

CITI Training

Here is the link that describes the obligatory CITI training and the registration process for the University's ERICA system: <https://irb.utah.edu/training/index.php>

Outside the University of Utah

The person should reach out to the IRB at their institution/organization and ask what they will need to do to receive acknowledgment of an NHR project or for de-identified secondary analysis of data. If the organization doesn't do a formal NHR application, perhaps a memo can be written to be provided to the third-party vendor for the data.

Outside the US

Each country has its own research ethics boards. Just as within the US, the person should reach out to the Ethics Committee (or whatever it is called in that country) at their institution/organization and ask what they will need to do to receive a review or acknowledgment of a project completing secondary analysis of de-identified data. Other countries may not have the category "NHR" but they might have an equivalent.

The University of Utah IRB Application

Once a U of U-affiliated person has an ERICA profile, they can log into erica.research.utah.edu > IRB tab > *Create a New Study Application* > on page 1. Contacts and Title, question #4, select "Request for Non-Human Subject Research Review."

Note: An NHR application should only be requested for de-identified data analysis or analysis of a publicly available dataset.

ERICA Non-Human Subjects Research Application Information

1. Type of Project:

Select all that apply

- Program Evaluation
- Surveillance Activities
- Quality Improvement
- Case Report
- De-identified data/Sample Analysis
- Secondary Analysis of a Publicly Available Dataset
- Other

○ If Other, explain:

2. Number of participants to be enrolled during the entire project:

Provide specific numbers if possible. The use of records and databases containing human information should also be considered in the number of participants.

At Utah:

All Centers:

3. Describe the project objectives and all the procedures that will be conducted for the proposed project (e.g., participant identification, data collection, data analysis, etc.):
4. Will you collect data or specimens specifically for the proposed project through interaction or intervention with living individuals?
 - Yes
 - No
5. Will you collect identifiable, private information about individuals?
 - Individually identifiable, because either the identity of the participant is or may readily be ascertained by the investigator; OR the identity of the participant is or may readily be associated with the information
 - Private because either the information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place; OR the individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record)
 - Yes
 - No
6. Do you plan to publish or present data or findings from this project?
 - Yes
 - No
7. Does the project involve the use of a drug, other than the use of a marketed drug in the course of medical practice?
 - Yes
 - No
8. Does the activity involve the use of a medical device, other than the use of a marketed device in the course of medical practice?
 - Yes
 - No
9. Does the project involve one or more of the following items?
 - Food or dietary supplement that bears a nutrient content or a health claim
 - Food or color additive for human consumption
 - Infant formula
 - Biological product for human use
 - Electronic product for human use
 - Other articles subject to the FD&C Act
 - Yes

- No

10. Will individuals be receiving a test article or acting as a control?

- Yes
- No

11. Will a medical device be used on human tissues to determine the safety or effectiveness of the device?

- Yes
- No

12. Will the data from the project be submitted to, or held for inspection by, the FDA?

- Yes
- No

Notes:

- Section: Study Location and Sponsors
Sponsor: Second Language Teaching and Research Center (L2TReC*)
*The L2TReC is listed under the name "2ND LANGUAGE TEACH & RES CTR"