**Not Human Subject Research (NHSR):**

**How to Submit a Request for a NHSR Determination for a New Project &**

**How to Submit a Request for a Modification to an Existing NHSR Project**

**How to Submit a Request for an NHSR determination for a NEW project:**

1. **Go to** [**www.irbnet.org**](http://www.irbnet.org) **and log into your IRBNet account.**
2. **Select “Create a New Project” for the submission. Upload the following documents:**
3. **A memo (signed by the principal investigator) that includes:**
4. An explanation that the project is being submitted for an NHSR determination;
5. A brief description of the project (purpose, procedures, etc.). Note: If the project is being conducted solely for internal process‐improvement purposes and/or quality‐improvement purposes, or if the project involves a program evaluation (rather than research), please include information about this topic in the memo.
6. **Other relevant documents (below), if applicable to the project:**
7. Determination and/or approval letters from outside institutions and/or IRBs that are associated with the project (e.g., an NHSR determination letter from another IRB).
8. Grant applications, award letters, and/or executed contracts/agreements (if any) that are associated with the project (e.g., material transfer agreements, etc.)
9. If the project involves analysis of data that were originally collected for:

a) *non-research* purposes, submit a copy of the data collection sheet that includes the list of variables that will be analyzed for the study. Note: The dataset must be considered de-identified (no personal or HIPAA identifiers).

b) *research* purposes AND the research data have been de-identified, you now want to analyze the de-identified data, and you have no way to track the data to an individual person because no identifiers are linked, then:

1. Describe (in the memo) that this is the case;
2. Submit a copy of the data collection sheet that includes the list of variables that will be analyzed for the study; and
3. Submit an attestation (e.g., copy of an email) from the appropriate authority, confirming that you will be receiving only de-identified data for the purpose of this project.
4. If the project involves publicly available data: provide evidence that the data are publicly available (e.g., website link). Note that the evidence submitted should indicate that the data are de-identified (no personal or HIPAA identifiers).
5. If the project involves programmatic/quality improvement derived surveys and/or interviews: submit the survey/interview questions that were (or will be) used OR provide a general description (in the memo) of the types of survey/interview questions that were (or will be) used.
6. If the project involves use of cell lines and related data, submit:
7. A copy of any consent forms (clinical or research) that were used to consent the people whose cells and personal information the investigator will be obtaining.
8. If the cells/information will be from subjects who consented to participate through another research project, submit a copy of the IRB approval letter and the IRB-approved version of the protocol that are associated with the project.
9. If the cells/information were commercially purchased, please state this in the memo, and provide, if available, evidence that the cells/information were legally/ethically obtained, and are considered de-identified (e.g., an email from the appropriate officials, website link to the selling organization/bank, etc.).
10. *For HSC investigators:* Documentation from HSC’s Office of Sponsored Programs (OSP) (such as a copy of email communication from a member of the OSP team), clarifying whether any contracts/research agreements are needed for this project (e.g., memorandum of understanding, data use agreement, etc.). If contracts/agreements are needed, please also submit a copy of the executed contracts/agreements.
11. **Submit the package in IRBNet.**

**Please note that the following documents are NOT required for NHSR submissions**: a Wizard/New Project application form, a protocol synopsis, evidence of training in human subject research (such as CITI) for key personnel, or conflict of interest forms for key personnel.

**Should you have any questions regarding whether or not your project may qualify for a NHSR determination please seek NTR IRB guidance by setting up an initial consult (use the** [**initial consult form**](https://www.unthsc.edu/north-texas-regional-irb/request-a-consultation/)**). For additional assistance, please contact the NTR IRB at** **NorthTexRegIRB@unthsc.edu****, or 817-735-0409.**

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**How to Submit a Request for a MODIFICATION to an Existing NHSR project:**

Because a change to a project may alter a determination, researchers should seek NTR IRB review of any substantive, or major changes to a NHSR project. To do so, please:

1. **Go to** [**www.irbnet.org**](http://www.irbnet.org)**, log into your IRBNet account, and access the project that you want to modify.**
2. **Select “Create a New Package” for the submission in IRBNet.**
3. **Upload the following documents:**
4. A memo (signed by the principal investigator), describing the proposed modifications to the project.
5. Any other documentation that is associated with the proposed modifications (e.g., new data collection sheet, etc.)
6. **Submit the package in IRBNet.**