The IRB Process for Doctor of Ministry Students

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Research Coordinator
Food for Thought...

- What do you think of when you hear the word *research*?
Human Subjects Research

• Research
  – a systematic investigation designed to develop or contribute to generalizable knowledge

• Human Subjects Research
  – involves obtaining information about living individuals
What Does the IRB Do?

• Protects people who take part in research studies affiliated with the university

• Examines each study’s design to ensure it is:
  – Ethical
  – Does not involve unnecessary risks
  – Includes adequate safeguards for participants
Biblical Basis for the IRB

• Ethical principles outlined in scripture:
  • Mark 12:31
    – “You shall love your neighbor as yourself”
  • Matthew 7:12
    – “Therefore, whatever you want men to do to you, do also to them”
Historical Basis for the IRB

Nuremburg Trials

Willowbrook Experiment

Tuskegee Syphilis Experiment
Federal Oversight

• Federal Government Requirements
  – Department of Health and Human Services
    • Office for Human Research Protections (OHRP)
    • Food and Drug Association (FDA)
      – 45 CFR 46
QUIZ!

• What type of data is obtained when human subjects research is conducted?
  A. Private information about living individuals.
  B. Anonymous information about living individuals.
  C. Information about living or dead individuals that is publicly available.
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Questions, Questions, Questions...

• How do I recruit participants?
• How do I collect data?
• Where can I get help with my application?
• How do I get my study approved by the IRB?

• If you have questions, feel free to ask at any time, or write them down on the card provided. We will review questions toward the end.
Scenario: How to Conduct Research

• To help you see the big picture, let’s pretend...
  – I am a world-renowned researcher.
  – You are enthusiastic, willing participants.

• This should give you an idea of what you yourself will be doing when you begin your research.
I Want You!

• **Step 1: Recruitment**
  – I will contact you to tell you a little bit about myself, what I am researching, what I want you to do, and why I want you to participate.
  – I can call you, email you, talk with you in person, or connect on social media.
Hello Pastor Bob,

My name is John Smith. As a graduate student in the School of Divinity at Liberty University, I am conducting research as part of the requirements for a D. Min degree. The purpose of my research is to study church-wide fellowships and the effect meal selection has on the quality of the fellowship experience. I am writing to invite you to participate in my study.

If you have pastored a church with over fifty members for more than five years, and are willing to participate, you will be asked to complete an anonymous online survey. I estimate the survey should take no more than 15 minutes. Your participation will be completely anonymous, and no personal identifying information will be collected.

To participate, I ask that you go to the following link: fakepastorfoodstudy.com, to complete the survey.
Tell Me More!

• **Step 2: Consent**
  – You say, “What an exciting study, count me in!”
  – I will then provide you with a consent form, which contains more detailed information about my study.
    • Procedures
    • Time
    • Compensation
    • Risks & Benefits
CONSENT FORM

Meal Selection and its Effect on Fellowship Quality

John Smith
Liberty University
School of Divinity

You are invited to be in a research study of meal preferences for church-wide fellowships. You were selected as a possible participant because you have pastored a church with more than 50 members for more than five years. I ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by John Smith, a D. Min. candidate in Liberty University’s School of Divinity.

Background Information

It is well known that church-wide fellowships frequently involve meals. Fellowship is vital to the unity of the church; therefore, the researcher is hoping that the findings of this research may serve to enhance the fellowship experience. The researcher is hoping to deduce whether evangelical pastors prefer potluck or catered meals.

Procedures

If you agree to be in this study, I would ask you to do the following things: Complete an online, anonymous survey. The survey should take no longer than 15 minutes.
Collecting Data

• Step 3: Data Collection
  – Once you agree/sign the consent form, I will perform the study procedures.
  – This is where I would hand out my survey, ask you my interview questions, etc.
How to Collect Data

- Surveys
- Questionnaires
- Interviews
- Focus Groups
Surveys

• Yes/No:
  – Do you believe in Jesus?
    • Yes
    • No

• Check the appropriate box:
  – □ Male
  – □ Female

• Likert Scale:
  – How happy are you?
    • ○ 1 (Least)
    • ○ 2
    • ○ 3
    • ○ 4
    • ○ 5 (Most)

Submit your survey questions with your application!
Options for Conducting a Survey

• Pen & Paper
• Survey Monkey
  – Limits # of questions
  – Usually only one free survey
• Qualtrics
  – Free to LU affiliates
  – Must submit an IT ticket to receive blackboard training/access
  – More analytical tools
• Lime Survey, Excel Survey, Google Survey
Questionnaires

• **Example Question 1:**
  – Please describe your relationship with Christ:
   • “I believe that I am closely aligned with the teachings of Jesus Christ. I rely on him for my strength.”

• **Example Question 2:**
  – Please list what you think are the 3 most important qualities in a pastor:
    • Friendly
    • Reverent
    • Cheerful
Interviews

• Take place at a specified date, time, and place
  – If information is “sensitive,” meet in private area
• Researcher asks questions, and participant answers
• Types of Interviews:
  – In-Person
  – Phone
  – Skype/Online

Submit your interview questions with your application!
Focus Groups

• Take place at a specified date, time, and place with a small handful of individuals
• Researcher guides the discussion with pre-determined questions
• Considerations:
  – Cannot guarantee confidentiality
  – Responses can be biased because other participants are present

Submit your focus group questions with your application!
Scenario: How to Conduct Research

• To recap:
  – Step 1: Recruitment
  – Step 2: Consent
  – Step 3: Data Collection

• Please remember; this is a simple illustration. Your study may be slightly different, but the format should be similar.
Your Turn!

• Now we get into the details of how to complete your research application...
General Overview

• **Step 1:** Explore the IRB Website
  – [www.liberty.edu/irb](http://www.liberty.edu/irb)
  – Click on “School of Divinity”

• **Step 2:** Download the Application Checklist

• **Step 3:** Complete CITI Training

• **Step 4:** Download the Divinity Application
  – Application instructions & example applications are also available
General Overview

- **Step 5:** Download Templates
  - Recruitment, Consent, etc.
- **Step 6:** Fill out the application/templates
- **Step 7:** Submit for IRB approval
- **Step 8:** Complete requested revisions
- **Step 9:** Receive Approval!
Creating Your Documents: **Permission**

- Asking to use or gather data from an organization or leader
  - Pastors
    - Asking permission to contact congregation members
  - Conferences or Organizations
    - Asking permission to use databases containing phone numbers or emails
- **How to Request Permission**
  - Use the template!
  - Formal Letter/Email

Submit proof of permission with your application!
Dear Pastor Dale E. Bread:

As a student in the School of Divinity at Liberty University, I am conducting research as part of the requirements for a D. Min degree. The title of my research project is The Effectiveness of Christian Outreach Programs on Church Growth. The purpose of my research is to determine which Christian outreach programs have the largest impact on recruiting new church members.

I am writing to request your permission to access your church member list to recruit participants for my study.

Participants will be asked to go to lets.get.more.people.to.church.com to complete an anonymous survey, which should take no more than 15 minutes. The data will be used to determine which programs are most effective. Participants will be presented with informed consent information prior to participating. Taking part in this study is completely voluntary and anonymous.

Thank you for considering my request. If you choose to grant permission, please respond by email to jsmith**@liberty.edu indicating that you have given me permission to access your church member list.
Creating Your Documents: Recruitment

• How you “advertise” your study
  – What do you say?
  – How do you say it?

• Methods include:
  – Letters
  – Email
  – Social media
  – Phone/Verbal
  – Flyers

Submit recruitment materials with your application!
Creating Your Documents: Consent

• Provide detailed study information
  – Potential participants must be able to decide whether or not they want to participate

• **Templates** available on the IRB website:
  – Informed consent
  – Child assent
  – Short form consent

Submit informed consent materials with your application!
Creating Your Documents: Consent

• Use the template!
• Clear, straightforward language
• Sixth-grade reading level in most cases
• See the IRB website for more details
  – Avoiding Pitfalls
    • Informed Consent
Collecting Signatures on Consent

• Informed consent form provided, but without a signature
  – Minimal risk anonymous surveys
    • No more than everyday risk
  – Unrecorded anonymous interviews
    • Not able to identify the individual

• The IRB will notify researchers if their study qualifies
Completing the Application: Privacy

• Privacy and Confidentiality
  – Privacy of participants?
    • Location of interviews should be private
  – Hard copy data?
    • Locked filing cabinet or drawer
  – Computer data file?
    • Password-protected
  – Written verbal transcript?
    • Use pseudonyms (fake names) or number codes
Scenario: Data Security

- You are studying the impact of Christian outreach programs on substance abuse
- Your data is in plain view in your office, and a member from your church walks in to see:

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Participant Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mackenzie Jackson</td>
<td>55</td>
<td>Alcohol Abuse</td>
</tr>
<tr>
<td>Carlos Rodriguez</td>
<td>25</td>
<td>Non-User</td>
</tr>
<tr>
<td>Jason Waters</td>
<td>28</td>
<td>Drug Abuse</td>
</tr>
</tbody>
</table>
Scenario: **Data Security**

- What if someone saw this instead?

<table>
<thead>
<tr>
<th>Subject</th>
<th>Age</th>
<th>Participant Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>2207</td>
<td>55</td>
<td>1</td>
</tr>
<tr>
<td>2208</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>2209</td>
<td>28</td>
<td>3</td>
</tr>
</tbody>
</table>
Scenario: Data Security

• Ideally, no one should see anything!
• The data should be:
  – Locked in a file cabinet
  – Saved in a password-protected file
• The researcher should:
  – Maintain a list that links pseudonyms or number codes to identities
  – Store the list in a separate location from the data
Completing the Application:

Safeguarding Data

• Be specific as to how you will protect your data:
  – “I will assign each pastor I interview a number. I will store the list linking the pastors to the numbers in a separate, locked filing cabinet.”

• Christ’s Golden Rule (Matthew 7:12)
  – A useful guideline for data handling safeguards
  – How would you want your information protected?
Completing the Application: Confidentiality vs. Anonymity

- **Anonymity**
  - The researcher does not know who said what
  - Example:
    - Anonymous online survey

- **Confidentiality**
  - The researcher knows who said what, but promises to keep identities private
  - Example:
    - Face-to-face interview
QUIZ!

• Which of the following is an example of an anonymous study?

A. A recorded, one-on-one interview.

B. An online survey that does not ask for personal, identifiable information.

C. An unrecorded focus group.
QUIZ!

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  A. A recorded, one-on-one interview.
  B. An online survey that does not ask for personal, identifiable information.
  C. An unrecorded focus group.
QUIZ!

• Which of the following is an example of a confidential study?
  A. A recorded, one-on-one interview where the researcher uses the participant’s real names.
  B. An interview about marital abuse conducted in the middle of the local Starbucks.
  C. A recorded, one-on-one interview where pseudonyms or numbers are used in the publication.
• Which of the following is an example of a confidential study?
  A. A recorded, one-on-one interview where the researcher uses the participant’s real names.
  B. An interview about marital abuse conducted in the middle of the local Starbucks.
  C. A recorded, one-on-one interview where pseudonyms or numbers are used in the publication.
Considerations: **Special Situations**

- **Special populations**
  - Prisoners, children, those with disabilities, etc.

- **Audio or video recording**
  - Recorded interviews
Considerations: Special Populations

- Does your study **focus** on any of the following?
  - Specific ethnic/cultural group
  - Low socio-economic status (SES) specific
  - Children or adolescents (under 18)
  - Military personnel
  - Any person who cannot give legal consent to participate
    - Prisoners
    - Mentally disabled
Considerations: Audio or Video Recording

• Data collection with audio/video recording or photography:
  – Helps you in transcribing and interpreting data
  – Requires a more thorough IRB review

• Participants will have to sign consent forms
  – Participants must give specific permission for you to record or photograph them (checkbox)

• Audio or video recording is NOT anonymous
The IRB: Process & Timeline

• Process overview

• Timeline

• Pitfalls

• Suggestions
The IRB: **Use the Checklist!**
The IRB: CITI Training

- [www.citiprogram.org](http://www.citiprogram.org)
- Use the instructions from the website to create an account
- Self-paced modules
  - Can be completed at different intervals
  - Readings followed by quizzes
- A basic overview of conducting research involving human subjects
The IRB: CITI Training
The IRB: Timeline

- Application Submitted to the IRB
- Preliminary Review
- Revision Cycles
- Approval Process
The IRB: Application Process

• Obtain Mentor approval/signature
• Complete the application
• Complete CITI Training
• Email the following to irb@liberty.edu:
  – Word Documents:
    • Application
    • Consent form
    • Surveys/Assessments/Interview Questions
    • Recruitment Letters/Scripts
  – Pdfs or Faxes:
    • Permission Letters (if necessary)
    • Signed Signature Page
The IRB: Application Process

• Status Email
• Preliminary review
• Revisions requested
• Student revises application and returns it to IRB
  – Expect multiple requests for corrections and clarifications
• IRB makes its final decision
Pitfall: Your Expectations

- “I need a decision on this by Friday.”
- “The semester is almost over, and I have to get my project done.”
- General total timeline: 1-2 months
  - Simple projects
    - 1 month
  - More elaborate
    - 1-2 months
Tips: Avoiding Delays

- **Minimize the following problems:**
  - Grammar, spelling, or punctuation errors
  - Lack of professionalism
    - lack of consistency or clarity on the application or supporting documents
  - Incomplete applications
    - BE **BRIEF**, YET **THOROUGH** WITH YOUR ANSWERS
- Errors cause delays in your processing time
- **Complete** requested revisions quickly
Tips: **Use Current Materials!**

- Go directly to the IRB website to download your application and templates.
  - www.liberty.edu/irb
- Current materials have been updated with you in mind to make your life easier!
- As of January 1\textsuperscript{st}, 2017, we no longer accept outdated applications!
Tips: **Use Current Materials!**

**USE THIS:**

**NOT THIS:**

II. GENERAL INFORMATION

1. Name and information for the student doing the study:
   - Student Name: 
   - Student ID: 
   - Student Phone: 
   - Student Email: 

2. Name and information for the faculty mentor overseeing the study:
   - Faculty Mentor Name: 
   - Faculty Mentor Phone: 
   - Faculty Mentor Email: 

3. Study Dates (Approximate dates):
   - From: 
   - To: 

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**LIBERTY UNIVERSITY INSTITUTIONAL REVIEW BOARD**
Tips: Sample Applications
Tips: Application & Instructions

Rawlings School of Divinity - IRB Overview

General IRB Requirements
Tips: Finding Templates & Forms
The IRB: Contact Us

• If you have questions, we’re here to help!
• IRB Office
  – Location
    • Green Hall 1887
  – Phone
    • 434-592-5530
  – Fax
    • 434-522-0506
  – Email
    • irb@liberty.edu
Questions