

# INSTITUTIONAL REVIEW BOARD (IRB) MANUAL FOR INVESTIGATORS

*Partnering with you to make scholarly inquiry a reality.*

Gonzaga University  
[www.gonzaga.edu/irb](http://www.gonzaga.edu/irb)

[IRB@gonzaga.edu](mailto:IRB@gonzaga.edu)

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**CONTACT:** [IRB@gonzaga.edu](mailto:IRB@gonzaga.edu) or [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb)

It's not unusual for researchers to experience some discomfort or difficulty when first submitting their protocol to the IRB. New investigators often encounter a new vocabulary and may be required to develop a new understanding of human subjects research. It may not be clear on what to expect or what is expected of you, and it can bring a sense of intimidation or feeling inadequately prepared. This resource guide can help allay any discomfort.

Once comfortable with this information, you may want to explore the IRB website further:  
([www.gonzaga.edu/irb](http://www.gonzaga.edu/irb))

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## I. BECOMING INFORMED

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### A. What Is An Institutional Review Board (IRB)?



Gonzaga University operates an **Institutional Review Board (IRB)** to review and approve all research involving human subjects. At Gonzaga, the IRB, which reports to the Academic Vice President, oversees human subjects protections through program oversight, education, policy setting, and outreach.

The IRB functions as a surrogate “human subject advocate.” Its role is to **safeguard the rights and welfare of human research subjects** by evaluating the research to assure an acceptable balance of risks to benefits. The IRB has the authority to approve, require changes to the study procedures, or disapprove proposed research projects.

The IRB at Gonzaga is empowered to review all human subjects research proposals which are conducted by Gonzaga faculty, staff, and students. The researchers and participants are expected to honor the terms under which they have agreed to participate in the research process.

### B. The IRB Is Guided By The Belmont Report

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research wrote “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.” The Belmont Report sets forth the basic three ethical principles expected to be followed when doing research involving human subjects: respect for persons (autonomy), beneficence, and justice.



### ***Respect for Persons***

“Respect for persons incorporates at least two ethical convictions: first, individuals should be treated as autonomous agents, and second, persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.” This states that the person must be capable of making the decision on whether or not to participate in a human subjects research project.

### ***Beneficence***

“Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.”

### ***Justice***

“Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.”



### C. How Does The IRB Assess My Submission?



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. They review protocol submissions that have a signed cover sheet and a protocol form, plus all materials for conducting your research.

The IRB considers the following criteria:

- The protocol and method of data analysis used to 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.
- The actual protocol review form is available in FAQs #10:  
<https://www.gonzaga.edu/about/offices-services/institutional-review-board/faqs>

### D. What is Research and Who are Human Subjects?

Human subjects research differs in many ways from other kinds of research. When humans voluntarily enroll in research studies, a high level of respect is required to honor that choice. Federal regulations define “**human subject**” and “**research**” in a way that differs from common use of those terms.

The following are the federal definitions (45 CFR 46, also known as the “Common Rule”):

**Research\*** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A **human subject\*** is a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual; or (2) Identifiable private information.



### E. Working With Another Institution With An IRB

See FAQ #13: <https://www.gonzaga.edu/about/offices-services/institutional-review-board/faqs>

As of Spring 2018\*, if you are cooperating on non-exempt research (e.g., conducting a project at a research hospital or working with another researcher at another University), you have an option. You can obtain both institutions’ IRB approvals and ongoing approvals. Or, Gonzaga’s IRB may be able to establish a reliance agreement with the other institution’s IRB. In this case, you would submit your

protocol to the local IRB and the second IRB would complete some paperwork to show that they will accept the first IRB's decision. This paperwork is called an Interagency Agreement (IAA) form. No research project may continue to recruit, enroll, or treat subjects or analyze data after the IRB approval expiration date (except where doing so would cause harm to the subjects).

\*Note: The federal government is changing this policy. Anyone working with another institution after the Fall of 2018 should check the IRB website FAQs for updates.

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## II. PREPARING FOR MY STUDY

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### A. Human Subjects Training Certification

Faculty, staff, or students conducting human research, or involved as key personnel in a research or training project including human subjects, should complete an online educational tutorial and certification. Gonzaga uses an online educational and certification program called NIH Human Subjects Research. You may also use the CITI Human Subject Research Training.

You can navigate to NIH or CITI sites by going to [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb) and clicking on the References link.

### B. Do I Need A Letter of Support?

See FAQ #12: <https://www.gonzaga.edu/about/offices-services/institutional-review-board/faqs>

- **1) OUTSIDE ORGANIZATIONS.** 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 obtain written confirmation of that they understand their role and they give you permission to do the intended research.
  - If you are working with an outside organization or institution, (e.g., school, church or business) you are responsible for determining what is required to obtain approval for its role in your research. *For example*, some organizations may require you to present your research proposal to a committee before they will approve it.
  - 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.
  - Plan enough time for their approval processes **before** you submit your protocol to the IRB.
- **2) GONZAGA STUDENTS.** Accessing Gonzaga students during a scheduled time requires permission from the relevant authority (e.g., if you will interact with students during class time, you must provide confirmation that the course instructor understands your plan and supports it.)
  - If you are doing research with 1 class, obtain written permission from the professor.
  - If you are working in 2 or more classes within the same department, obtain permission from the Department Chair.

- If you plan to do research university-wide, obtain permission from the Vice President for Student Development.
- **ATHLETIC TEAMS.** Working with members of a Gonzaga athletic team or other students under contract may have special stipulations. You are responsible to determine what is required for these students to have permission participate in your research, and you must submit documentation of this permission with your protocol submission.

### C. Do I Need An Informed Consent Form?

See FAQ #6: <https://www.gonzaga.edu/about/offices-services/institutional-review-board/faqs>

**Informed Consent** involves a person's voluntary agreement to participate in research, once they've understood the possible risks and benefits of participation. Consent may be written or oral in defined circumstances or translated from a language other than English.

Informed consent is the process of informing potential subjects about the key facts of a research study and what their participation will involve. The purpose of Informed Consent is to ensure that human participants are a) informed of the research process and procedures, b) informed of the risks and benefits, and are c) protected against any possible violation of privacy or confidentiality that could cause harm to themselves or their relatives.

If the subjects are from a **vulnerable population** such as pregnant women, prisoners or children, additional protections are required.

**EXEMPT RESEARCH** does not necessarily require a standard signed consent form. If appropriate, you can use **verbal consent** and/or provide a **simple information sheet** with no signature line. You may also use a full waiver of informed consent in some studies.

#### HERE ARE THREE TYPES OF CONSENT:

1. **Consent** – An adult subject, capable to give permission to participate in a research study, can provide consent. The subject must be 18 years of age and competent to make the decision to participate.
2. **Parental Permission** – When children/minors are included in research, the parent/guardian must sign a parental permission consent document.
3. **Assent** – Assent is a child's affirmative agreement to participate in research. If the subject is 5-17 years of age, assent must be obtained.

## D. What Elements Should Be Included In An Informed Consent?

For human subjects to participate in a research study, they need to have enough information to give a truly voluntary informed consent. Information subjects must be given include:

- *Purpose* of the research
- *Procedures* involved in the research
- *Alternatives* available should a subject decide not to participate in the research (e.g., when choosing to opt out of in-class surveys)
- All reasonably *foreseeable risks and discomforts* to the subject
  - Note: these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- *Benefits* of the research to the individual human subject and society
- *Length of time* the subject is expected to participate
- *Payment* for participation (if applicable)
- *Person to contact* for answers to questions or in the event of a research-related injury or emergency
- Statement that *participation is voluntary* and that refusal to participate will not result in any consequences or any loss of benefits that the person is otherwise entitled to receive
- Subjects' *right to confidentiality and/or privacy* (see below)
- Subjects' *right to withdraw* from the study at any time without any consequences



## E. What About Privacy Or Confidentiality?

The investigator should describe plans to protect the subject's identity as well as the confidentiality of the research records. Privacy and confidentiality are extensions of the principles of autonomy (respect for persons) and beneficence from the Belmont Report.

- **Privacy:** The concept of privacy relates to the means for obtaining the data from subjects. For example, when a researcher is interviewing a participant, they must make provisions to protect what is being discussed. Holding the interview in a private office is one method to protect the participant's privacy.
- **Confidentiality:** The investigator must provide a plan to keep research records confidential. For example, storing research records in locked file cabinets and password protecting electronic files helps to ensure confidentiality. Investigators should also describe, in their IRB application, who has access to the research records.
  - Subjects should be informed of whether the data collected will be retained, and if so, for what purpose and for what period of time.

- Video and audio taped data, as well as photographs require specific plans for confidentiality since these media can provide additional means for subject identification.

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### III. WHICH FORM SHOULD I USE?

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There are three levels of review for human subjects research: Exempt, Non-Exempt, and Full Board.

Quality Improvement may also be reviewed to determine Exempt status. For information on Quality Improvement, see the table link in FAQ #2: <https://www.gonzaga.edu/about/offices-services/institutional-review-board/faqs>

Each protocol form must be accompanied (as applicable) by a Cover Sheet, Informed Consent, Letter(s) of Support, and all research tools such as recruiting materials, surveys, interview guides, etc.

**FORMS:** You can find all the forms at [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb) in the forms link on the right hand menu.

**A. Cover Sheet.** The cover sheet must be completely filled out and must have all required signatures. Submit the cover sheet along with all your study documents.

**B. Quality Improvement.** Will take approximately 2 weeks to review. Use Exempt form.

See FAQs #2: <https://www.gonzaga.edu/about/offices-services/institutional-review-board/faqs>

- 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
- 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.

*The table below shows key distinctions between QI and research.*

## WHAT IS QI & HOW DOES QI DIFFER FROM RESEARCH?

### Research vs. Quality Improvement Comparison

	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

*Special thanks for this table goes to Virginia Commonwealth University.*

### C. Exempt Research.

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

**\*Note:** As of spring 2018, investigators in Exempt studies are responsible for protecting the study's participants; please adhere to ethical standards. Students, please consult with your advisor about any decisions you make regarding the humans who participate in your study.

**\*Note:** the federal government is changing the exempt categories somewhat. (For example, they will add a category for benign interventions). Also, anyone working with another institution in the fall of 2018 should check the IRB website FAQs for updates

Exempt research takes approximately 2 weeks to review. Use the Exempt form when your study 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

## D. Non-Exempt Research.

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

Investigators in Non-Exempt studies are responsible for protecting the study's participants; please adhere to ethical standards. Students, please consult with your advisor about any decisions you make regarding the humans who participate in your study.

A Non-exempt study takes approximately 3 weeks to 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).



"Hold still, Mrs. Brown while I draw your blood."

- Non-invasive measures of performance on:
  - Cognitive
  - Perceptual
  - Neuropsychological
  - Behavioral
  - Other related tasks

## E. Full Board Review.

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

Investigators in full board review studies are responsible for protecting the study’s participants; please adhere to ethical standards. Students, please consult with your advisor about any decisions you make regarding the humans who participate in your study.

Use the Non-exempt form for full board review studies. Full board reviews require approximately 4-5 weeks. Submit your study at least 2 weeks prior to the IRB meeting which occurs the last Wednesday of the month from September through April. 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

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## IV. INSTRUCTIONS FOR FILLING OUT THE EXEMPT FORM

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All studies will be submitted to the IRB via SharePoint. You may find all forms and submission information at [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb).

**FIRST:** Fill in the Date, your Name, and your Study’s Title

### SECTION I: PROJECT OVERVIEW

#### 1. Location of Activities: Check either Gonzaga, Other, or both.

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.

- a. *Example: The study will examine medical records from the Behavioral Health Department of the Spokane Veteran's Hospital. The records will be compiled and provided to the researcher with all identifying information removed.*

**2. Briefly describe your research study. This can be 1-2 paragraphs and it will include your study's purpose statement or hypotheses.**

- a. *Example: The purpose of this study is to explore how meaningful language is expressed through resonant relationships. This provides insights into how to become an authentic servant-leader. I will be interviewing and audio recording six to eight adults who are recognized as servant-leaders by myself and others. They are over 18 years of age. The interviews will last for 60-90 minutes each. The content of the interview includes the following questions: 1) How did positive role models help you make personal choices? And 2) How did your positive role models display authentic servant-leadership?*

**3. Provide the details of your study's participants. Are they children under 18? Are they adults over 18? Do they speak English as a second language?**

- a. *Example: All interviewees are English speaking adults who are 18 to 26 years of age and who are screened to verify that they do not suffer from PTSD.*
- b. *Example: All survey participants are Spanish speaking children between 13 and 17 years of age at Mission Secondary School*

## **SECTION II: NOT HUMAN SUBJECTS RESEARCH (E.G., QUALITY IMPROVEMENT)**

If you decide your study falls into the Research Category, **skip to Section III**

If your study is Quality Improvement or Program Evaluation:

1. Obtain a letter or email of support from the site(s) where you will be doing your study. This must include information on what the project entails and how the project will help improve agency processes or outcomes.
2. Answer questions 1-6.
3. Submit your study to the IRB via SharePoint

## **SECTION III: EXEMPT CATEGORIES FOR HUMAN SUBJECTS RESEARCH**

- Choose which category (or categories) your research falls into place a checkmark in that section.
- Fill out the information in the selected category.

## **SECTION IV: ADDITIONAL QUESTIONS**

1. Describe how you will obtain information from your study participants. You will submit all surveys, interview questions, etc. that you use for your study. You can include these items as Appendices.

- a. *Example: I will be doing open-ended interviews with 6-8 adults whom I already know to be servant-leaders in their fields of expertise. I will interview them individually for 60-90 minutes to learn more about how they became a servant-leader.” My email requesting interviews and my interview questions are attached as Appendix 1 and Appendix 2.*
  - b. *Example: I will be conducting a survey of four sociology classes. The recruitment flyer, survey and letter of support from the department chair are attached as Appendix 1 and Appendix 2.*
2. If you are conducting your research in a foreign language, include this information along with all translations of the consent/assent form and any recruiting or study materials.
  3. How will you identify study participants? How will recruitment be fair? You need to submit all recruitment flyers, recruiting emails, phone scripts, etc. You can include these items as Appendices.

**Note on Potential Coercion:** Consider any possible reasons that someone might think the research was coercing potential participants. Then explain the steps you will use to be sure there is no coercion involved. This is particularly important when power dynamics are involved between the investigator and the potential participants.

- a. *Example: when teachers collect data on their own students, a third party can explain the study, distribute and track the consent forms, and then manage the distribution and collection of surveys to the students who have both assent forms and parental permission forms on file.*
  - b. *Example: when a quality improvement project is taking place in a work setting and the supervisor has determined that all employees should participate. In this case, participants can voluntarily decide whether they want their data included in the study, even though they are participating in the activities as per their boss' mandate.*
  - c. *Example: The interviewees are people whom I already know personally or by reputation to be authentic servant-leaders. They have consistently exhibited servant-leadership traits, formally and/or informally, within their fields of expertise. I will email the potential participants, contact them in person, or by phone with a simple request such as, “I’m currently doing a study that involves researching the connections between leadership, meaningful language, and resonant relationship. I will be interviewing 6-8 adults whom I already know to be servant-leaders in their fields of expertise and I would like to interview you for 60-90 minutes to learn more about how you became a servant-leader.”*
  - d. *Example: I will place recruitment flyers in the student residences. These flyers will have my contact information. My flyer is attached.*
  - e. *Example: I will email potential participants. I will obtain the emails from \_\_\_\_\_. Note: be sure to explain how you will confidentially store and eventually destroy the email list when you answer questions 8 and 9*
  - f. *Example: Recruitment will be fair because there are no requirements for being participants other than the age requirement. There are no gender or population requirements. These are simply people I already know.*
4. How will your participants be informed of the study? Are you verbally informing them? Will you use an Informed Consent form?
    - a. Exempt research does not necessarily require a standard signed consent form. If appropriate, you can use verbal consent and/or provide a simple information sheet with no signature line.

- b. You need to submit your Informed Consent form, a copy of your verbal consent statement, or your information sheet along with your study.
  - c. **Example:** *The participants will be given an Informed Consent Form to read and sign. They may ask any questions they have before signing and may opt out of the study at any time upon writing to the Principal Investigator.*
- 5. Indicate if you are audio or video recording. Most of the time a Non-Exempt form will be used if you are video recording because the participants can easily be identified.
- 6. Is any payment being made to participants? If course credit or extra credit is offered, what options will those who opt out of the study be offered?
- 7. Will your participant be under 18? Are they prisoners? Are they mentally disabled? Explain how they will be protected.
- 8. How will you maintain privacy for the participant? Will the interviews be conducted in a quiet place or in a public setting?
  - a. **Example:** *Interviews will be conducted in a mutually conducive area where privacy can be maintained. For example, this can be done at the participant's office, home or in a quiet corner of a coffee shop.*
- 9. How will confidentiality be maintained?
 

**Example:** *All data will be kept on a secure, password protected computer for a period of three years after the study has been completed. At that time it will be destroyed. To protect confidentiality, I will follow these procedures:*

  - 1. *I will audio record all interviews and take field notes.*
  - 2. *I will transcribe all interviews.*
  - 3. *All interviewees will be given pseudonyms.*
    - a. *The list linking pseudonyms to respondents will be kept on my password protected computer. This file will never be placed on a shared drive.*
    - b. *Pseudonyms will be used in all interview transcripts, notes, analysis files, and presentations.*
    - c. *Consent forms will not include a participant's pseudonym.*
    - d. *In cases where pseudonyms may not be sufficient to conceal a participant's identity, other characteristics may be altered or excluded from reports (articles, presentations, etc.) in order to ensure confidentiality.*
  - 4. *Audio recordings, field notes, and consent forms that contain identifying information will be stored in a secure area and will destroyed three years after the completion of the study. I will destroy audio or visual recordings of participants as soon as all transcripts of the recordings are completed and verified.*
- 10. Minimizing risk.
  - a. **Example:** *There are no risks involved in this study.*
  - b. **Example:** *All interviews will be conducted in private and all recordings and data will be stored in a password protected computer.*
  - c. **Example:** *In the event that the topics discussed result in negative psychological reactions, a list of mental health providers will be provided to the participants and they will be informed that they may opt out of the study at any time. This list is attached as Appendix 1.*

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## V. HOW DO I SUBMIT MY STUDY?

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**SUBMISSIONS:** All studies are to be submitted through the IRB's SharePoint system. Navigate there by going to [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb).

**Note:** This information is from the SharePoint site as of spring 2018. The submission process may change over time, so please check the website for the most current submission guidelines: <https://www.gonzaga.edu/about/offices-services/institutional-review-board/submission-process>

**You will submit:**

- ✓ Cover sheet (Students use the Student Investigator cover sheet) – be sure to obtain **ALL** required signatures before submitting via SharePoint.
- ✓ Protocol form – either Exempt or Non-Exempt
- ✓ Informed Consent – see info above or FAQ #6 on the IRB website
- ✓ Letter(s) of Support – see info above or FAQ #12 on the IRB website
- ✓ Research Tools - any interview guides, surveys, email scripts, recruiting materials, advertising flyers, and any other documents you will use to conduct your study.

1. **NAVIGATE TO THE IRB SITE:** Go to [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb) and click on the Forms page.
  - A. Download, fill out, and save your forms for uploading into SharePoint.
  - B. Once you fill out your forms and have all your study documents prepared, you can link to SharePoint from the IRB Submissions page.
2. Go to the IRB Submissions page, click on **Submit Your Study Materials**. This takes you to SharePoint.
3. In SharePoint, click **New Submission Form** on the left hand menu and fill out the requested information.
  - A. Attach all the documents you will use in your study. (Such as the signed Cover Sheet, Exempt or Non-exempt protocol form, Informed consent, letter(s) of support, and research tools.)
  - B. After you submit all your study documents through SharePoint:
    - You will receive an email notifying you that your study protocol was received. If you do not receive an email from the IRB in 3 business days, let the IRB know at [irb@gonzaga.edu](mailto:irb@gonzaga.edu).
    - 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.

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## VI. WHAT HAPPENS AFTER MY STUDY IS APPROVED?

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Once you have been fully approved to proceed with your research, what are your responsibilities as you carry out this study?

- When your study is **Complete**, notify the IRB via email at [irb@gonzaga.edu](mailto:irb@gonzaga.edu). Include your assigned protocol number.
- If your study changes, submit an **Amendment** form.
- If your Non-Exempt study lasts beyond the approval date, submit a **Continuation** form.



### Other Instructions:

- Destroy audio or visual recordings of participants as soon as all transcripts of the recordings are completed and verified.
- You are also responsible for following any additional requirements as defined by other units at Gonzaga or by the entity or organization where this project is conducted. Students, be sure your advisor has approved your work as meeting all requirements of your department, College or School as well as the site where the project is carried out.
- The procedures should be implemented as approved. Any changes planned for the research must be submitted for review and approval by the IRB prior to implementation. (The Request for Amendment form is available online at Gonzaga's IRB webpage for forms.)
- If an adverse event occurs, report it to the IRB. Students, tell your advisor if anything went not according to plan.
- Students must work with their advisors to complete any additional documentation. The advisor serves as the Responsible Project Investigator who will monitor and be liable for the conduct of the research.
- In all correspondence with the IRB about this study, please refer to the Protocol number you will receive after you submit your study via SharePoint.

### What about at the completion of the study?

- When you end this study please notify Gonzaga's IRB via email at [IRB@gonzaga.edu](mailto:IRB@gonzaga.edu).
- Following the completion of the project, the following must be retained for at least 3 years. Students must work with their advisors to ensure this occurs.
  - This Determination of Exemption
  - A copy of the protocol and all materials as approved
  - Data collected, analyzed and reported.

If you have any further questions at this time or throughout the duration of your study, please contact the IRB at [IRB@gonzaga.edu](mailto:IRB@gonzaga.edu).

### **A. How Long Do I Keep My Research Data?**

Generally, you need to keep your research data for 3 years after completion of the research. However, in some cases, such as with children, it is advisable to retain the data for 7 years after they turn 18.

### **B. How Long Is My IRB Approval Good For?**

Once you receive your IRB Letter of Determination for a Non-Exempt study, you will have up to one year to complete your research or the length of time indicated on your coversheet if less than one year. If you need longer than a year, you will need to submit a Continuing Review form.

### **C. What If My Study Goes Longer Than Approved?**

You will submit a Continuing Review form when you feel that your study will continue past the approved study period. Each investigator must abide by the approval period imposed by the IRB at the time of the most recent IRB approval. Each IRB approval notice designates a period of time during which activities involving human research subjects may be undertaken. You can find the Continuing Review form at [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb) under the forms link.

### **D. What If My Study Changes After I Start?**

You will submit an Amendment form when you experience any changes to an approved study. Any proposed change to a previously IRB approved research project must be submitted to and approved by the IRB **before** the change is implemented, except when necessary to eliminate apparent immediate hazards to the subjects. Amendment forms can be found at [www.gonzaga.edu/irb](http://www.gonzaga.edu/irb) under the forms link.

### **E. What If There Are Adverse Events Or Unanticipated Problems During My Study?**

After an Adverse Event or an Unanticipated Problem occurs, the principal investigator is required to submit a reportable event in a timely manner to the IRB via email at [IRB@gonzaga.edu](mailto:IRB@gonzaga.edu). The principal investigator's report should contain enough information for the IRB to determine whether the event increases the level of risk to participants, requires a research design change or necessitates modification to the informed consent form.

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## **VII. GLOSSARY OF COMMON TERMINOLOGY**

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*Special thanks goes to the University of California IRB for the terminology definitions below.*

### ***Adverse Event/Effect (AE)***

Any untoward physical or psychological occurrence in a subject participating in research. An AE can be any unfavorable or unintended event including an abnormal laboratory finding, or a symptom or disease associated with the research. Adverse events may or may not have a causal relationship with the research.

### ***Assent***

Agreement to participate in research obtained from an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person). An assent form is like an informed consent form but is tailored to the status/age of the individual not competent to give consent. It is only binding in conjunction with parent/guardian consent.

**Belmont Report**

The National Commission for the Protection of Human Subjects in 1978 authored the Belmont report. It establishes the basic ethical principles for conducting human subjects research: autonomy, beneficence, and justice.

**Beneficence**

Beneficence is an ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

**Benefit**

A benefit is a valued or desired outcome; an advantage.

**Compensation**

Payment for participation in research.

**Competence (Capacity to consent)**

A legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

**Confidentiality**

Pertains to the handling of information/data that an individual has disclosed in a relationship of trust. The expectation is that the information/data will not be divulged to others without permission, or in ways that are inconsistent with the original disclosure.

**Continuing Review**

Periodic review of a research study by an IRB to evaluate whether risks to participants remain reasonable in relation to potential benefits and to verify the study continues to meet regulatory and institutional requirements. Continuing review shall be conducted at intervals appropriate to the degree of risk but not less than once per year.

**Data Analysis**

The process of applying statistical techniques to describe, summarize, and compare data to extract useful information and facilitate conclusions.

**Deception**

Deception, when referring to studies, is the intentional misleading of subjects or the withholding of full information about the nature of the study. Deception increases ethical concerns because it interferes with the ability of the subject to give fully informed consent. However, deception is arguably necessary for certain types of behavioral research to prevent biased behavior or answers.

**Design**

A research design is a plan or analytical approach for answering research questions. Some examples of research designs are experimental, correlational, observational, and single case. The selection of a particular study design depends on the information sought.

**Exempt Research**

Exempt research is Human Subjects Research that meets one of the minimal risk categories in the federal regulations.

**Full Board Review**

Review of proposed or continuing research (primarily greater than minimal risk research) by a convened IRB meeting, at which a majority of the voting membership is present.

**Guardian**

An individual who is authorized under applicable state or local law to give permission on behalf of a child or make decisions for an incompetent adult [[45 CFR 46.402\(c\)](#)].

**Grant**

Financial support provided for a research study. Fund givers typically do not exercise strict control over the grants they have awarded.

**Human Subjects**

Under the federal regulations (45 CFR 46), human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**Identifiable Personal Information**

Data containing enough information to reveal the identity of the subject.

**Informed Consent Document**

A document that provides prospective participants with the purpose, procedures, potential risks and benefits of involvement in a research study, as well as alternatives to participating. This document is also what participants sign to demonstrate their consent to participate in research.

**Institutional Review Board (IRB)**

To protect the welfare of human subjects participating in research, a specially constituted review body designated by an entity to review human subject research protocols.

**International Studies**

Procedures and policies that apply to research taking place outside the U.S. often differ from those set forth in the U.S. federal policies. U.S. federally funded research activities in a foreign country may be approved only if the ethical protections are equivalent to those in the U.S. This is also true for FDA approval of drugs/devices/biologics tested outside the United States.

**Justice**

An ethical principle discussed in the Belmont Report requiring fairness in the equitable distribution of burdens and benefits within the study population.

**Minimal Risk**

A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

**Minor**

Persons who have not attained the legal age to consent to treatment or procedures in research, as determined under the applicable law of the jurisdiction in which the research will be conducted

**Non-exempt Expedited Review**

A review undertaken per federal regulations by two designated voting members rather than the entire IRB.

**Principal Investigator (PI)**

The researcher with ultimate responsibility for the design and conduct of a research project.

**Privacy**

Control over the extent, timing, and circumstances of sharing oneself (physically or behaviorally) with the PI or other research staff.

**Protocol**

The formal design or plan of an experiment or research activity.

**Recruitment/Recruitment Materials**

Recruitment is the process by which potential subjects are informed about a study. Recruitment materials, such as fliers, email messages, newspaper ads, and phone calls, must be accurate, non-coercive, and must not emphasize monetary compensation. These materials must be approved by the IRB.

**Research**

Systematic investigation, including research development, testing, and evaluation, designed to produce or contribute to generalizable knowledge.

**Respect for Persons**

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

**Risk**

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations only define “minimal risk”.

**Serious Adverse Event (SAE)**

Defined by the FDA as an event that jeopardizes the research subjects and may require medical or surgical treatment (e.g., death, a life threatening experience, hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly and/or birth defects).

**Sponsor**

A person, federal agency, corporation, or other entity that provides funds for a research project.

**Survey**

A means to obtain information from respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

**Unanticipated Problem Involving Risks to Subjects or Others (UPX)**

Any event that is unexpected, related or possibly related, and suggests that the research places subjects or others at a greater risk of physical or psychological harm than was previously known or recognized.

**Voluntary**

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's willingness to participate (or continue to participate) in a research activity.

**Vulnerable Populations**

Any individual who may be subject to coercion due to a situation or a malady can be considered vulnerable in that context. Federal regulations however, define only three groups of vulnerable subjects: (a) prisoners, (b) children, and (c) pregnant women, fetuses, and neonates.