#11842 - This is the USU IRB's NHSR Determination Template

**Submission Type**  
New

**Status**  
In Progress

### Basic Information

**Principal Investigator**  
Perry, Daniel Leroy

**Department**  
Vice President - Research

**Protocol Title**  
This is the USU IRB's NHSR Determination Template

Please select your anticipated start date for this research, taking care to allow ample time for IRB review.  
March 2, 2021

**Is this research externally funded?**  
This research is funded by the Center for Growth and Opportunity

**Will this project be used, in part or whole, for a thesis or dissertation project?**  
No

**Please indicate what type of review or action you are requesting.** When you make a selection, more information about the type of review will display.  
Non-Human Subjects Research Determination

**Non-Human Subjects Research Determination:** You should make this selection if a) you are uncertain whether your project requires IRB approval, or b) you believe that your project does not require IRB review and you want official documentation from the IRB to that effect. This
is the only way any member of the IRB can tell you whether your project requires IRB review; determinations outside of this system are not permitted.

If this is the correct application type for you, please click the Next button; otherwise please make another selection above.

As you work through this protocol submission, Kuali will autosave your information every 10-20 seconds. **It is very important that you only complete this protocol in one browser/browser tab at a time.** Kuali will autosave the last active version, so if your last active version open is a less complete protocol, you will lose your work. More user documentation regarding Kuali Protocols is available on [Kuali’s website](https://usu-stg.kuali.co/protocols/protocols/603e6160b6dc7e003306cb71/print), as well as the [USU IRB](https://usu-stg.kuali.co/protocols/protocols/603e6160b6dc7e003306cb71/print).

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### Study Personnel

#### USU Personnel

Please enter all of your USU study personnel to the list below by clicking "Add Info" or "Add a Line." You may double check that they have completed CITI training [at this link](https://usu-stg.kuali.co/protocols/protocols/603e6160b6dc7e003306cb71/print); unless this is a Non-Human Subjects Research Determination, please do not submit your protocol until all staff are CITI trained.

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**You only need to add personnel who will serve as an investigator on this project.** An **investigator** is an individual who interacts with or intervenes with living people for research purposes; obtains, studies, interprets, or analyzes identifiable private information; obtains informed consent; or interacts with the IRB relating to this study. Individuals assisting with the analysis of de-identified data, for example, would not be investigators under this definition.

#### Name

Perry, Daniel Leroy

#### Role

Principal Investigator

#### System Role

Admin

Full Access
Project Details

This short form will assist the IRB in determining whether your project requires some substantive level of IRB review, or whether it falls outside of the regulations governing human subjects research.

Complete each of the fields below, providing as much detail as you can.

Our office will review this form and return an official determination to you regarding whether this project requires further IRB review. This process is typically complete in 1-2 days.

Please provide a brief summary of the project. Address each of the following:

1. Describe the purpose of the project (e.g. program evaluation, quality improvement, improving educational outcomes in your course, completing a dissertation)
2. Describe the intended audience or outputs for the project (e.g. publication in a peer reviewed journal, presentation at an academic conference, on campus symposia, report to funding sponsor, other researchers and professionals in your field)
3. Describe the sources of the data, information, or specimens.

If applicable, supply URLs, names of datasets, etc.

Research

The first assessment an IRB makes regarding a project is whether it constitutes "research" under the definition provided in 45 CFR 46. Not everything we call research in a university setting is the type of research that requires IRB review.

Research that requires IRB oversight is defined as a systematic investigation, including research development, testing and
evaluation, designed to develop or contribute to generalizable knowledge. The following questions will help determine whether the project described in this submission meets that definition.

If you already know that your project meets the definition of "research" and your only question is whether your project involves a human subject, you can skip this section by selecting "My project meets the definition of research" below. Our office will assume the project meets the definition of "research" and will only assess whether it involves a "human subject." We encourage you to not to skip this section, as these determinations are specific to the human subjects research context and are not always particularly clear.

Describe your study design, or the manner in which you are planning to complete this project. The IRB is looking for whether the project is a "systematic investigation." Hover over the question mark to learn more about the criteria that factor into this assessment.

Please explain whether your project will yield results that hold across contexts and/or populations. The IRB uses this information to determine whether the project has the ability to contribute to "generalizable knowledge." Hover over the question mark to learn more about the criteria that factor into this assessment.

What outcomes or outputs are likely to be produced as a result of this project?

Human Subjects

The second assessment an IRB makes regarding whether a project is subject to its oversight is whether the project involves a human subject. A human subject is defined as a living...
individual about whom an investigator conducting research obtains: 1) data or specimens through intervention or interaction with the individual; or 2) identifiable private information. The following questions will help determine whether the project described in this submission includes "human subjects."

If your only question is whether your project involves "research," (as defined in the section above) you may skip this section by selecting "My project involves a human subject" below.

Our office will assume the project involves a "human subject" and will instead focus on whether the project is "research" as defined in the federal regulations. We encourage you to answer all questions, as these determinations are specific to the human subjects research context and are not always particularly clear.

I am uncertain about whether a "human subject" is involved in this project

Will researchers in this project gather data about living individuals through interaction OR intervention?
I am uncertain

Please explain what circumstances or specifics make you uncertain.

Will researchers gather or obtain information about living individuals that is private?
I am uncertain

Please explain the circumstances that make you uncertain regarding whether the information or data is private.

Will the researchers obtain information about or biospecimens originating from living individuals that is/are identifiable?
I am uncertain

Please explain what circumstances make you uncertain regarding whether the biospecimens or information is identifiable. Provide links or other information as applicable.

Submit your NHSR Request
If you have any information which would assist the IRB in making a determination about your project, please upload that information here.

Is there anything else you'd like us to consider or be aware of as we process this Non-Human Subjects Research Determination Request? If so, please provide that information here.