Do I Need to Submit an IRB Application?

In accordance with federal regulations, research projects involving human subjects require Institutional Review Board (IRB) approval or determination of exemption prior to implementation. However, some activities that involve people (including their data or specimens) do not meet the federal definition of *human subjects research*, and do not require IRB review. When review is not required, investigators do not need to submit an IRB application. The purpose of this self-test is to help investigators determine whether or not IRB review is required for their projects.

These are complex determinations in some cases. Examples of projects that generally do and do not require review are found at the end of this form. ORR staff is available to provide additional guidance to researchers who have questions or are unsure.

Please note that these determinations are *not* related to the characteristics of project participants (e.g., vulnerable populations) or nature of project procedures. For example, a project that does not meet the definition of research or include human subjects does not require IRB review, even if vulnerable populations are included.
### Self Test

**Step 1: Is the project research?**

<table>
<thead>
<tr>
<th>A. Does the project:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>• involve the use of a drug on humans, other than the use of a marketed drug in the course of medical practice?</td>
<td></td>
<td></td>
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<tr>
<td>• involve the use of a medical device on humans or human specimens to evaluate safety or effectiveness of that device?</td>
<td></td>
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<tr>
<td>• involve a <em>clinical study</em> of a food product, food additive, biologic, dietary supplement, or medical device, that includes the consumption by humans of any kind of food product or dietary supplements or use of a medical device on humans?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If any of the responses are “yes,” STOP! IRB review is required.
If all responses are “no,” proceed to Part B.
If any are “unsure,” contact the IRB, IRB@iastate.edu, 294-4566.

<table>
<thead>
<tr>
<th>B. Does/is the project:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>• involve a <em>systematic investigation</em> (i.e., follows a predetermined plan that incorporates data collection, either quantitative or qualitative, to answer a research question, test hypotheses, develop theory, etc.)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• <em>designed</em> to develop or contribute to <em>generalizable knowledge</em> (i.e., is the purpose or intent of the project to test or develop scientific theories or hypotheses; or to draw conclusions that are intended to be applicable to populations or situations beyond that being studied)?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Note:** If there is no intent to disseminate the results (or reasonable expectation that the results will be disseminated) beyond those involved in the project (e.g., beyond the course instructor or POS committee, project participants, the company/organization/client who requested the project, etc.), the project is not designed to contribute to generalizable knowledge.

If the response to either or both is “no,” STOP! IRB review is not required.
If the response to both items is “yes,” proceed to Step 2.
If any are “unsure,” contact the IRB, IRB@iastate.edu, 294-4566 or 294-4215 or 294-1329.
### Step 2: Does the research include *human subjects*?

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the information being obtained <em>about</em> specific living individuals (i.e., about their behaviors, attitudes, opinions, personal characteristics, demographics, biological specimens, physical or physiological responses, etc.)?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

If “no,” STOP! IRB review is not required.
If “yes,” proceed to the next question.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the data obtained through <em>interaction</em> or <em>intervention</em> with individuals?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Interaction**—communication or interpersonal contact between researchers and subjects (e.g., survey or interview procedures, participant observation, etc.). Online surveys, even if anonymous, involve interaction.

**Intervention**—physical procedures or manipulations of the subject or his/her environment (e.g., taking blood samples, exercise trials, food or supplement consumption, use of devices, completion of cognitive tasks, etc.).

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the data include information that is both <em>identifiable</em> and <em>private</em>?</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

**Identifiable**—the identity of the individuals to which the data pertain can be readily ascertained by the investigator or others, *directly or indirectly through the use of codes or a combination of data elements*.

**Private**—information about behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place (e.g., in one’s home, an exam room, a public restroom, etc.); OR, has been provided for specific purposes with a reasonable expectation that it will not be made public (e.g., data from student or medical records, employee files, etc.).

If all responses are “no,” IRB review is not required.
If any of the responses are “yes,” IRB review is required.

*If any are “unsure,” contact the IRB, IRB@iastate.edu, 294-4566 or 294-4215 or 294-1329.*
A Note about Publication:

The intent to publish or otherwise disseminate study results (i.e., presentation at academic conferences, technical reports, white papers, etc.) does not necessarily mean a project meets the federal definition of research. Results of non-research activities (e.g., program evaluations, case reports, etc.) are regularly published or disseminated for a variety of purposes. The important factor is whether a project is designed to develop or contribute to generalizable knowledge. For example, a program evaluation may serendipitously discover knowledge that is widely applicable, even though it was designed solely to examine the effectiveness of a specific program. **Such a program evaluation would not have required IRB review, but can still be published.**

A Note about Class Projects:

Iowa State University recognizes that some student projects conducted to fulfill course requirements involve activities (e.g., data collection procedures) that, in a different context, might be viewed as research. As a general rule, when those activities are conducted solely to fulfill a course requirement, an element of the federal definition of research—the intent to develop or contribute to generalizable knowledge—is lacking. Iowa State University considers classroom assignments involving research activities to be educational in nature and not subject to IRB review when the results of the classroom assignment, including audio/video recordings, photographs, etc., are only used and shared as follows:

1. In the classroom or with the course instructor or POS committee; and/or,

2. If the project involves gathering data from or about a company, agency, or organization, the data/results are shared only with that company, agency, or organization; and/or

3. Project results are presented at departmental or interdepartmental seminars designed to exhibit coursework or to continue the learning process related to presentations (including Honors Program poster presentations, Undergraduate Research and Create Expression seminars, Honors presentations at the State Capitol).

Examples of activities that generally require IRB review:

- Research studies that collect data about human subjects through interaction or intervention with subjects, such as surveys (paper, online, telephone, etc.), interviews, focus groups, cognitive testing, usability studies, studies of food or supplement consumption or physical activities, tests of the efficacy of educational interventions, etc.
- Research studies that include test subjects or their specimens to examine devices, products, food, drugs, etc.
- Unobtrusive observation of private behavior for research purposes.
- Use of identifiable data from medical records, student records, employment records, or other private sources.
- Use of identifiable biological specimens.
- Use of an existing dataset that includes identifiable information.
- Research conducted for Master’s Theses or Doctoral Dissertations that meets the definition of human subjects research (see [IRB Oversight of Student Projects Involving Human Participants](#) for more information).

### Examples of activities that generally do NOT require IRB review:

- Data collected for internal departmental or administrative purposes, such as teaching evaluations, student performance data, etc.
- Studies designed solely for quality improvement or evaluation of a particular program, unit, course, activity, etc. (e.g., customer service surveys, needs assessments, course assessments designed to improve the delivery of a particular course or the teaching skills of a particular instructor, etc.).
- Observational studies of public behavior (including television and open internet chat rooms, blogs, etc.) when there is no interaction or intervention with subjects.
- Use of publicly available information (newspapers, blogs, existing literature, etc.) or datasets (e.g., census data, labor statistics, school enrollment data, etc.).
- Use of existing data when:
  - Data were collected for purposes other than the proposed project; and
  - Data are provided to the investigator without any identifiers. Identifiers include such things as ID codes that can be linked back to participants, names, addresses/email addresses, phone numbers, exact dates of birth, SSN, photographs, etc.
- Communication with persons to obtain factual information about things, products, policies, organizations, etc. (e.g., interviews with school officials to obtain information about policies, surveys of company presidents about the products they provide, etc.).
- Oral histories or biographies (unless data will also be used to contribute to generalizable knowledge).
- Training activities, unless the training activity is conducted for research purposes.

### Document History

**Created:** 8.4.2011  
**Revised:** 10.3.2017