

## IOWA STATE UNIVERSITY Institutional Review Board

### Research Requiring IRB Review

The ISU Institutional Review Board (IRB) is a committee established to protect the rights and welfare of human research participants involved in research activities as prescribed by federal regulations. The IRB must ensure compliance with regulations of both the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA).

At ISU, the IRB must review and approve all research involving live humans before any such research activities may begin. In addition, only the IRB can determine if a project is exempt from the requirements of the federal human subject regulations.

Federal regulations define research involving human subjects as follows:

#### **DHHS Definition of Research** (from 45 CFR 46.102)

“A *systematic* investigation, including research development, testing and evaluation, *designed to* develop or contribute to *generalizable* knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>

Important in this definition are the words “designed to contribute to generalizable knowledge.” A study must be systematic and *designed* to contribute to generalizable or transferable knowledge in order to be considered research that must meet the requirements of the human subject regulations. Although publication is often viewed as evidence of research status, it is not the only criterion. In fact, “systematic investigations” often result in published studies, yet they do not qualify as research because they were not designed to contribute to generalizable knowledge. In general, activities that contribute to generalizable knowledge are those that

- attempt to make comparisons or draw conclusions from the gathered data;
- attempt to reach for generalizable principles of historical or social development;
- seek underlying principles or laws of nature that have predictive value and can be applied to other circumstances for the purpose of controlling outcomes;
- create general explanations about all that has happened in the past; or
- predict the future.

Generalizable knowledge is not limited to quantitative studies designed to produce generalizations. Qualitative studies may also contribute to generalizable knowledge through the use of focus groups, case studies, ethnographies, interviews, or other means to identify general themes that the reader can choose to transfer to another situation.

## Clarification of the DHHS Definition of Research

In the Office of Research Integrity publication, the *ORI Introduction to the Responsible Conduct of Research*, author Nicholas Steneck offers clarification of the DHHS definition of research cited above. He says, “This means that a project or study is research if it

- is conducted with the intention of drawing conclusions that have some general applicability and
- uses a commonly accepted scientific method.

The random collection of information about individuals that has no general applicability is not research.”

## FDA Definition of Research (from 21 CFR 50.3(c))

“Any experiment that involves a test article and one or more human subjects that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(i), or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit.” The term does not include experiments that are subject to the provision of 21 CFR 58, regarding nonclinical laboratory studies.

Under FDA regulations, the terms “research” and “clinical investigation” are synonymous. A test article means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug and Cosmetic Act (21 CFR 50.3(j)).

FDA regulations generally require IRB review and approval of research involving FDA-regulated products (e.g., investigational drugs, biological products, medical devices and dietary supplements) (21 CFR Part 56).