IRB Training

April 2018

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Comments or suggestions for us?

- We take input and feedback seriously.
- Take a few moments to write anything you want us to know about IRB processes at Gonzaga.
- You can share your experiences if you'd like. Please just provide the year for reference whenever possible.

- If you want to tell us more later, feel free to email IRB@Gonzaga.edu

Belmont Report – ethical principles

- Respect for Persons

- Beneficence

- Justice

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Belmont Report – ethical principles

- Respect for Persons – autonomy and protections for vulnerable populations

- Beneficence –don't harm research subjects; maximize benefits and minimize harms

- Justice – burden and benefits of research are distributed

Operationalizing the Belmont Report

HHS.gov
U.S. Department of Health & Human Services

ASH > OHRP Home > Regulations > Human Subjects Research (45 CFR 46)

- OHRP Home
- About OHRP
- Regulations
  - Human Subjects Research (45 CFR 46)

Code of Federal Regulations

Code of Federal Regulations

Research
Human Subjects
Institutional Review Board (IRB)
Minimal Risk
Exempt
Non-Exempt
Full Board Review

Aligned with the Belmont Report and 45 CFR 46

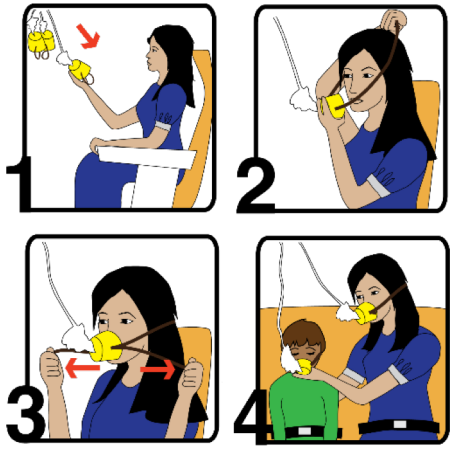
- Gonzaga has an Institutional Review Board (IRB)
- Researchers share their plans with the IRB by "submitting a protocol"

- Then the protocols are reviewed, depending on the level of risk:
  - **Exempt** research, by the Chair of the IRB
  - **Non-Exempt** research, by a couple of Board members
  - **Full board** reviews are conducted monthly for research
    - on sensitive topics,
    - on vulnerable populations, OR
    - with more than minimal risk

How to plan research aligned to the Belmont Report and 45 CFR 46

- Imagine you're going on a trip
  - Plan your route (e.g, how you will invite voluntary participation and protect the confidentiality of data once you have it)

- Then give good directions to the destination
  - Describe your plan in detail (e.g., no vague or missing steps)



- Be ready to give the "pre-flight safety speech", too
  - Think about what could go wrong and know how you'll respond should the worst-case scenario occur

Website demo

- Cover sheet – Faculty/Staff vs. Student
- Exempt sheet with QI section

Quality Improvement/ Program Evaluation

- 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

Sharepoint Demo

- How to get to Sharepoint
- How to submit

How will my protocol be reviewed?

Belmont Report – ethical principles and applications

- Respect for Persons – autonomy

Informed Consent
Subjects enter research **voluntarily** and with adequate **information** that is shared in a way they can **comprehend**

- Beneficence – maximize benefits and minimize harms

Risk vs. Benefit
The research is designed well and any risks are justified

- Justice – burden and benefits of research are distributed

Selection of Subjects
Researchers are **fair** and avoid "social, racial, sexual and cultural biases institutionalized in society"

- Federal Criteria (45 CFR 46.111)
- Also that permissions are secured
- Our protocol review form

What happens after the review

- CONDITIONAL APPROVAL– requests a few changes
- After you submit the changes, you'll receive an email stating that the protocol has been approved
- APPROVAL
  - For exempt protocols, we have updated our letters of determination

Institutional Review Board <no-reply@sharepointonline.com>

Hughes, Kara; IRB Mailbox; Hughes, Kara; Radmer, Elaine

11:05 AM

Determination of Exemption for Protocol Number TESTTUESALSE22

The Gonzaga Institutional Review Board (IRB) evaluated the information and materials submitted for the study titled "**Test Tues AL-SEx2**" (Protocol # **TESTTUESALSE22**) and has determined that the study satisfies the criteria for exempt research **under category, 45 CFR 46.101(b) (3)** As of today's date, this study is approved without further delays and will be registered with the IRB at Gonzaga University. You may conduct the study according to the approved protocol without further review. Throughout the project, the faculty member will be liable for the conduct of the research.

What are your responsibilities as you carry out this study?

- Investigators in exempt studies are still responsible for protecting your 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.
- 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: **TESTTUESALSE22**

What about at the completion of the study?

- When you end this study (Protocol #TESTTUESALSE22), please notify Gonzaga's IRB via email at 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. Remember to mention the Protocol number (TESTTUESALSE22) in any correspondence about this study.

Gonzaga IRB Protocol Number: TESTTUESALSE22
Approval/Determination Date: 4/17/2018
Study Category: Approved; 45 CFR 46.101(b) [%Current Item:Govt Exempt #%]
Funded? Yes
Approval Letter: AL-SE

Any Questions?

Thanks!

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Faith Gilbert

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