



Gonzaga University

INSTITUTIONAL REVIEW BOARD TRAINING SESSION

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www.gonzaga.edu/irb



FREQUENTLY ASKED QUESTIONS

PLEASE NAVIGATE TO THE IRB WEBSITE FAQS PAGE FOR MORE INFORMATION ON THE QUESTIONS BELOW:

<https://www.gonzaga.edu/about/offices-services/institutional-review-board/faqs>

IS IT QUALITY IMPROVEMENT, PROCESS IMPROVEMENT OR PROGRAM EVALUATION? See IRB FAQ #2

What is QI & how does QI differ from research?

Research vs. Quality Improvement

QUALITY IMPROVEMENT

Comparison RESEARCH

	RESEARCH	QUALITY IMPROVEMENT
INTENT	Develop or contribute to generalizable knowledge (e.g., testing hypothesis)	Improve a practice or process within a particular institution or ensure it conforms with expected norms; not designed to contribute to generalizable knowledge
DESIGN	Systematic; follows a rigid protocol that remains unchanged throughout the research; may involve randomization	Adaptive, iterative design; may or may not be systematic; generally does not involve randomization
MANDATE	Activities not mandated by institution or program	Activity mandated by institution or clinic as part of its operations
EFFECT ON PROGRAM OR PRACTICE EVALUATED	Findings are not expected to directly affect institutional or programmatic practice	Findings are expected to directly affect institutional practice and identify corrective action(s) needed
POPULATION	Usually involves a subset of individuals; no obligation to participate; may involve statistical justification of sample size to achieve endpoints	Responsibility to participate as a component of the program or process; information on all or most involved in the practice of process is expected to be included; exclusion of some individuals significantly affects conclusions

WILL I NEED A LETTER OF SUPPORT? SEE FAQ #12

- If your research requires the participation of an organization or group, (e.g., using their facility; interacting with their employees, attendees, or members; accessing their non-public data, etc.) you must document confirmation of understanding of its role and permission to do the intended research. A letter or email must accompany your protocol submission that provides adequate detail of the organization or group's involvement and understanding. This must match the information provided in the protocol.

HOW DOES THE IRB ASSESS MY PROTOCOL? See IRB FAQ #10

Gonzaga's Institutional Review Board (IRB) reviews human subjects research to verify that it meets the generally accepted ethical and professional standards for the protection of human subjects. We review protocol submissions that have a signed cover sheet and a protocol form, plus all materials for conducting your research.

The [protocol review form](#) shows what we consider as we verify that a protocol meets the following criteria:

- The protocol and method of data analysis answer the research question
- The risks to subjects are reasonable relative to benefits
- Recruitment /informed consent processes are appropriately documented
- Provisions are adequate to ensure the privacy and safety of subjects

STUDENT AND FACULTY & STAFF COVER SHEET

<https://www.gonzaga.edu/about/offices-services/institutional-review-board/forms>

Please note that there are now 2 distinct coversheets for investigators: 1) Student Investigators and 2) Faculty & Staff Investigators.

IS IT QI, EXEMPT, NON-EXEMPT, OR FULL BOARD?

1) QUALITY IMPROVEMENT / PROCESS IMPROVEMENT / QUALITY ASSURANCE

- Designed to have its findings applicable to the local institution and bring about immediate improvements
 - Not designed to generalize to other settings
 - Quality assurance procedures fit here (e.g., data collected to monitor implementation or effectiveness of a program...and the data are only examined by administrators at the institution)
- If you see your work as QI, pay attention to your claims.
 - Call your project “Quality Improvement” in the title and throughout the protocol. And be aware that you can NEVER call it research at any stage of your data collection or dissemination of findings.
 - Limit your conclusions and don’t generalize
- Also have a letter of support from the agency that speaks to the ways the project will help them improve their processes or outcomes OR have the local IRB approve it as QI
- **Quality Improvement or Process Improvement:** You may choose to use the exempt form for quality improvement or process improvement projects. In this case, the federal definition of research does not apply.

2) EXEMPT

Research is exempt when it fits into one of the federally-defined categories:

Category 1: Your research will be conducted in established educational settings on normal educational practices

Category 2: Your research will:

- Use educational tests with children or adults
- Use surveys with adults on non-sensitive topics
- Use interviews with adults on non-sensitive topics

Category 3: Your research will involve observation of public behavior of adults

Category 4: Your research will collect only existing data

Category 5: Your research will focus on public benefit or service program

Category 6: Your research will focus on taste and food quality evaluation and consumer acceptance studies

3) NON-EXEMPT, DESIGNATED REVIEW

- Choose the **NON-EXEMPT** form in the following situations:
 - Low-risk behavioral research (e.g., non-invasive physical or behavioral tasks; manipulation of the subject's environment and similar methods commonly used in cognitive, behavioral, social, ethnographic, educational, health, and epidemiologic research)
 - Video, digital, or image recordings made for research purposes. (e.g., Using video recordings to examine communication styles between professors and college students)
 - Noninvasive procedures routinely employed in clinical practice (e.g., Weighing, muscular strength testing, body composition assessment, and flexibility testing).
 - Minimally invasive procedures routinely employed in clinical practice (e.g., Physical sensors that are applied either to the surface of the body or at a distance).
 - Non-invasive measures of performance on:
 - cognitive
 - perceptual
 - neuropsychological
 - behavioral
 - other related tasks

4) NON-EXEMPT, FULL BOARD

Plan enough time for a full board review when:

- Your study involves more risk than would be ordinarily encountered in daily life or during routine physical or psychological examinations/tests
- Any of the subjects are confined in a correctional or detention facility.
- Pregnancy is a prerequisite for serving as a subject.
- Any subjects are presumed not to be legally competent.
- The research involves children and the investigator will
 - interview the children
 - manipulate the environment or interact with the child as part of the data gathering

How Do I Submit My Study Protocol?

IRB INFORMATION: If you would like more information about the IRB, click this link:

<https://www.gonzaga.edu/about/offices-services/institutional-review-board>

SUBMISSIONS: All studies are to be submitted through the IRB's SharePoint system.

NAVIGATE TO SHAREPOINT:

<https://gonzaga.sharepoint.com/teams/sponsoredresearch/irb/SitePages/Home.aspx>

- A. In SharePoint, on the left hand menu, click on **OTHER FORMS**
 - This links you to the **IRB Webpages** where you can decide which forms you will need; you can also learn more about the IRB submission process here.
 - Here are some forms you may need to download from the IRB and submit through SharePoint:
 - **COVER SHEET:** Complete the Cover Sheet; you must have **all** required signatures and approvals before you can submit to SharePoint.
 - **PROTOCOL FORM:** Complete the Protocol Submission form. Use either the Exempt or Non-Exempt form, depending on your study details.
 - **INFORMED CONSENT:** This is a sample form; see IRB FAQ #6 for information on Informed Consent/Assent.
 - Other documents you may need:
 - **LETTER(S) OF SUPPORT:** Attach a letter of support if your research requires the participation of an organization or group. See IRB FAQ #12 for more information.
 - **RESEARCH TOOLS:** Attach your Research Tools (i.e., interview guides, surveys, scripts, recruiting materials, advertising, etc.)
 - Download, fill out, and save your forms for uploading into SharePoint
 - Be sure to obtain all signatures and approvals **before** you submit on SharePoint
- B. Back in SharePoint, on the left hand menu, click **New Submission Form** and fill out the requested information.
- C. Attach any of the documents you will use in your study.
 - i.e., cover sheet, Exempt or Non-exempt protocol form, Informed consent, letter(s) of support, research tools (i.e., interview guides, surveys, scripts, recruiting materials, advertising, etc.)
- D. After you submit your study documents through SharePoint:
 - You will receive an email notifying you that your study protocol was received
 - You will receive a protocol code that you will use whenever you refer to your study
 - This protocol code is very important. You will need to refer to it whenever you discuss your study with the IRB.