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Cornell University
Office of Research Integrity and Assurance

Human Participant Research Newsletter

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The Human Participant Research Newsletter is a publication of the Office of Research Integrity and Assurance (ORIA). This publication is intended to provide information on ethical standards and expectations, regulatory compliance, and other practical matters related to the Human Research Protection Program. Recipients are encouraged to share the Human Participant Research Newsletter with colleagues, students, staff and others in the research community at Cornell University.

In This Issue

Exemptions from IRB Review

At Cornell University, there are three general means by which human participant research can receive approval: after full committee review by the Institutional Review Board for Human Participants (IRB), after expedited review by a designated member of the IRB, or via a determination of exemption by the Office of Research Integrity and Assurance (ORIA).

It has come to ORIA's attention that some investigators may be unfamiliar with the fact that research projects may be deemed exempt from IRB review in certain circumstances, and this article is intended to help inform faculty, students, and staff about the exemption process.

It is important to note that, under university policy, investigators cannot determine that their research projects are exempt from regulations. Investigators must submit an Initial Approval Request form to ORIA and receive written notice of exemption before they begin their research activities.

An exemption is a formal determination that a proposed research project fits within one of six predefined categories of exemption

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ORIA Office Moving

On August 7th, ORIA moved from 35 Thornwood Drive to the new East Hill Office Building just north of East Hill Plaza. Our new address is

395 East Hill Plaza
Suite 320
Ithaca, NY 14850

All IRB-related materials (new applicaitons, amendments, etc.) should be sent to the new address. Materials can still be sent via campus mail, and all other IRB and ORIA contact infomation will remain the same. ■

Exemptions

described in federal regulations (45 CFR 46.101) and adopted by the Cornell University IRB. Information on the exemption categories as specified under the federal regulations can be found on the IRB web site (www.irb.cornell.edu) under the "Submission Requirements & Meeting Schedule" link.

When a protocol application that seeks to include human participants in research is submitted, ORIA makes an initial evaluation of the protocol. Protocols that meet the exemption criteria are determined to be of less than minimal risk to potential research participants and, thus, are not sent to the IRB for review.

Instead, the principal investigator will receive a written Notice of Exemption Classification from ORIA. This notice includes information on an investigator's responsibilities in conducting the research protocol. Primarily these responsibilities consist of ensuring the welfare of research participants, and notifying ORIA of any changes that are planned for the protocol (such as adding a new survey or questionnaire) before those changes are implemented so ORIA can be sure the risk profile of the study has not been altered. ■

But I'm Not Doing *Research*: Program Evaluations and Other Activities That May also Be Research

Under its Federalwide Assurance – the document that specifies the university's commitment to ethical standards and federal regulations regarding research with human participants – Cornell has committed to having all such research reviewed and approved by the IRB, or be deemed exempt from IRB review by ORIA, regardless of the funding source.[1] While this commitment is straightforward enough, it is important to note that it also applies to activities that meet the regulatory definition of research with human participants, whether or not they are conducted or supported under a program that is considered research for other purposes.

More specifically, a number of activities that typically may not be considered research actually may have smaller components which meet the definition of research with human participants. For example, some demonstration and service programs may include surveys or questionnaires, which might be covered by the regulatory definition of "research." In such instances, the components of those activities are required to have IRB review and approval or be deemed exempt by ORIA.

Program evaluations and other activities

Program evaluations, often in the form of surveys or questionnaires, are among the more common components that may bring an activity across the "research" threshold. Program evaluations are rather common at Cornell University and its affiliated educational, outreach, and service programs, and their value in assessing a program or initiative's effectiveness is

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[1] This also includes all unfunded research activities.

easily recognized. Frequently, though, they are also used to collect data that is used for research purposes, and in such instances may constitute research that involves human participants.

The difficulty, of course, is distinguishing when components such as surveys or questionnaires used in activities like service or educational outreach programs begin to drift into the territory of what requires submitting a human participant protocol to ORIA. It is worth noting, though, that the federal regulations specifically list activities such as service programs and program evaluations as ones that may constitute research with human participants.

So, how can I tell if it's research?

There are two general criteria for determining when an activity is considered research with human participants:

- an activity is considered to involve *human participants* when information about living individuals is being collected through intervention, interaction, or observation, *or* identifiable private information is being used; and
- an activity is considered to be *research* when it involves the systematic collection of information that will be used to develop or contribute to generalizable knowledge.

However, at times it may be difficult to determine when human participants are specifically involved in the research and/or when information is being used for "geralizable knowledge."

When are human participants involved?

When trying to determine whether or not a survey, questionnaire or similar instrument involves human participants, it is important to consider what types of questions are being asked. For instance, if an evaluation of Cooperative Extension services in agriculture were to ask questions that focus exclusively on the farming activities – How much corn did your farm produce the year before the associate starting providing services? How much corn did your farm produce for each of the three years after the agent provided services? What services were provided? [with a menu of answers] – then that evaluation may not include "human participants" in the regulatory sense. Likewise if a labor relations project were to focus on business characteristics – How many employees are in your business? How many employee complaints were there the year before program services started? How many have there been per year after services began? That is, evaluations, surveys, etc., that focus exclusively on institutional or business characteristics, and/or the effects of program involvement on some feature of those characteristics, might not include any research involving human subjects.

However, if a similar evaluation (or survey, questionnaire, or the like) were to include any questions that dealt with people's knowledge, opinions, ability to maintain a service program's routine, etc., then that evaluation would meet the criteria of including human participants.

What makes something generalizable knowledge?

The phrase "generalizable knowledge" can be trickier to understand because of how broadly it appears to apply. That is, generalizable knowledge is generally defined

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as information that is disseminated through publication or presentation, or used toward the completion of any undergraduate or graduate thesis or dissertation. However, the phrase also includes disseminating information through websites, newsletters, brochures, and other similar types of media, depending upon the nature of how the collected information is used.

Quite often, the intent to publish or present information is a helpful indicator of whether an activity meets the definition of research, but it is not always completely reliable. That is to say, some projects may operate in a gray area of the university's policy and the federal regulations. For instance, intending to broadly advertise a program or service, but only including a statement such as "hundreds of positive responses to our service," does not make the activity research simply because that information will be published in a brochure, newsletter, or website.

On the other hand, if the aggregation of data from a number of surveys used for program evaluations would strengthen the reliability of the data, then use of that data to publish or present the aggregated results would meet the generalizable knowledge definition. Thus, as a general (though perhaps occasionally fluid) rule, ORIA would consider published or presented information research if it was collected systematically and it included elements of analysis of or made conclusions from that information.

Further questions?
As always, ORIA encourages investigators and research personnel to consult the decision tree (on the IRB website at www.irb.cornell.edu) and/or contact Matthew Aldridge (ma354@cornell.edu) or Sarah Demo (irbhp@cornell.edu) for additional clarification and assistance. ■

Research for Course Instruction Purposes

As described in the previous *Human Participant Research Newsletter*, students who are conducting research as a course assignment may not need to submit an individual approval application to ORIA, provided they will not use the data they collect for publications, presentations, or an undergraduate or graduate thesis or dissertation. All instructors planning courses which will include research activities that involve human participants, however, should note the important requirements for which they are responsible.

First, course instructors will need to complete and submit a "Research as Class Instruction" form (available on the IRB website) and include a copy of the course syllabus and detailed assignment information.

Second, after receiving the written approval notice – which specifies that any data collected may only be used for course purposes – instructors must also distribute a copy of the approval to students enrolled in the course. And last, because approvals are only valid for one semester, instructors will need to submit a new application for any subsequent semester the course is being offered. ■