Conducting Research at WakeMed

A Guide for IRB Submissions

GUIDE FOR WRITING AND SUBMITTING RESEARCH PROTOCOLS
A research protocol is a document which sets out a plan for a research project. A well written protocol works like a road-map. It helps to focus ideas and provides direction to guide a project through all phases of planning, implementation and evaluation of a research activity. The following document should be completed for all investigator and sponsor initiated research projects, including student research projects.

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Title of the Research
[The title should accurately reflect the purpose of the study. Provide the complete full-length title for the study.]

Background
[This section constitutes the scientific justification (rationale) for the study; i.e., the need for the research and how it will contribute to existing knowledge.

- Describe the nature of the problem your project will address and why is it important.
- Describe the scope/magnitude of the problem, including its probable cause, prevalence and distribution.
- Summarize the work others have done in this area, if applicable (Provide a brief bibliographic review of the subject).]

Hypotheses
[A hypothesis is a logical supposition, a reasonable guess, or a suggested answer to a problem. A hypotheses may provide further direction for the research effort by setting forth a possible explanation for an occurrence.

Example of Hypotheses for one study:

- The proportion of immunization rates in children between the ages of 19 and 35 months living in the United States at the time of the National Immunization Survey (NIS) conducted by the Center for Immunizations and Respiratory Diseases (NCIRD) in 2012 will be 90% or higher.]
Research Question
[Research questions are generally used in lieu of hypothesis. Sometimes the use of research questions indicates that the research project is not experimental and does not lend itself to the formulation of hypotheses. The research question is specific as to topic and population.]

Example of a research question for one study:

- Are childhood immunization rates in the United States remaining stable at high levels?

Goal
[This is a concise statement about what you aim to demonstrate by conducting this research project.]

*Example Goal for one study: (*http://www.cdc.gov/nchs/nis/nis_faq.htm#PURPOSE)*

- “The goal of the National Immunization Survey (NIS) is to monitor the immunizations of children across the country.”
- “By monitoring immunization across the country, the Centers for Disease Control and Prevention will be able to assess the extent to which the country, States, and certain metropolitan areas are reaching the immunization goals of the Childhood Immunization Initiative.”

Specific Objectives
[The specific objectives reflect the study milestones to be reached to achieve the primary goal. They should be a concise description of what is to be determined, identified, compared, or confirmed. Each specific objective implies interpretation of the data, and the objectives overall represent the main goal of the study.]

*Example Objectives for one study: (*http://www.cdc.gov/nchs/nis/nis_faq.htm#PURPOSE)*

- “The study will collect data by interviewing households in all 50 States, the District of Columbia, and selected large urban areas. The interviews will be conducted by telephone with households selected by random chance.”
• “The National Immunization Survey (NIS) data will provide current, population-based, State and local area estimates of vaccination coverage produced by a standard methodology. Each quarter, estimates of vaccination coverage levels will be calculated and valid comparisons of State efforts to deliver vaccination services will be made.”

• “As well as evaluating progress towards national vaccination goals, the Centers for Disease Control & Prevention (CDC) will use the NIS data to identify States with the highest and lowest rates.”

• “To assure the accuracy and precision of the estimates, immunization data for surveyed children will also be collected through a mail survey of their pediatricians, family physicians, and other health care providers. The parents and guardians of NIS-eligible children are asked during the telephone interview for consent to contact children’ vaccination providers.”

Study Design & Procedures

[Describe your proposed study design (e.g., randomized trial; conducting a survey; chart review). Describe in order of occurrence, the procedures (e.g. physical exams, blood draw, surveys, interviews etc.) that will be done and by whom. This section should describe how you would accomplish the goals and objectives of the study, and the means by which the data will be collected.]

Methods

[The methods section should describe the steps that will be taken to achieve the goal and objectives of the study.]
Participants

a) [Who will be studied? (Population from which sample will be taken).
b) Include the expected number of subjects to be recruited.
c) Justify the sample size.
d) Describe expected duration of the subject’s participation.
e) Describe inclusion/exclusion criteria.
f) Describe demographics, age, gender, ethnicity, health status (if applicable) and any specific characteristic of the subjects to be recruited.]

Recruitment (Answer all that is applicable to your study design)

a) [How will potential participants be identified and]
b) [By whom (e.g. study coordinator, nurse, student) and where will they be approached for participation? (Procedures that will be used to recruit subjects).]
c) [Describe any relationship that the recruiters have with potential participants other than in their role as staff for the study, and how this will be handled if it might lead potential participants to feel pressure to participate (e.g., in small communities they may be neighbors, friends, or parents with children in the same school)]
d) [Describe recruitment materials (ads, letters, flyers, recruitment script, etc) to be used and if applicable, attach a copy of these materials as an appendix to the protocol.]

e) [If your project falls within one of the exempt categories, you should be prepared to provide the participants with an information sheet/cover letter that describes the following items:]
f) 1. Name and number of PI to contact if the subject has questions.
2. A brief description of the study purpose.
3. A statement that participation is voluntary.
4. A statement that participants may skip any questions they wish to, for any reason. Explain that choosing to not participate will not affect any services which the person is receiving at the study site or for which s/he would otherwise be eligible.
5. Confidentiality considerations.
6. Participation in the survey implies consent.]

[Note: surveys/questionnaires that will be administered by students must include:]

1. The name of the student
2. The student’s class affiliation
3. A description of the curriculum activity that is being fulfilled by the survey.
Survey/Questionnaire Instrument

a) [Submit the survey(s), instrument or interview questionnaire that will be used and describe the instrument including key points such as:

1. Whether it is hard copy, or web-based survey,
2. The rationale for your questions, i.e. why the type of information you are collecting is necessary to achieve the goal (e.g., demographics, feeling, beliefs, health status, diagnosis, opinions, pain management, knowledge, etc).
3. The type of questions (multiple choice, Likert rating scales, open-ended questions)
4. Who designed and/or reviewed the survey prior to submission (did you give this survey to an expert for his/her input, is this a standardized survey for which its validity has already been assessed?)
5. How long you think this survey will take to be completed by each participant?
6. Whether data in the survey will be recorded with or without identifiers (i.e., will the participants be identified directly, will there be a link back to their identity, or will the data be anonymous (i.e. no identifiers, no codes)? If your data is to be coded, describe how the code is derived.
7. If applicable, strategies to get surveys completed and submitted (e.g., reminders letters to return self-stamped envelope with Survey)
8. If applicable, explain that your data is to be collected in the field (e.g., in another country, schools, hospital, etc). NOTE: you cannot change the objective of the survey or significantly alter the questions being asked without IRB approval.]
Procedure

Research Location

[Provide the name and location of the place(s) (description of the area) where the project will be conducted. If your project is conducted in the U.S. but in a place other than WakeMed, describe who will grant permission to conduct the research on the premises of that facility and confirm their authority to do so (e.g. superintendent of schools). Explain that you have obtained a permission letter and provide such letter as an attachment.

If the study is being conducted outside of the U.S., describe the experience of the Principal Investigator and yourself, and if applicable other study staff, that will enable the study to be conducted with appropriate cultural sensitivity.]

Consent process

[If applicable to the Study (i.e. Full Board and or Expedited studies)), describe in detail the process for obtaining consent including elements such as the following:

- When consent will be obtained (e.g., after potential participants have made a phone call to the recruiters in response to a flyer, or in response to a poster/ad)
- Where the consent process will take place, giving consideration to the need for privacy of the subject.
- Who will be authorized to obtain consent from participants?
- The step-by-step process for obtaining consent (e.g., The person obtaining consent will review the information presented in the [information sheet/cover letter or inform consent] with the potential participants, section-by-section; after reviewing the material the participants will be asked if they have any questions, if not they will be asked to summarize their understanding of what enrollment in the study involves. If they cannot do this adequately the material will be reviewed again. If after three tries the potential subject still cannot adequately summarize the information, s/he will not be enrolled).
- The estimated time allotted for discussion, and how it will be ensured that participants must have enough time to consider their decision regarding participation prior to consenting.
- The plans to minimize the possibility of coercion or undue influence during the consent process (ensuring voluntary participation).]
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- If non-English speaking participants are likely to be enrolled, describe plans for ensuring that information in the Consent form or Information sheet is presented in a language understandable to the participants.

Screening for Eligibility:

[If applicable, describe how study staff will screen potential participants to determine eligibility. Describe who will conduct screening for participants. Explain if any screening will be conducted prior to obtaining informed consent. Describe the necessity of this information prior to informed consent. Describe what will be done with identifiable information collected on screened failures (if you are collecting identifiers please review Health Insurance Portability and Accountability Act (HIPAA) in Research For Survey Studies: [Describe in detail how and where will your survey be administered (e.g., web-based, in a classroom, face-to-face, phone, mail). Describe how the survey will be implemented, e.g., the time points at which the procedures occur (How often will participants be contacted, and why).]

Risks

[If applicable, describe any potential risks associated with this protocol/project, and the procedures to protect against or minimize potential risks; consider all types of risk (e.g. physical, sociological, economical, psychological, etc.).]

[Note: the two most common risks, although not the only ones, are that participants may feel uncomfortable answering some questions and that people other than authorized research personnel may see personal information that is collected.]

Confidentiality:

[Indicate how the information obtained from the participants in the study will be kept confidential (e.g., all data will be maintained in (describe storage locations, e.g., a locked cabinet accessible, who will have access to data, hardcopies, electronic data?). How will data be labeled? Identified? Coded? De-identified? For commercially available survey products, describe their confidentiality features.)

[Electronic data on laptop computers must be and stored on password protected files. Describe procedures to continue to protect confidentiality after study closure (how long will information be stored? (e.g. on-going storage and security of hard copy data, electronic records). Describe plans for destruction of all data?]

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Data Analysis

[Analysis of the data collected allows you to determine whether the goal and objectives of the study were achieved.]

[Describe how you will analyze your data or outcome(s), including the methods of analysis and relevant statistical procedures.]

[Are you going to use descriptive statistics or inferential statistics or both?]

[Descriptive Statistics (straightforward presentation of facts) describe the main features (characteristics) of collected data quantitatively. For example summarize sample size, population demographics, clinical characteristics (average age, percentages of males and females in the study, proportion of participants with related diseases or characteristics, etc.).]

[Inferential statistics /analysis of the data: inferential statistics may use the sample data to draw inferences about the broader population from which the sample was drawn. Inferential statistics may be used to estimate the likelihood that an observed difference between groups is a dependable one, or is merely due to chance. The specific statistical procedures to be employed should be selected before collecting the data, based on their appropriateness for providing information relevant to the goal of the study.]

Timetable

[Provide a detailed timetable scheduling all aspects of the research. This will include data collection (e.g. time taken to administer questionnaires, complete interviews, abstract data from charts), analyze data, write reports etc. You may reference an attached flow diagram, including expected start and completion dates, and/or describe the time table here: For example:]

<table>
<thead>
<tr>
<th>Major Research Activities</th>
<th>June, 2011 –– April, 2012</th>
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<td><strong>IRB Approval</strong></td>
<td><strong>June</strong></td>
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<td><strong>Recruitment of Participants</strong></td>
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Budget / Resources
You need to think about what you will need for your research and whether those resources are available to you. The IRB will want to know that you have thought carefully about what resources are needed and from where you expect to obtain these and whether or not a budget workbook needs to be completed. Some types of research are more resource intensive/expensive than others and you will have to consider this when deciding upon your research method.

Dissemination
[Describe how you intend to disseminate the results of your research, e.g. dissertation, presentation, web site, journal article.]

References / Literature Review
[Compile a list of the literature that was cited in this protocol. Each literature citation must include the title, names of authors, book or journal, volume number, page numbers, and year of publication.]

Annexes
[Include flyers/ads used for participants’ recruitment, inclusion/exclusion criteria list, interview instruments (survey/questionnaires), cover sheet/information sheet, or consent form.]

Uploading Your Documents
Now that you've completed your documents, it's now time to upload them into IRBNet for IRB review and approval. If you have not registered with IRBNet, please do so at this time.

IRBNet Registration:
You can obtain registration access by going to the IRBNet website at https://www.irbnet.org. When initially registering on IRBNet, you must identify "WakeMed Health & Hospitals" as your location. This is so you can have access to all of the WakeMed IRB forms.

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To help you gain a better understanding on how to create and upload your package, please review the following Energizers located in Library Manager of IRBNet:

a) IRBNet Training – New Submissions
b) IRBNet Training – Advanced

These Energizers are extremely helpful and will assist you with everything from creating your package through submission.

**NOTE:** If you have not completed the CITI or NIH training on Human Subject Protection, please do so at this time by going to [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php) – this is a requirement for IRB submission. Also, don’t forget to reference the PI New Submission Checklist found on IRBNet Library Manager. This document will assist you in ensuring you’ve submitted all required documents for submission.

***Make sure to download and check off all the required items from the PI New Submission Checklist, which can be found on IRBNet to ensure you have all the necessary documents for IRB review.***

Still have questions please contact IRB Administration at: wakemed_irb_office@WakeMed.org or call (919) 350-8795