Ten Tips for A Perfect IRB Application!

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Lourdes University IRB

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Objectives

- Lists the functions of the IRB
- Review the submission process
- Discuss appropriate information needed for various sections of the IRB application
- State the indications for the use of the exempt versus expedited IRB application
- Recall the IRB application process
- Locate IRB resources on the University website

Tip #1 Complete CITI training

- Why CITI training?
- CITI Training
  - Stage 1 : good for 3 years
  - Stage 2 and 3: good for 3 years
- Keep copy of training certificate
- Advisors and students must be CITI trained

TIP #2 Involve Advisor in the IRB Process

- Advisor responsibilities
- Review signature page
- Electronic signatures are needed

Tip #3 Be familiar with the IRB website

- How to get there
  - http://www.lourdes.edu/academics/institutional-review-board/ or
  - www.lourdes.edu click on academics and click on Institutional Review Board
- Locate Forms
- Getting Started – Questions to Ask:
  - What is research?
  - Are human subjects involved?
  - Is the research exempt versus expedited?

OK- SO IT IS RESEARCH

- ✓Obtain permission from the site where data collection will happen
- ✓Review agency permission
- ✓Use of Lourdes' permission form

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Tip #4 Recall the Belmont Report

Three Basic Ethical Principles:

- Respect for Persons
  - Individual autonomy
  - Protection of individuals with reduced autonomy
- Beneficence
  - Maximize benefits and minimize harms
- Justice
  - Equitable distribution of research costs and benefits

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Tip #5 Look at Decision Trees to Determine Exempt or Expedited

- Review – Exempt, Expedited, or Full Board Review
- Decision - Exempt versus expedited?
  - Go to *"federal regulations"*
    - Click *on decision charts*
  - Go to *"IRB definitions"* – Read about exempt versus expedited
  - Note #6 & 7 under *"expedited"* – MAJORITY of Lourdes University Research falls under these two categories

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Tip #6 Complete All Sections and Summarize Information for A General Audience

- Review the check list
- Summary of the proposed study in professional voice but use terms that are understood by all disciplines
  - Significance of the problem- Gap/problem noted in the literature – cite key references
  - How do you want to proceed with the study?
  - What do you want to find out as a result of the study?
  - Summary denotes that all words have meaning
  - Be concise – unnecessary to fill the entire space

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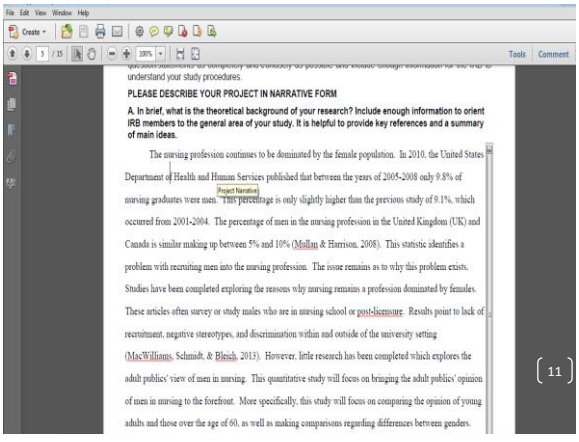

understand your study procedures.

PLEASE DESCRIBE YOUR PROJECT IN NARRATIVE FORM

A. In brief, what is the theoretical background of your research? Include enough information to orient IRB members to the general area of your study. It is helpful to provide key references and a summary of main ideas.

The nursing profession continues to be dominated by the female population. In 2010, the United States Department of Health and Human Services published that between the years of 2005-2008 only 9.8% of nursing graduates were men. This percentage is only slightly higher than the previous study of 9.1%, which occurred from 2001-2004. The percentage of men in the nursing profession in the United Kingdom (UK) and Canada is similar making up between 5% and 10% (Mullan & Harrison, 2008). This statistic identifies a problem with recruiting men into the nursing profession. The issue remains as to why this problem exists. Studies have been completed exploring the reasons why nursing remains a profession dominated by females. These articles often survey or study males who are in nursing school or post-licensure. Results point to lack of recruitment, negative stereotypes, and discrimination within and outside of the university setting (MacWilliams, Schmidt, & Bleich, 2013). However, little research has been completed which explores the adult publics' view of men in nursing. This quantitative study will focus on bringing the adult publics' opinion of men in nursing to the forefront. More specifically, this study will focus on comparing the opinion of young adults and those over the age of 60, as well as making comparisons regarding differences between genders.

Expedited - Continued

- Research questions – in question form
- Research method – what research approach are you using to obtain the data ?
- Setting – where is the research taking place (i.e. where is the data collection occurring)
  - Need permissions, IRB approval from other institutions in order to be in that setting
- Participants
  - Who are they?
  - Why are they chosen?

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Expedited - Continued

- Recruitment of participants
  - How - check the type of communication
  - Process – state where and who the communication comes from,
  - Order of events
- Detailed description of *informed* consent process
  - Written? Implied? Signature waived? When to waive?
  - Email script to serve as " informed" portion of informed consent*
  - Participants must be informed regardless of method
  - Provide Rationale for using a vulnerable group
  - Participants – number, type, ability to give consent
  - Smaller numbers of participants may be associated with more risk to identity

  * See sample email script

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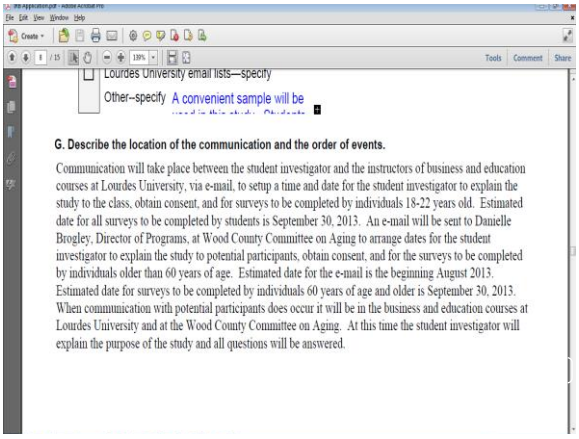

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Other--specify A convenient sample will be

G. Describe the location of the communication and the order of events.

Communication will take place between the student investigator and the instructors of business and education courses at Lourdes University, via e-mail, to setup a time and date for the student investigator to explain the study to the class, obtain consent, and for surveys to be completed by individuals 18-22 years old. Estimated date for all surveys to be completed by students is September 30, 2013. An e-mail will be sent to Danielle Brogley, Director of Programs, at Wood County Committee on Aging to arrange dates for the student investigator to explain the study to potential participants, obtain consent, and for the surveys to be completed by individuals older than 60 years of age. Estimated date for the e-mail is the beginning August 2013. Estimated date for surveys to be completed by individuals 60 years of age and older is September 30, 2013. When communication with potential participants does occur it will be in the business and education courses at Lourdes University and at the Wood County Committee on Aging. At this time the student investigator will explain the purpose of the study and all questions will be answered.

Expedited - Continued

- Data and Consent Collection
  - Methods
  - Instruments/tools for collection
    - Need evidence of permission to use another's tool
    - Or state that the "tool was created by the researcher"
- Identifiers versus non identified information
- Privacy protection and data storage- use of password protected websites, password protected computers
  - Survey Gizmo and Survey Monkey

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Expedited - Continued

- **Risk**
  - Choose risk criteria
  - Potential for deceit, coercion, *peer* pressure
  - Compensation
  - Benefits to participants if any
  - Contributions to general knowledge in the discipline
  - Choose risk category
  - If greater than minimal risk – full IRB review is required
  - 3rd parties – consider presentations, manuscripts, etc. or if participant is harmed then disclosure is necessary but must be stated in the consent form
  - Attach all documents – consent forms, surveys, agency permission forms, CITI training certificate
  - Email to irb@lourdes.edu

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Tip #7 Summarize and complete **Exempt** applications.

- Final determination of the application status rests with the IRB
- Complete exempt category and screening questions – return with application
- Similar to Expedited in that you should be brief but succinct
- Include all requested information – use lay terms
- Attach all documents – consent forms, surveys, agency permission forms, CITI training certificate
- Email to irb@lourdes.edu

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8 Always Proofread

- This means more than spell check

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Tip #9 Attach Appropriate Forms

- E copies
- IRB Application
- Recruitment Flyer/s
- Survey/s
- Agency permission
- Waiver of consent signature if appropriate
- Consent form
- IRB approval letters from other institutions**

** Agreement with ProMedica

Please Note >>>>>>>>>>

Under no circumstances may research begin until the IRB approval letter is received.

Tip # 9.5 Inform IRB for Changes in Protocol/Procedure

- Approval is good for one year
- Approval is for the research protocol as outlined in the applications
  - ***Changes to the protocol can be made by using an AMENDMENT Form found under Forms on IRB webpage***

Tip #10 Remember to complete the closure form

- Necessary to close the project down –for research protocols that required expedited and full board reviews.
  - Project is finished
  - Final of report of adverse events
  - Summary of findings
- Alternative to a closing a research protocol is a Continuing Review: Another form of course!

Service with A Smile Understand the IRB Administrator Process

- Procedure
- Review process
  - Exempt
  - Expedited
  - Full
  - # of reviewers
- Timeline – 7 to 10 Days for review (each cycle)
- Forms
- Notifications/communications- use Lourdes' email system
- Advisor is copied on all emails from IRB

Questions!