Is it Research: What is "Contributing to Generalizable Knowledge?"

This document provides information regarding the federal definition of research and what it means to "contribute to generalizable knowledge" and complete a "systematic investigation." This document should help clarify many issues regarding research and assessment, evaluation, class projects, pilot work, feasibility studies, presentations, and dissemination of data and findings. An activity may be research, but may not meet the criteria for regulated research as defined by the federal regulations governing research with human subjects (45 CFR 46 - opens in a new window)

The federal regulations governing research with human subjects defines research as "a *systematic investigation*, including research development, testing, and evaluation, *designed to develop or contribute to generalizable knowledge*."

There are two aspects of this definition that make a research project regulated, and both aspects must be present in a research project for it to be reviewed and approved by the IRB. These aspects include the practice of a systematic investigation, and the contribution to generalizable knowledge.

A systematic investigation does one or more of the following:

- Involve a methodical procedure and plan
- Be theoretically grounded
- Specify a focused and well-defined research problem or question
- Be informed by the empirical findings of others
- Be analytically robust
- Provide a detailed and complete description of data collection methods
- Involve a prospective research plan that incorporates data collection and data analysis

Contribute to generalizable knowledge:

- Generalizable knowledge is knowledge that is expressed in theories, principles, or statements of relationships that can be generally applied to our experiences
    - Activities designed to contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual(s) or an internal program(s)
    - The information is collected to share with others and is created for the purpose of making a broad statement (conclusion) about a group of people, procedures, or programs.
- The *intent* to develop or contribute to generalizable knowledge makes an activity research
    - The intent to contribute to "generalizable (scholarly) knowledge" makes and experiment or data collection research, regardless of publication.
    - Research that is never published is still research. Participants in research studies deserve protection whether or not the research is published.

A research project is considered “contributing to generalizable knowledge” when any of the following activities will occur:

- The information contributes to a theoretical framework or an established body of knowledge
- The information expands the knowledge base of a scientific discipline or scholarly field of study
- The primary beneficiaries of the study are other researchers, scholars, stakeholders, and practitioners in the field of study where they may use the end product to inform their daily practices, policy, or their research design, instruments, devices, data collection methods, and drugs or biologics
- Publication, presentation or other distribution of the results are intended to inform the field of study. Distribution of results may involve an oral presentation such as a lecture or conference talk, a written presentation such as a published research article, scholarly book, conference poster, other display that is made available to persons beyond the University
- The findings are intended to be replicated in or transferable to other settings
    - Generalizability is applied by researchers in an academic setting. It can be defined as the extension of research findings and conclusions from a study conducted on a sample
    - Transferability is applied by the readers of research. Although generalizability usually applies only to certain types of quantitative methods, transferability can apply in varying degrees to most types of research including qualitative research. Unlike generalizability, transferability does not involve broad claims, but invites readers of research to make connections between elements of a study and their own experience
- The findings are intended to inform a larger study, the design of a device, drug, or biologic, or to aid in future planning of research activities
- If it is likely that members of the public will make inferences from the data you are collecting and findings you plan to share, this is an indicator the research is designed to contribute to generalizable knowledge
- Results that are intended to be used to develop, test, or support theories, principles, and statements of relationships. This includes pilot work and some feasibility studies (please see pilot/feasibility guidance found on the IRB website)

The following projects ***<u>are not</u>*** considered research:

- Internal reporting activities to sponsors, supervisors, and offices
- Program assessment and evaluation where the intention is for program improvement or measurements of outcomes and not intended to generalize to others. For example, a quality assurance/quality improvement/organizational effectiveness study where the intent is to assess, improve, or develop programs or services for an organization is not research, because outcomes will remain specific to the organization, programs or services, although other organizations may **<u>NOT</u>** use the results for their own programs

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected
    - An oral history or journalistic piece is published materials that are limited to documenting or reporting on events, situations, policies, institutions, or systems without the intent to form hypotheses, draw conclusions, synthesize information about, or generalize findings
    - Such oral histories or journalism will not involve stories that will or may draw broad conclusions about the population, cultures, norms, and practices
        - *Note that an article reporting on findings from a project may be considered contributing to generalizable knowledge*
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters)
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions
- Classroom or educational research activities and class projects assigned and conducted to teach methods, not to contribute to generalizable knowledge. The intent may be to provide the student with practical experiences, information gathering techniques, and report writing. However, when the primary focus and initial intent of the class activities are to collect data to be used by students or other researchers beyond the classroom thereby contributing to “generalizable knowledge,” IRB review may be needed. Please see Appendix B for guidance regarding class projects
- Biography research involving a living individual that is not generalizable beyond that individual

Appendix A

"Does this count as research that may be subject to IRB review and approval?"

If you are completing research with human subjects and disseminating the results, it is one of the ways considered "contributing to generalizable knowledge" Below is a list of mediums that can be considered as platforms to contribute to generalizable knowledge.

NC State University Symposiums

Symposiums are forums wherein NC State faculty, staff, and students disseminate findings from their research projects. As a result, any project presented at an NC State Symposium that involves research with human subjects – requires IRB review and approval. Some NC State symposiums are noted below.

- NC State University Research Symposium by the Office of Research and Innovation (opens in a new window)
- State of North Carolina Undergraduate Research and Creativity Symposium (opens in a new window)
- NC State University Annual Symposium – Office of Undergraduate Research (opens in a new window)
- NC State University Graduate Student Research Symposium (opens in a new window)
- NC State University Post Doctoral Research Symposium (opens in a new window)

Dissertations and Thesis

All projects involving human subjects that are completed for a dissertation or thesis must undergo IRB review and receive approval before initiation.

Capstone Projects

A capstone project may require IRB review and approval under certain circumstances. If the capstone project is meant to serve as a final product, presentation, or performance not intended to contribute to generalizable knowledge, and it is not published, posted in a public forum or the library, then it will not require IRB review and approval before implementation. However, if the project will be published in the library (much like a thesis) or another public forum, then it likely will require IRB review and approval before implementation.

Class Projects

The primary goal of class projects is to provide students with experiential learning in research methods, including study design, data collection, and analysis. Class projects and research methods classes may involve data collection activities for training purposes that do not require IRB review and oversight because the intent is to teach methods, not to contribute to generalizable knowledge. The intent of class projects may be to provide the student with real world experiences, information gathering techniques, and report writing. There is no intent to contribute to generalizable knowledge. In these cases, these projects do not require IRB review and approval.

However, some projects have as an additional goal, the intent of contributing to generalizable knowledge (presenting publicly or otherwise disseminated, data from the project will be stored and used by researchers as data). These class projects constitute research with human subjects and IRB review and approval is required before recruitment, consent, data collection, or analysis of identifiable data may commence.

Course instructors are responsible for determining whether a project qualifies as research involving human subjects and, therefore, requires prior IRB review. You may contact the IRB office for consultation. Instructors and students must be aware that IRB approval cannot be granted retroactively. Please see the Class Projects that are Not Regulated Research (Google document) and the Faculty Point of Contact guidance (Google document) for guidance.

Podcasts

A podcast is a method for communicating and broadcasting ideas to the public. It provides the opportunity to reach a large audience, while also targeting content towards the audiences' interests. Some podcasts are designed for entertainment, act in a journalistic manner, or share oral histories. Other podcasts are intended to make theoretical or academic ideas accessible to a broad audience may require IRB approval before implementation of the research. Podcasts are considered a method for disseminating findings from a research project and IRB review and approval would be required to use this medium to share findings from research with human subjects. "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected."

Press Releases and News Articles

Occasionally, a press release or a news article can be used to disseminate information, ideas, and to make theoretical or academic ideas more accessible to people. This includes disseminating research findings. If the press release or news article does not discuss research findings that can be generalized or transferred, then the release or news article will not require IRB review and approval. However if findings are shared, then your project should have undergone IRB approval before recruitment, consent, data collection, or analysis of identifiable data. If you are completing a project solely for journalistic endeavors – your project does not require IRB approval. "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected."

Magazines

A magazine is a periodical publication containing articles and illustrations, typically covering a particular subject or area of interest. Oftentimes contributing to a magazine does not require IRB review and approval because it is a journalistic endeavor. Occasionally, a magazine can be used to disseminate information, ideas, and to make theoretical or academic ideas more accessible to people. This may include disseminating research findings. If the contribution to the magazine represents findings that can be generalized or transferred, then the project will require IRB review and approval before recruitment, consent, data collection, or analysis of identifiable data. "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected."

Newsletters

A newsletter is a publication that gets circulated at regular intervals to a targeted audience. The publication typically pertains to issues that the subscribers are interested in. Oftentimes contributing to a newsletter does not require IRB review and approval. Occasionally, a newsletter can be used to disseminate information, ideas, and to make theoretical or academic ideas more accessible to people. This may include disseminating research findings. If the contribution represents findings that can be generalized or transferred, then the project will require IRB review and approval before recruitment, consent, data collection, or analysis of identifiable data. "Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected."

Pilot Study (Word document)

A pilot study is a preliminary investigation usually conducted on a small scale that may be exploratory in nature, designed to test or develop procedures, to test study design (including survey or instrument development), or to test methods that are intended for a larger study. A pilot study is usually (but not always) completed with a participant group related to the intended target population. Pilot studies are considered research with human subjects and will require IRB review and approval before implementation. Reasons to complete a pilot study include exploring a new topic, testing instruments, testing study design and procedures, and preparation for a grant application.

Feasibility Work (Word document)

Feasibility work is an assessment of the practicality of a proposed plan, method, or use of an instrument for data collection, often involving colleagues or experts who can evaluate if the proposed method/design/instrument will result in sufficient information to answer the research questions. Feasibility work is not always considered research with human subjects and more likely than not will not require IRB review and approval before implementation. Reasons to complete feasibility work include: assessing the practicality of a research plan is practicable, assessing whether the research is needed, and garnering feedback regarding methods/instruments used in data collection.