NEW FORM & PROCESS for Submitting a Not Human Subjects Research Project

If you are unsure that your project fits this category OR

If you need IRB documentation for a project that definitely fits this category
Common Examples of Non Human Subjects Research

- Demonstration Projects
- Instrument construction
- Development of non-FDA regulated devices
- Grant-only Submission
- Program Evaluation/Quality Assurance Review/Quality Improvement Project
- Case Report
- Course-Related Activity
- Journalistic or Documentary Activity (including Oral History)
- Research Using Public or Non-Identifiable Private Information about Living Individuals

- Other projects that do not meet the Federal definition of Human Subjects Research (see Human Research Determination Form HRP-503 for details)
Use **NEW FORM** Human Research Determination Form (HRP-503) to decide if your project falls into this category

- **Review**
  - Section 1: Definitions
  - Section 2: Examples of projects that are not considered Human Subjects Research

- **Complete**
  - Section 3: Description of Activity
    - Include enough detail so the IRB Office can make a determination
    - Refer to HRP-310 WORKSHEET Human Research Determination to review what the IRB Office will be looking for

Submit in eIRB+ *(please do not email the form to the IRB)*
Log into eIRB+ and Select “Create New Study” from your Inbox
Basic Information

1. **Title of study:**
   Not Human Subjects Research Demo

2. **Short title:**
   NHSR Demo

3. **Brief description:**
   This is not a real study, but if it were, it wouldn't be human subjects research.

4. **Which selection best describes your study?**
   - Social Behavioral
   - Biomedical
   - Clear

5. **Principal investigator:**
   Suzanne Sokalski

6. **Does the Principal Investigator have any significant financial interests related to this research?**
   - Yes
   - No

7. **Will an external IRB act as the IRB of record for this study?**
   - Yes
   - No

8. **Attach the protocol:** (Include the investigator protocol and full sponsor protocol)
   - Document:
     \- hrp-503-human-research-determination-form.docx (0.01)
   - Category: IRB Protocol
   - Date Modified: 3/26/2015

Protocol templates can be found at the following link:

- [http://irb.northwestern.edu/templates-forms-sops](http://irb.northwestern.edu/templates-forms-sops)

Upload your completed Human Research Determination Form in place of a protocol.
Complete the rest of the application
• Sections that do not apply can be skipped unless noted with a red asterisk (*)

Complete the RSS
• Sections that do not apply can be skipped unless noted with a red asterisk (*)

Submit the project in eIRB+

The NU IRB Office will review your submission according to the requirements found in HRP-310 WORKSHEET Human Research Determination
If your submission meets the requirements found in HRP-310 WORKSHEET Human Research Determination, you will receive an email notification of the IRB’s Not Human Research Determination.

Notification of Not Human Research Determination

To: Suzanne Sokalski
Link: NHSR Demo
P.I.: Suzanne Sokalski
Title: NHSR Demo
Description: The committee reviewed this submission and assigned a determination of Not Human Research. For additional details, click on the link above to access the project workspace.
The formal IRB determination letter can be downloaded from the main study page in eIRB+.
Provide your determination letter in response to requests for IRB documentation

NOT HUMAN RESEARCH

March 26, 2015
Suzanne Sokalski
750 N. Lake Shore Dr
Robieff 5th Floor
Chicago, IL 60611
312-503-3259
suzanne.sokalski@northwestern.edu

Dear Suzanne Sokalski:

On 3/26/15, the IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Determination Date</th>
<th>Title of Study</th>
<th>Investigator</th>
<th>Funding Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>3/26/2015</td>
<td>Not Human Subjects Research Demo</td>
<td>Suzanne Sokalski</td>
<td>Name: Northwestern University</td>
</tr>
</tbody>
</table>

Documents Reviewed:
- irp-503-human-research-determination-form.docx
  Category: IRB Protocol

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

This determination applies only to the activities described in the eIRB+ submission and does not apply should any changes be made. If changes are being considered and there are questions about whether IRB review is needed, please contact the IRB Office to discuss those changes. You may be asked to submit a new study in eIRB+ for a determination.

This determination does not constitute nor guarantee institutional approval and/or support. Investigators and study team members must comply with all applicable federal, state, and local laws, as well as NU Policies and Procedures, which may include obtaining approval for your research activities from other individuals or entities.

Sincerely,

Heather Gipson
Eileen Yates