Writing a Research Protocol

IRB Forum
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Certain elements must be included in a research protocol

Protocols should outline

- Research Team
- Background and Purpose
- Study Design (Methods, Procedures, Subject Selection)
- Human Subjects (Recruitment, Consent, Risks and Benefits)
- Data management and Security
- Results
First and Foremost

Title

Personnel
Title Page

Include version date on the title page or throughout on header or footer

Title page should include:

- Name of Study
- Name of PI
- Name of Sponsor (if any)
- Important Additional Information (contract #, IND#, IDE#)
Personnel-Research Team Members

List all research team members, their affiliation, and roles.

Assure ALL research team members have completed CITI (this does not need to be in the protocol but should be part of the development process)

Example:

Cortni Romaine   GWU   Consenting   CITI: 05MAY2011
Melissa Ball     GWU   Data Collection  CITI: 12SEP2011
Glen Fuhrmeister NIH   Data Analysis  CITI: 04JUN2012
Personnel-Conflicts of Interest

Detail whether or not any team members have conflicts of interest.

These can include: financial, academic, professional, scientific conflicts of interest.

Refer to GW’s Policy on Conflicts of Interest (see the GW Compliance Website: http://my.gwu.edu/mod/upolicy/index.cfm).
Personnel - Collaborators

List any collaborators on the study.

Collaborators can be institutions, persons or organizations.

Example: We will work with Quest Diagnostics to process the samples.

Indicate whether or not outside IRB approval will be sought by any collaborators (again something to consider during the development process).
Background and Purpose

Specific Aims
Justification
Hypothesis
Specific Aims

List the broad, long-term objectives and describe concisely and realistically what the specific research described in your proposal is intended to accomplish, and the hypothesis to be tested.

- **Example**: What is the impact of standard operating procedures (SOPs) on the rate of MRSA infection?
Justification

Why is this research being done?
What are the knowledge gaps?
What literature is already published?

- Provide the IRB with references to support your planned work.
Hypothesis may be used to examine an outcome.

**Example:** The rate of MRSA detection among students at school district 1 with an established SOP for MRSA will be lower than the rate of MRSA detection among students at school district 2 without an established SOP for MRSA.
Hypotheses

Not all studies will have a standard hypothesis.

Qualitative research may not use hypothesis.
Study Design

Study Type
Subject Population
Methods
Procedures
Study Design

How will you obtain information to test your hypothesis and answer your research question?

- Chart/record review (retrospective)
- Focus groups
- Interviews
- Surveys
- Intervention such as test or drug/device
- Case study
Subject Population

How many subjects will you enroll? How many do you need for calculation? Why did you choose this number?

- Example: Two districts with 6 schools each and two first grade classes with 25 children in each class would mean a potential sample pool of 600 first grade students. The target is to enroll half of those students with equal representation of both districts. Therefore, we anticipate enrollment of 300 students and will cease enrollment when 50% of each district is enrolled.
Subject Population

Include gender, age, race, ethnicity and any vulnerable populations of subjects.

Example: Male and female first grade students will be eligible for this study. No exclusions will be made regarding ethnicity.
Subject Population- Inclusion and Exclusion

Who is eligible for your study and why?

Inclusion criteria: First grade students in School District X and Y.

If excluding any groups, explain why.

- **Example:** Any student above first grade cannot enroll due to previous exposure to closed group environments such as school.
Methods and Procedures

What exactly will you do to obtain information?

- **Example**: Data collection will include reviewing each district’s SOPs and performing nasal swabs on the children.

Be detailed here. Explain as if you are teaching someone how to conduct the study.
Methods and Procedures

Where will the study take place?
Which facilities will be involved? What equipment will be used?

Example: Swabs will be obtained in the school nurse office and transferred to the local laboratory for assay testing. The assay used will be Polymerase Chain Reaction (PCR). PCR is used to detect the presence of MRSA DNA and has a 98.7% detection rate. Results can be returned in 24-48 hours.
Human Subjects

Recruitment
Consent
Compensation
Cost
Recruitment Methods

- How will you inform people about your study? Flyers? Radio ads? Emails?
- How will you identify eligible subjects?
- Will you use a listserv?
- Will you use direct or snowball sampling?
Recruitment Methods

**Example**: Materials will be sent home to parents explaining the study, the purpose and what will be done with the results. Investigator contact information will be included in the packet for additional questions or concerns regarding the study.
Consent Methods

Who will obtain consent from the subjects? Is the person an authority figure? Can they influence the subject?

Where will consent take place? Is it private and allow for a conversation?

**Example:** If both the child and the parent agree to participation, the parent will sign the parental permission and the child will sign the assent. Both will be returned to the school nurse office to be placed in a secure box in order to protect the confidentiality of the child.
Consent Methods

Which type of consent will be used?
- Standard, Waiver of Documentation, Waiver of Consent and why?

Consent should be a conversation and include:
- the nature of the information to be provided to prospective subjects, payment for participation (if applicable), and the method of documenting consent.
Consent Methods

- If enrolling vulnerable populations, outline safeguards to protect those populations.
- Eliminate feelings of coercion or undue influence.

**Example:** Both parents and children will have an opportunity to ask any questions. A demonstration of the swabbing will be included in these meetings. Lack of dissent on the part of the child does not indicate agreement to participate. The child must agree fully and sign the assent in or to enroll in the study.
Will subjects be compensated for their participation?

How will compensation be determined?

How will compensation be distributed?

**Example:** Subjects will be provided with a $20 gift card to Target for their participation. This amount is nominal and not considered coercive.
Cost

Will the subject incur a cost to participate in the research?

Example: There is no cost to the subject in this study.

OR

Example: The subject may incur costs related to study participation such as additional out of pocket expense for prescription medication. The subject should contact their insurance provider to determine whether or not these costs will be absorbed. This information will be included in the consent process and discussed at length with the subject.
Risks and Benefits

Minimizing Risks
Risk/Benefit Ratio
Risks

What risks are there to participation in the study?

- THERE IS ALWAYS A RISK!

Procedures for minimizing risks

Use CABLES model to determine risk

Cognitive
Affective
Biological
Legal
Economic
Social
Risks

Example:

- Discomfort during swabbing.
- Stress over possible positive result.
- Loss of confidentiality.
Benefits

A study may not always have a direct benefit to the subject.

Include how the study may benefit society at large.

Example:

Knowledge regarding the effectiveness of SOPs on the presence of MRSA in schools.

If swab results are positive, steps can be taken to prevent infection.
Risk/Benefit Ratio

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may be reasonably expected to result.

Example: The risk of minor discomfort anticipated by the subject is small in relation to the possible benefit of learning how to better protect school children from infectious diseases.
Data Management

Security and Confidentiality

Analyses

Results
Security and Confidentiality

How will you control who has access to study documents?

Where will the be kept?

What information will you collect?

What do you want to know? What do you need to know?

- Want: Date of Birth
- Need: Age at time of enrollment
Security and Confidentiality

Will you create a code to identify subjects? When will the codelink be destroyed?

**Example:** A codelink will be kept in a password protected database separate from the blinded codes.

Subject coding will be as follows:
School District#1, School #1, Subject #1: 1-1-1
School District#2, School #1, Subject #1: 2-1-1

No other identifying information will be coded. Subject initials, age, or any possibly identifying information will not be included in the code. This codelink will be destroyed after all swab results have been reported.
Data Analysis

Explain statistical analyses.

- Saying that the data will be analyzed by a statistician is not sufficient.

- Will you use SPSS? Will the data be categorized to assess patterns?
What Will be Done with the Results?

Will results be published or presented?
Will they be used to influence guidelines or standards?

- **Example**: This study can help influence the ways schools control infectious disease outbreaks such as MRSA. Knowledge gained may yield further knowledge regarding the effectiveness and impact of SOPs on the presence of MRSA in schools.
What Will be Done with the Results?

- Explain how results will be communicated.
- Aggregate, attributable to subject by name, position, etc?

**Aggregate Example:** Subjects in both groups experienced no additional stress levels beyond those defined.

**Attributable Example:** A supervisor at one school district stated, “District cleaning procedures are adhered to strictly.”

**Attributable Example:** One teacher, Barbara Nichols encouraged pre-enrollment swabbing, “We vaccinate for infectious disease so we should test for MRSA, too.”
Conclusion
Conclusion

Be detailed and use easy to understand words.

If being technical, explain the procedure or phrase.

Give the protocol to a friend or family member to read and provide feedback.

Make sure that IRB application = protocol = consent form.

Make sure that everyone on the research team is trained on the protocol.
And Remember…

A protocol is a living document.
OHR is here to help if you get stuck.
Minimizing risks to subjects is #1 in the eyes of the IRB.
Questions??

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