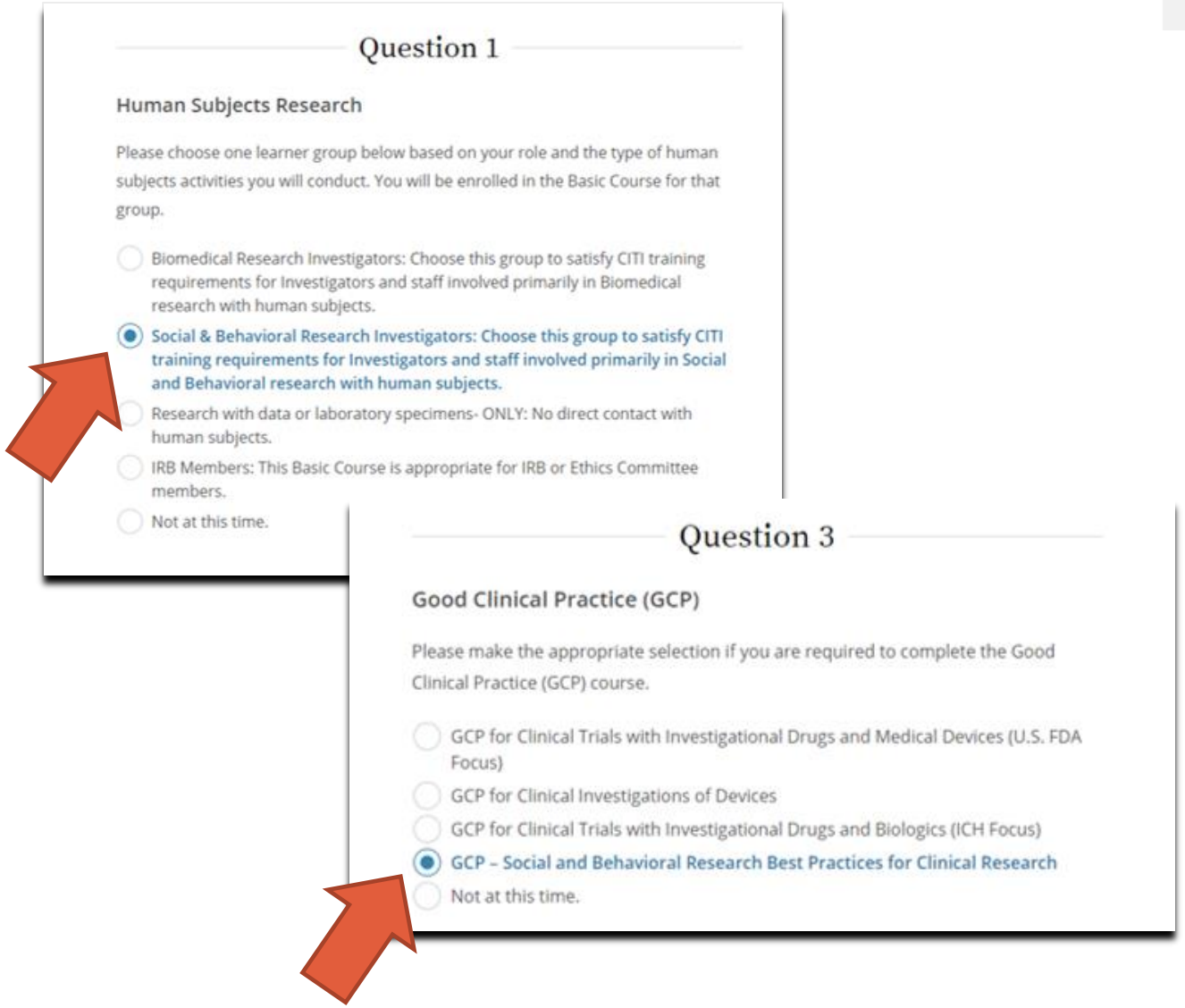
- Once you have a user name and password, login to the front page
- Select “Add a Course”



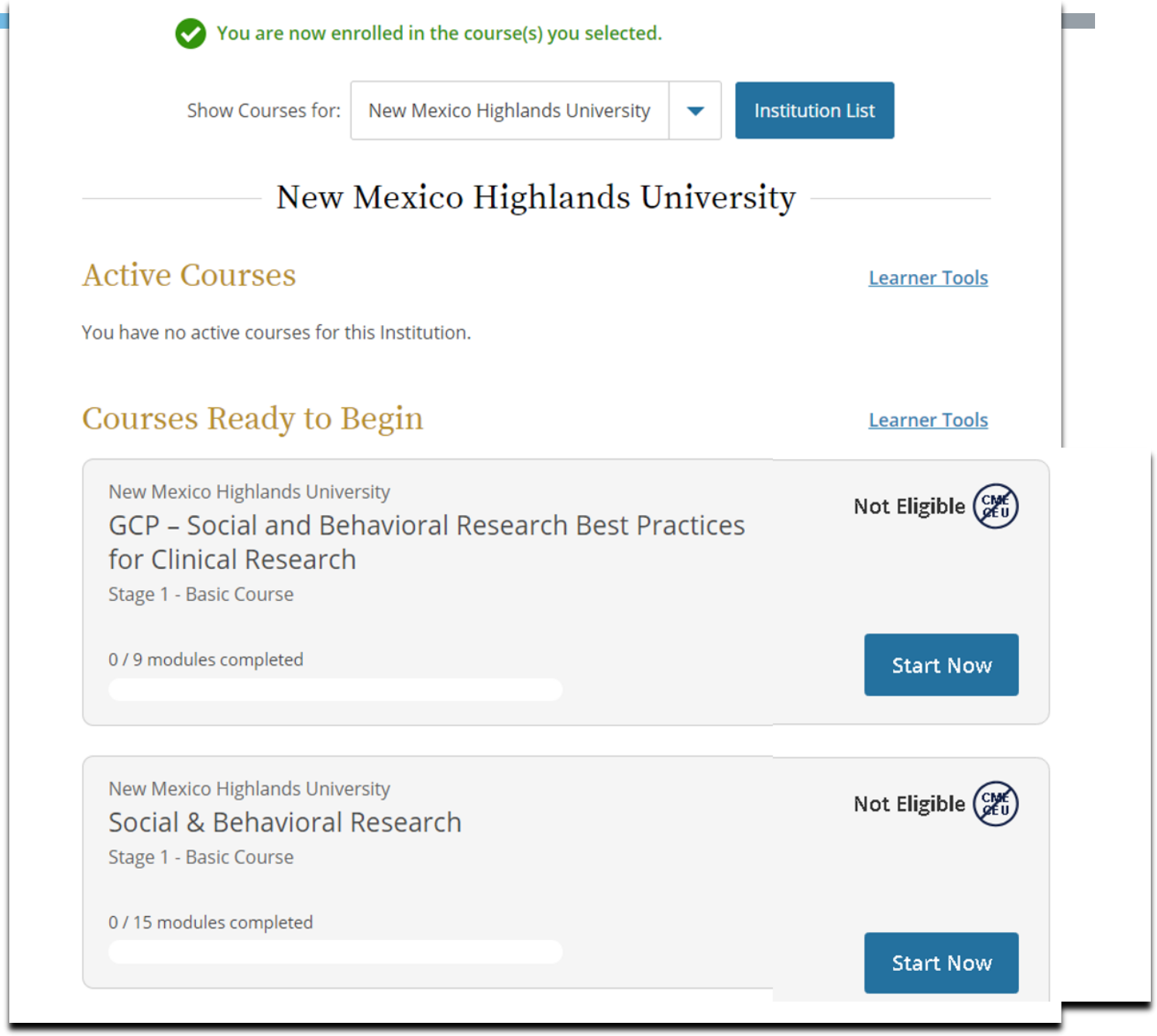
Select Curriculum

New Mexico Highlands University

- You will be directed to answer an opening questionnaire about your training focus/needs.
- This will set up the courses on your profile list.
  - You can add additional courses later if need be.
- For NMHU IRB you MUST select the pictured choices on Questions 1 and 3.



- Once you've selected your courses, you will have access to the modules.
  - *Note that "Not Eligible" means you will not get 'credit' for the course, but you will still get a certificate of completion. These courses are still accessible.*
- Complete the required courses and you can download completion certificates for your records and/or submission to the IRB



NEED HELP?

- If you have issues with CITI, contact customer support:
  - Phone: 888.529.5929

- If you have questions about the IRB or IRB applications, contact IRB Chair, Lara Heflin, PhD
  - Email: lheflin@nmhu.edu
  - Phone: 505.454.3547