Research Protocol Development

2016 Mary Lipscomb Hamrick Research Course

MAJ Amelia M. Duran-Stanton, PhD, DSc, PA-C
Deputy Chief, TMMD

Thermal and Mountain Medicine Division (TMMD)
U.S. Army Research Institute of Environmental Medicine
Natick, MA 01760

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Learning Objectives

• Discuss the military research process
• Identify the requirements for conducting research
• Determine the type of research to conduct
• Identify the components of a protocol
• Identify the IRB requirements throughout the research process
• Identify common pitfalls

DISCLAIMER: The opinions or assertions contained herein are the private views of the presenter and are not to be construed as official or as reflecting the views of the Department of Defense, United States Army, and MEDCOM.
Protocol – why needed?

• A protocol is a detailed written plan of a study
• Forces investigator to clarify thoughts
  – Reveals a plan adequate to answer the questions
  – Identifies the resources and feasibility
  – Provides enough detail to allow another researcher to complete and arrive at comparable conclusion
• Provides a guide for the research team
• IRB requires a protocol with human subjects or experimental animals
• Essential element if requesting funding
What’s needed for military research?

• CITI (Collaborative Institutional Training Initiative) Ethical Research Course (All PIs/AIs)
• Curriculum Vitae (All PIs /AIs)
• Research Protocol
• Consent/Assent forms (aka ICD/ACD)
• HIPAA (Health Insurance Portability and Accountability Act) forms
• Funding request (if applicable)
• Impact Statement (if applicable)
• Summary Sheet
Before Creating Protocol

- DEVELOP A RESEARCH QUESTION
  - Conduct a literature search
  - Identify the type of research design
  - Identify resources needed
  - Network if collaborations are needed
  - Identify your coordinating DCI/IRB
  - Obtain IRB templates
  - Search for funding
Research Question

• What is the problem?
• What are you trying to prove or answer?
• Asking good questions makes clear connections between scientific research and areas where evidence based knowledge is needed for practice
Before Creating Protocol

- Develop a research question
- **CONDUCT A LITERATURE SEARCH**
  - Identify the type of research design
  - Identify resources needed
  - Network if collaborations are needed
  - Identify your coordinating DCI/IRB
  - Obtain IRB templates
  - Search for funding
Conduct Literature Search

- Has your question already been answered?
- What are the gaps in current knowledge or practice?
- Already studies published supporting or refuting your question?
- What are the outcomes associated to answer my research questions?
- What types of methods have been used in other studies?
Before Creating Protocol

- Develop a research question
- Conduct a literature search
- IDENTIFY THE TYPE OF RESEARCH DESIGN
  - Identify resources needed
  - Network if collaborations are needed
  - Identify your coordinating DCI/IRB
  - Obtain IRB templates
- Search for funding
# Research Design Types

## Experimental and Quasi-Experimental Studies

<table>
<thead>
<tr>
<th>Study Design Type</th>
<th>Distinguishing Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Randomized Controlled Trial (Class A)</strong></td>
<td>Investigators manipulates treatment/intervention (independent variable)</td>
</tr>
<tr>
<td>Preferred for therapy and prevention questions</td>
<td>Randomization to groups; always have a control group</td>
</tr>
<tr>
<td><strong>Non-Randomized Trial (Class B)</strong></td>
<td>Investigators manipulates treatment/intervention (independent variable)</td>
</tr>
<tr>
<td>Frequently used for therapy and prevention questions</td>
<td>Always have a control group</td>
</tr>
</tbody>
</table>

## Observational Studies

<table>
<thead>
<tr>
<th>Study Design Type</th>
<th>Distinguishing Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Comparison of 2 or Groups (Class B)</strong></td>
<td>Comparison of existing “convenient” groups getting different interventions or exposures</td>
</tr>
<tr>
<td>Also called prospective cohort; Preferred for etiology, causation, or harm questions</td>
<td></td>
</tr>
<tr>
<td><strong>Single Group Before-After or Time Series (Class D)</strong></td>
<td>Subject serves as own control</td>
</tr>
<tr>
<td><strong>Sensitivity and Specificity of Diagnostic Test (Class D)</strong></td>
<td>Dichotomous (yes/no) outcome comparison with “gold standard”</td>
</tr>
<tr>
<td>Preferred for diagnosis questions</td>
<td></td>
</tr>
</tbody>
</table>
## EPIDEMIOLOGICAL ANALYTIC STUDIES

<table>
<thead>
<tr>
<th>Study Design Type</th>
<th>Distinguishing Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cohort Study (Class B)</strong></td>
<td>Membership based on defining characteristic or factor</td>
</tr>
<tr>
<td>Preferred for natural history and</td>
<td></td>
</tr>
<tr>
<td>prognosis questions</td>
<td></td>
</tr>
<tr>
<td><strong>Case-Control Study (Class C)</strong></td>
<td>“Cases” with outcome identified then “matched” with non-cases (controls) from same population</td>
</tr>
<tr>
<td>Preferred for etiology, causation,</td>
<td>look back for exposure</td>
</tr>
<tr>
<td>or harm questions</td>
<td></td>
</tr>
<tr>
<td><strong>Cross-Sectional Study (Class D)</strong></td>
<td>Outcome (dependent variable) and exposure</td>
</tr>
<tr>
<td>Preferred for diagnosis questions</td>
<td>independent variable) measured at same time</td>
</tr>
<tr>
<td>Used for etiology, causation, or</td>
<td></td>
</tr>
<tr>
<td>harm questions</td>
<td></td>
</tr>
</tbody>
</table>

## DESCRIPTIVE STUDIES

<table>
<thead>
<tr>
<th>Study Design Type</th>
<th>Distinguishing Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Case Series (Class D)</strong></td>
<td>Describe process and outcomes</td>
</tr>
<tr>
<td>No comparisons</td>
<td>prospectively, “natural history” with no intervention</td>
</tr>
</tbody>
</table>
Before Creating Protocol

- Develop a research question
- Conduct a literature search
- Identify the type of research design

**IDENTIFY RESOURCES NEEDED**
- Network if collaborations are needed
- Identify your coordinating DCI/IRB
- Obtain IRB templates
- Search for funding
Identify Resources

- Special equipment for outcome variables
- Software requirements
  - Statistical
  - AOC (Area of Concentration) Specific Analysis
  - Support of Equipment Needs
- Testing provided by another discipline
- Administrative assistance and resources
- Storage cabinet for research files
- Participant incentives
Before Creating Protocol

• Develop a research question
• Conduct a literature search
• Identify the type of research design
• Identify resources needed
• NETWORK IF COLLABORATIONS ARE NEEDED
  • Identify your coordinating DCI/IRB
  • Obtain IRB templates
• Search for funding
Collaboration Networking

- Who do you need assistance from?
- May need another disciplines assistance
  - Protocol design
  - Use of specific equipment
  - Data collection
  - Administrative assistance
  - Funding
  - Statistics
Before Creating Protocol

- Develop a research question
- Conduct a literature search
- Identify the type of research design
- Identify resources needed
- Network if collaborations are needed
- IDENTIFY YOUR COORDINATING DCI/IRB
- Obtain IRB templates
- Search for funding
Department of Clinical Investigation (DCI)

Locations

Madigan AMC
JBLM, WA

USARIEM
Natick, MA

Walter Reed AMC
Bethesda, MD

Womack AMC
Fort Bragg, NC

Brooke AMC/
San Antonio MMC
San Antonio, TX

USARIEM
Natick, MA

Eisenhower AMC
Fort Gordon, GA

Tripler AMC
Honolulu, HI

William Beaumont AMC
Fort Bliss, TX

MAJ Amelia Duran-Stanton / (508)233-4861 / amelia.m.duranstanton.mil@mail.mil

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Before Creating Protocol

- Develop a research question
- Conduct a literature search
- Identify the type of research design
- Identify resources needed
- Network if collaborations are needed
- Identify your coordinating DCI/IRB
- **OBTAIN IRB TEMPLATE(S)**
- Search for funding
Typical IRB Research Templates

• Research Protocol
  – Full
  – Expedited
  – Exempt

• Consent/Assent Forms

• HIPAA Forms

• Impact Statement

• Summary Sheet

• IRB Calendar with Timelines
Before Creating Protocol

- Develop a research question
- Conduct a literature search
- Identify the type of research design
- Identify resources needed
- Network if collaborations are needed
- Identify your coordinating DCI/IRB
- Obtain IRB templates

SEARCH FOR FUNDING
Funding

- Internal department funding
- Graduate Medical Education
- Inter-facility/Other department funding
  - i.e. Lab testing - Impact Letter from department
  - Cost of operating special equipment
- Retired Army Medical Specialist Corps Association (RAMSCA)
- Numerous Special Grants with DoD
  - Telemedicine and Advanced Technology Research Center (TATRC), USAMRMC, Fort Detrick, MD http://www.tatrc.org
  - Congressionally directed DoD research http://cdmrp.army.mil
  - Intramural Applied Research and Advanced Technology Development Awards – Defense health program
- Specific SP Corps AOC resources and organizations
- Other Governmental Agencies
- Henry M. Jackson Foundation http://www.hjf.org/
- The Geneva Foundation http://www.genevausa.org/
Research Protocol Development Form

Name: ____________________________

Research Question:

Study Hypothesis:

Independent (Intervention) Variables(s):

Dependent (Outcome) Variables(s):

Extraneous (Potentially Confounding) Variables (list at least 3):

List inclusion and exclusion criteria for your study:

Inclusion Criteria

1. ________________________________
2. ________________________________
3. ________________________________
4. ________________________________
5. ________________________________
6. ________________________________
7. ________________________________

**Exclusion Criteria**

1. ________________________________
2. ________________________________
3. ________________________________
4. ________________________________
5. ________________________________
6. ________________________________
7. ________________________________

Proposed Study Design (e.g., RCT, cohort, cross-sectional):

Research Protocol Development Form (2)

Name: ____________________________

Sampling method:

Randomization? (If yes, how?):

Proposed Study Measurements (e.g., Hct, P, O2, Pain) **How measured** (ABG machine, VAS, etc.)

1. ________________________________
2. ________________________________
3. ________________________________
4. ________________________________

Post Intervention **When (timing)**

3. ________________________________
4. ________________________________

Are the Primary Study Measurements or Scales Validated? (how?)

Study Size Calculation:

How many patients will you need to perform your study and adequately answer your question?

These calculations generally require information about:

1. The expected rate of the dependent variable in the study population.
2. The percent or amount of difference in the primary outcome measure that would be clinically significant to detect in your study.
3. The desired alpha (usually 0.05) and desired beta (usually 0.1 or 0.2) and anticipated variance in the outcome measure (educated guess, pilot data or from similar studies).

Sample size calculations can be done using computer programs, tables in the Hulley and Cummings text, internet sites or a statistician.

How many study subjects will you need in each group? ________________________________

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MAJ Amelia Duran-Stanton / (508)233-4861 / amelia.m.duranstanton.mil@mail.mil

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Time to develop your Protocol

Let’s get started....
## Final Protocol Format

<table>
<thead>
<tr>
<th>Title</th>
<th>Human Subject Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>Recruitment</td>
</tr>
<tr>
<td>Associate Investigators</td>
<td>Benefits</td>
</tr>
<tr>
<td>Location</td>
<td>Risks</td>
</tr>
<tr>
<td>Research Plan</td>
<td>Safeguarding for Protecting Subjects</td>
</tr>
<tr>
<td></td>
<td>Risk: Benefit Assessment</td>
</tr>
<tr>
<td></td>
<td>Alternatives</td>
</tr>
<tr>
<td>Purpose</td>
<td>Data Analysis</td>
</tr>
<tr>
<td>Hypothesis/Question</td>
<td>Sample Size Estimation/ Power Analysis</td>
</tr>
<tr>
<td>Significance</td>
<td>Duration of Study</td>
</tr>
<tr>
<td>Military Relevance</td>
<td>Funding</td>
</tr>
<tr>
<td>Literature Review</td>
<td>Staff Monitor</td>
</tr>
<tr>
<td>Research Methods/Design</td>
<td>Research Assistants</td>
</tr>
<tr>
<td>Source of Research Material</td>
<td>Investigational Drugs/Devices</td>
</tr>
<tr>
<td>Instrumentation</td>
<td>Bibliography</td>
</tr>
<tr>
<td>Inclusion / Exclusion Criteria</td>
<td>Signature Section</td>
</tr>
<tr>
<td>Number of Subjects</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td></td>
<td>All Associate Investigators</td>
</tr>
<tr>
<td></td>
<td>Department Chief</td>
</tr>
<tr>
<td></td>
<td>Joint Study Investigators</td>
</tr>
<tr>
<td></td>
<td>Appendices</td>
</tr>
</tbody>
</table>

- Recruitment
- Benefits
- Risks
- Safeguarding for Protecting Subjects
- Risk: Benefit Assessment
- Alternatives

- Data Analysis
- Sample Size Estimation/ Power Analysis
- Duration of Study
- Funding
- Staff Monitor
- Research Assistants
- Investigational Drugs/Devices
- Bibliography
- Signature Section
  - Principal Investigator
  - All Associate Investigators
  - Department Chief
  - Joint Study Investigators

- Appendices
### Brooke Army Medical Center
**Department of Clinical Investigation**
**Office of the Institutional Review Board**

**INITIAL APPLICATION FOR RESEARCH EXEMPT FROM INSTITUTIONAL REVIEW BOARD OVERSIGHT**

`Note:` Words that appear in italics and/or red on your screen should be replaced with the appropriate language for your study, used when applicable, and deleted when no longer needed.

You should use this form ONLY if your research falls into one of the exemption categories below. Please consult Form P0 – Protocol Submission Instructions or contact the Office of the Institutional Review Board (OIRB) if you have any questions. Approval under the exempt category permits you to conduct your research in accordance with local policy only; provided the status of your protocol does not change during its conduct. Please consult the BAMC IRB Policies and Procedures for additional information regarding investigator responsibilities during the conduct of exempt protocols.

<table>
<thead>
<tr>
<th>Study Title</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of application: ____________________</td>
<td></td>
</tr>
</tbody>
</table>

#### 1.0 STUDY CONTACTS

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Other Study Contact (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and Degree:</td>
<td>Name and Degree:</td>
</tr>
<tr>
<td>Title:</td>
<td>Title:</td>
</tr>
<tr>
<td>Mailing Address:</td>
<td>Mailing Address:</td>
</tr>
<tr>
<td>Phone Number:</td>
<td>Phone Number:</td>
</tr>
<tr>
<td>Email Address:</td>
<td>Email Address:</td>
</tr>
<tr>
<td>Fax Number:</td>
<td>Fax Number:</td>
</tr>
</tbody>
</table>

#### 2.0 KEY STUDY PERSONNEL (if more space is needed attach additional pages to the end of the application)

List all key personnel including the Principal Investigator (PI) and Other Study Contacts, along with a brief statement of their study role(s) and responsibilities. If more space is needed, attach an additional page to the end of this application. NOTE: Key personnel are persons who have contact with identifiable data or specimens.

<table>
<thead>
<tr>
<th>Key Personnel</th>
<th>Study Roles and Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Study Role(s):</td>
</tr>
<tr>
<td>Affiliated Institute:</td>
<td>Responsibilities:</td>
</tr>
<tr>
<td>Name:</td>
<td>Study Role(s):</td>
</tr>
<tr>
<td>Affiliated Institute:</td>
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</tr>
<tr>
<td>Affiliated Institute:</td>
<td>Responsibilities:</td>
</tr>
</tbody>
</table>
3.0 EXEMPTION CATEGORY

Select the category below that best fits the description of the study. If none of the categories apply and you still believe the study meets exempt criteria, contact the IRB.

The bulk of research approved for exemption locally falls into the first three categories:

a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: 1) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND, 2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. Additionally, survey or interview procedures involving children qualify for exemption only under narrow circumstances.

b. Research involving the study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available, or if the information is recorded by the investigator in such a manner that the subjects cannot be identified directly, or through identifiers linked to the subjects.

c. Research conducted in established or commonly accepted educational settings (e.g., teaching hospital), involving normal educational practices such as (1) research on regular and special educational strategies including those used in medical education, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

d. The remaining exempt activities are rarely invoked locally and include research when elected or appointed public officials are the proposed subjects, taste and food quality evaluations, and research and demonstration projects conducted by federal departments or agencies.

4.0 PURPOSE. List the broad, long-term objectives of the study. (For Example: The purpose of this study is to describe the associations of symptoms of disease X with drug Y.) As much as possible, use non-technical terms.

4.1 HYPOTHESES/RESEARCH QUESTIONS. State the specific hypotheses or research questions you wish to test. For example, a testable hypothesis might be phrased as “There is a statistically significant association between the pain reduction recorded in the chart and the amount of drug X administered.” This is often termed as hypothesis generating research and is perfectly acceptable when the data cannot support formal hypothesis testing.

5.0 SIGNIFICANCE. State concisely the importance and health relevance of the research described by relating the specific aims to the broad, long-term objectives. State the practical application(s). Significance is often demonstrated using numbers affected, cost of care, impact on quality of life, etc. Generally 1-2 paragraphs suffice. If this is an initial study with only a research question, outcomes may not show strong significance directly. For example, “this retrospective data review will provide information to prepare a hypothesis generating study.”

5.1 MILITARY RELEVANCE. With regard to military needs and mission requirements (e.g., Casualty care, Readiness, TriCare), this paragraph should provide a brief and succinct military justification for the research. (e.g., benefit healthcare of military beneficiaries). Generally 1-2 paragraphs suffice.

6.0 BACKGROUND/REVIEW OF LITERATURE. Briefly describe the background leading to the present study. Critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. 3-5 paragraphs are typical. Include more for complex or involved studies. Link all references to the Bibliography section (6.1).

6.1 Bibliography: Generally 5-10 references, with more for complex studies. All references in the bibliography should be linked to section 6.0 Background/Review of Literature, or other portions of this document.

7.0 RESEARCH DESIGN AND METHODS. Use the following subsections to describe how the research will be conducted. In many cases 1-2 sentences for each subheading is sufficient.

7.1 Setting. Briefly describe the locations or institutions of the subjects during the period of interest. Generally speaking, this is the location the raw data will first be generated by the subjects. For example, in a study of medical records it would be the physical location of the patients at the time of diagnosis or treatment. For educational studies list the location of the students at the time they will be studied, and for surveys list the locations the survey will be targeted (e.g., “mailed to the subject’s home”).

7.2 Subjects. Briefly describe the sample population being studied. Use qualifiers for age, sex, beneficiary status, diagnosis, or other descriptors to characterize the sample population. Specify if any special populations (e.g., children, military basic trainees, prisoners, detainees) are included or excluded. Of note, research on prisoners, including detainees, does not qualify under exempt rules.

For example, “all adult patients presenting to clinic XYZ with chest pain,” or “all military casualties, except for detainees, with gunshot wounds treated at field hospital ABC,” or “third-year residents assigned to a ward rotation.” State any relationship the PI or Al has, had, or will have with subjects (e.g., “some subjects were the PI’s patients,” or “subjects are the Al’s residents.”

7.3 Date(s) of Chart Review or Subject Interaction/Intervention. Specify the period of research interest. This should be the dates the raw data were generated. For record reviews, this is the inclusive dates of the medical encounters being studied. For educational and survey studies this is the period of subject involvement.

7.4 Interventions, Observations, or Data Sought. Briefly describe what data (not the source of the data) will be observed. For example, a chart review might seek ‘the blood pressures taken at clinic check-in,’ or ‘the dose of drug X used to treat nausea.’ For an educational study an
Final Protocol Format (BAMC Example)

example might be “Number of XYZ procedures performed by the residents and the corresponding test scores on the written examination.”

7.6 Methods and Measurements: For survey and educational studies, briefly discuss how and when measurements were taken. Discuss the precision and reliability of the measurements, as applicable.

7.6 Data Collection and Processing Briefly discuss who will collect the data and how it will be collected (structured medical record reviews, structured questionnaire, extracted from database). For record reviews, also describe how the data of interest will be identified for possible inclusion. For example “All charts will be manually screened at the end of each day for records of interest,” or “the database will be searched for all records with a diagnosis of chest pain.”

7.7 Outcome Measures: Briefly describe the study’s outcome measures. When possible, use outcomes that have been previously validated, or provide evidence of your own efforts to validate the measure.

7.8 Primary Data Analysis: Briefly describe the proposed primary analysis and state who will perform your data analysis. A statistical consultant is strongly recommended for any studies utilizing more than basic descriptive techniques. In any case the responsible individual should also provide their signature in section 10.4 of this protocol.

7.9 Number of Subjects: Specify the number of subjects (or records, encounters, or observations) that will be enrolled, from each institution specified in section 7.1. Setting. State whether the numbers are exact or estimates. For example, “This study will review records of 50 individuals >50 yrs old and collect all documented blood pressures in the last 24 months in each record. We anticipate collecting 2 blood pressures per chart will be obtained for this study.”

8.0 HUMAN SUBJECT PROTECTION

8.1 Source of Data
If this is a primary record review, specify where the records are located (if paper) or which systems they are stored on (for electronic). Primary records are records used for diagnosis, treatment, and form the legal medical record. They always contain patient identifiers.

If this is a secondary source, specify the database being used (e.g., JTTR, clinic log). Secondary sources contain extracts derived from primary records. Databases are generally compiled for research or administrative (such as billing and coding) purposes. They may or may not contain patient identifiers and this should be specified.

For all record/database studies:

1) Attach a copy of the record abstracting worksheet or specify the data fields examined in the database, and
2) include the statement “Only records or database entries in existence at the time of study approval will be examined in this study. All data will be recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers or codes linked to the subjects.”

If this is a survey or educational study, specify the instrument used to collect the data. Attach a copy as appropriate.

8.2 Benefits: Briefly describe any benefit that may be reasonably expected from the research. If no direct benefits to the subjects, state none.

8.3 Risks: Briefly describe any potential risks in the collection of this data. Virtually all studies at least carry a risk of inadvertent breach of confidentiality and this should be stated explicitly as a minimum. Educational or survey studies may have other risks that should be disclosed.

8.4 Safeguards for Protecting Information: Describe the procedures for protecting against the risks of breach of confidentiality and the provisions for storage and monitoring the data collected to assure the safety of the subjects.

A sample statement might be worded as: “Data collected will be deidentified prior to review and analysis by the investigator. It will be kept on a government computer assigned to the PI. The computer is password and CAC-card protected, and the system is firewall protected. There are no planned linkages with external databases, nor is transmission of the data for collaborative use anticipated. Following completion of the study the data will be stored and destroyed in compliance with policies implemented by the chief, IMD, BAMC.”

9.0 STAFF MONITOR (for resident and fellow projects) - State first and last name, grade, service branch, corps, specialty staff/resident/fellow/visiting, location, department, office symbol, phone and better number of person responsible for monitoring the PI.

10.0 FUNDING. Specify source and amount; if none, so state.

12.0 TIME REQUIRED COMPLETING THE RESEARCH (INCLUDING DATA ANALYSIS): State the number of months or years you anticipate completing this study.

13.0 STUDY CLOSURE PROCEDURES: Describe the procedures to be used to close your protocol. Include final data disposition, including any plans to maintain identification (repository studies), and disposition/location of final documents (including any ICD/HIPAA documents). Mention submission of a Protocol Closure Report.
Research Plan

• **Purpose**
  - List the broad, long term objectives of the study

• **Hypotheses/Research Questions**
  - State the specific hypotheses or research questions you wish to test

• **Significance**
  - State concisely the importance and health relevance of the research described
  - Relate the specific purpose to the broad, long-term objectives
  - State the practical application(s)
  - Significance is often demonstrated using numbers affected, cost of care, impact on quality of life, etc.
• **Military Relevance**
  - With regard to military needs and mission requirements (e.g. Readiness, Tricare, Build Health Communities)
  - Should provide a brief and succinct military justification for the research (e.g. benefit healthcare of military medical care beneficiaries)

• **Background/ Review of Literature**
  - Briefly describe the background leading to the present study
  - Critically evaluates existing knowledge, and specifically identify the gaps that the project is intended to fill
Research Plan

• **Research Design and Methods**
  
  - State in detail how will the research be designed to answer the hypotheses/research questions
  
  - Be very specific as to:
    
    • Who will perform what procedure
    
    • How each procedure will be performed and sequence of the procedure in the overall study
    
    • Be sure to indicate whether or not the specific procedures are “Standard of Care” (would be done even if the subject was not included in the study)
    
    • Define what measurements (operational definitions - independent and dependent variables) the study will evaluate to answer the research question
    
    • Provide information on collaborative efforts and delineate responsibilities among each
Research Plan

• Source of Research Material
  – Obtained from human subjects in the form of specimens, records, or data
  – Lists the variable for data collection
  – Collected as standard care or specifically for research purposes

• Instrumentation
  – For Measurement Equipment:
    • Describe the accuracy and precision of equipment you plan to use to measure the outcome variables
    • May be available in the manufacturer’s brochure
  – For Surveys, Questionnaires or other Psychometric Tools:
    • Include information on the reliability and validity
    • You must also include a copy of your survey/questionnaire as part of this protocol (Appendix)
Research Plan

• Inclusion/Exclusion Criteria
  – Describe the characteristics of the target population, including their anticipated age range, and health status
  – Describe exclusion criteria if based on:
    • Race, gender or age for other than obvious reasons
    • Specific justification for exclusion of these groups is required

• Number of Subjects
  – State the number of subjects from each location
  – Account for expected attrition
Components of a Consent Form

- Principal Investigator
- Description /Purpose of Study
- Procedures
- Risks and Discomforts
- Benefits
- Payment/Compensation
- Alternatives to Participation
- Confidentiality of Records of Study Participation
- Entitlements to Care
- Blood and Tissue Samples
- Voluntary Participation
- Contact Information
  - PI
  - Participant
  - Witness
  - Parent or Legal Rep if minor
- 8th Grade Reading Level
- If minor involved, also need an Assent Form
- Provide phone number for JAG and DCI protocol coordinator
Components of a HIPAA Form

AUTHORIZATION TO USE & DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

• Health information to be used & disclosed...
• What the information will be used for...
• The PI may use and share information with...
• Do not have to sign authorization...
• If change mind after signing...

• Signatures
  – Volunteer
  – Parent/Legal Rep
  – Witness

• Provide hospital Privacy Office Phone Number
CITI Training

Mandatory Research Ethics Training

**Step 1**: REGISTER at [http://www.citiprogram.org](http://www.citiprogram.org)
**Step 2**: SELECT the 4th drop-down menu (“Other”) and choose your institution. Continue to complete the registration form.
**Step 3**: SELECT the type of research you will be involved in (Biomedical, Social/Behavioral) or IRB Member if you are new to your institution’s IRB.
**Step 4**: REVIEW the Instructions Page available on the website for your specific requirements
(NOTE: the requirements for Biomedical, Social/Behavioral and Exempt research are different)
**Step 5**: COMPLETE modules specific your institution’s training site
**Step 6**: COMPLETE the Confirmation of Course Completion, print out the page and click on the submit button.
**Step 7**: NOTICE is automatically forwarded to your IRB of choice from CITI Webmaster. You will receive a Certificate of Completion from DCI via e-mail.

(It will be sent to the e-mail you used to enroll in CITI)
Common Pitfalls

- Not writing down research ideas
- Not properly exploring and developing a research idea
- Not collaborating
- Not paying attention to detail
- Not making all the edits recommended by IRB
- Not consulting with a statistician
- Not having a mentor or not asking for help (‘winging it”)
- Not using the correct/updated forms
- Underestimating time requirement for IRB approval
- Not including pertinent attachments and appendices for recruitment, surveys
- Not having a data collection form
- Not saving or having a good data management system (in case of an audit and manuscript preparation)
- Not having CVs and training requirements completed by all PIs and AIs
References

• Department of Clinical Investigation or Facility Website
  – San Antonio Military Medical Center (SAMMC), Fort Sam Houston, TX
  – Eisenhower Army Medical Center (EAMC), Fort Gordon, GA
    http://www.ddeamc.amedd.army.mil/clinical/Investigation/cipg_institutional_review.htm
  – Madigan Army Medical Center (MAMC), JBLM, WA
  – Walter Reed Army Medical Center (WRAMC), Bethesda, MD
    http://www.wramc.army.mil/Patients/healthcare/dci/Pages/default.aspx
  – William Beaumont Army Medical Center (WRAMC), Fort Bliss, TX
  – Womack Army Medical Center (WAMC), Fort Bragg, NC http://www.wamc.amedd.army.mil/dor
  – Tripler Army Medical Center (TAMC), Honolulu, HI http://www.tamc.amedd.army.mil/default.htm
  – US Medical Research & Materiel Command (USAMRMC), Fort Detrick, MD
    https://mrmc.detrick.army.mil/
  – US Army Research Institute and Environmental Medicine, Natick, MA http://www.usariem.army.mil/

• 2009 Evidence Analysis Library http://www.adaevidencelibrary.com


This concludes the Research Protocol Development slides as part of the pre-workshop for the 2016 MLH research course.

Please review any topics that you may need to repeat. Review the incomplete manuscript using the checklist to determine what is missing. Complete the Research Protocol Development Form based on your research idea(s). We will go over these during our first practical exercise in class.

Write down any questions you may still have so that we can address them in class if needed.

Thank you and see you then. Looking forward to meeting all of you soon!