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# Session 4 and 5

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**Part II: The Research Plan - cont.**

**Part III: Review of Submitted Abstracts**

# **D. Research Design and Methods**

(remainder of the 25 pages - usually 13-16,  
including tables and figures)

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- ▶ **The WHAT and HOW Section**
- ▶ **This section is used to tell the reviewers how you will do each specific aim**
- ▶ **It is important to distinguish the overall research design and the specific methods**
- ▶ **Need to state why your approach was chosen to address the problem**
- ▶ **Be focused and very clear - lead the reviewer**
- ▶ **Show that you really understand the methods you are proposing including the shortcoming of selected techniques**

# How to Write the Research Design and Methods Section

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- ▶ **Summarize specific aims**
- ▶ **Provide research design for each aim - don't repeat. Use general research design if it umbrellas all aims**
  - **What will be done to accomplish the specific aims**
  - **In what population**
  - **How many participants**
- ▶ **Indicate why study design was chosen - match to specific aim**

- ▶ **Describe and/or reference methods**
- ▶ **How the participants will be ascertained and recruited**
- ▶ **How the data will be collected (reference known protocols):**
  - **Exposures and outcomes**
  - **Tools - questionnaires, examinations, use of registries**
  - **How often**
  - **By whom**

▶ **How the data will be analyzed and interpreted**

- **Match to specific aims**
- **Don't leap to most sophisticated statistics**
- **Show understanding of process**
- **Indicate how you will assess for and address confounding**
- **Provide what findings would show the association being studied**

▶ **Include quality assurance methods**

- **Data collection - training, validation studies, laboratory**
- **Data management and analysis**

- ▶ **Include a power/sample size section**
  - **For each aim - show that your proposed study will have the power to address each aim (see association if one exists)**
- ▶ **If proposing new methods - explain why they are better than existing methods**
- ▶ **Discuss potential problems and limitations of the proposed procedures and alternative approaches to achieve the aims -**
  - **State possible problems and how you will deal with them**
  - **What are limitations of *your* design and/or methods - not a shopping list**
  - **Don't provide ammunition to kill your project**

- ▶ **Provide a *summarized* timetable of project (timeline or table with a paragraph is sufficient)**

# **E. Human Subjects – See new rules**

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- ▶ **No page limit but be brief**
- ▶ **Need approval from IRB (Institutional Review Board) before receiving award**
- ▶ **Shows the risks and benefits to participants**
- ▶ **Reiterate the number of participants to be studied and the power this yields to address your aims**
- ▶ **Use decision table to determine Human Subjects category and what needs to be addressed**
- ▶ **Most epidemiologic studies will use Scenario D: Clinical Research**
- ▶ **Use subheadings:**
  - **Protection of Human Subjects: Address all 4 points on NIH application form**
  - **Inclusion of Women and Minorities**
  - **Inclusion of Children**

**Link to Decision Table for Human Subject  
Research, Protection and the Inclusion of  
Women, Minorities, and Children**

# **1. Risks to the subjects**

- **Characteristics of subject population**
  - **How the human subjects will be involved**
  - **Number, ages, health status, gender, race**
  - **Rationale for including any specific vulnerable group - fetuses, pregnant women, children, prisoners, other institutionalized individuals**
  - **List collaborating sites where human subjects research will be performed, and describe the role of those sites**

- **Sources of materials**
  - **Identify sources of material obtained from individually identifiable *living* human subjects – specimens, records, or data**
  - **Specify whether existing material or will gather new material for this research**
  - **Describe the data that will be recorded on human subjects**
  - **Describe linkages to subjects, and who will have access to identities**
  - **State how the specimens, records or data are collected and whether they will be collected specifically for your project**

- **Potential Risks**

- **Physical, psychological, social, legal, other**
- **Assess likelihood and seriousness**
- **Don't give impression that risks exist if not serious**
- **Don't repeat the statements from informed consent**
- **“this study does not involve unusual physical or mental risks to subjects”**
- **If appropriate, describe alternative treatments and procedures, including their risks and benefits**

## **2. Adequacy of protection against risks**

- **Recruitment and consent procedures**
  - **Briefly describe how subjects will be recruited and consented (parental permission and child assent)**
  - **Circumstances under which consent will be sought and obtained**
  - **Who will seek consent**
  - **Nature of information provided to prospective subjects**
  - **Method of documenting consent**
  - **State whether IRB has authorized a modification or waiver of the consent elements or the requirements for documentation of consent**
  - **No need to include consent form**

- **Protection against risks**
  - **Procedures to protect against or minimize potential risks, including risks to confidentiality, and assess their likely effectiveness**
  - **Procedures for monitoring data collected to ensure subject safety**
  - **“All data and patient records will be confidential”**
  - **If no serious risks are involved “every effort will be made to minimize risks due to ... according to established medical practices (see Methods section) and procedures developed by our Institutional Review Board”**
  - **If great risk is involved, provide details for prevention and treatment in Methods section**

### **3. Potential benefits of proposed research to the subjects**

- **What are the potential benefits to subjects and others**
- **Why risks are reasonable in relation to benefits**

### **4. Importance of knowledge to be gained (benefit to society)**

- **Discuss importance of the knowledge to be gained**
- **Be concise in stating that the risk/benefit ratio for this study is appropriate**

# Inclusion of Women and Minorities

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- ▶ **NIH policy is that women and members of minority groups must be included in all of their sponsored research which involves humans**
- ▶ **State whether women and minorities will be included and to what extent**
  - **How many or what proportion**
  - **Use NIH Targeted/Planned Enrollment table**
  - **Recruitment process and rationale in terms of the scientific objectives and proposed study design**
  - **If excluded - provide convincing rationale**
    - **See examples on pages 15 and 16 of Supplemental Instructions for Preparing Human Subjects Section of Research Plan**

**(<http://grants.nih.gov/grants/funding/phs398/HumanSubjects.pdf>)**

# Inclusion of Children

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- ▶ **NIH policy is that children (defined as people under 21) must be included in all of their sponsored research which involves humans.**
- ▶ **Create section called Inclusion of Children**
  - **State whether children will be included or if not, why not (see examples)**
  - **Why certain age ranges are included or excluded**
  - **If included -**
    - **Expertise of personnel to work with children**
    - **Methods appropriate to children (forms, etc.)**
    - **Number sufficient to make meaningful contribution**

## Targeted/Planned Enrollment Table

**This report format should NOT be used for data collection from study participants.**

**Study Title:** \_\_\_\_\_

**Total Planned Enrollment:** \_\_\_\_\_

<b>TARGETED/PLANNED ENROLLMENT: Number of Subjects</b>			
<b>Ethnic Category</b>	<b>Sex/Gender</b>		
	<b>Females</b>	<b>Males</b>	<b>Total</b>
Hispanic or Latino			
Not Hispanic or Latino			
<b>Ethnic Category: Total of All Subjects *</b>			
<b>Racial Categories</b>			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
<b>Racial Categories: Total of All Subjects *</b>			

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

# **F. Vertebrate Animals**

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- ▶ **No page limit but be brief**
- ▶ **State whether any of the research involves vertebrate animals - not usually in most epidemiologic studies**
- ▶ **If it does, needs approval from Institutional Animal Care and Use Committee (IACUC)**

## **Address the 5 points:**

- 1. Detailed description of the proposed use of animals species, strains, ages, gender, number (use general terms)**
- 2. Justify**
  - **Use of animals, choice of species, number to be used**
  - **Best justification is that particular study cannot be done in vitro or simulated by computer model**
  - **Use scientific, not economic reasons for choice of animal**
- 3. Describe veterinary care of animals**

**4. Describe procedures to minimize animal's discomfort, distress, pain and injury (Discuss use of analgesics, anesthetics, tranquilizers, comfortable restraining devices)**

**5. Describe euthanasia methods**

- **Give reasons for selection**
- **State whether methods are consistent with recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, justify.**

# **G. Literature Cited**

**(6 pages although no page limit)**

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- ▶ **Contains all cited references**
- ▶ **No more than about 75**
- ▶ **Minimize references used to support statement but without critical comment**
- ▶ **Cite current literature - shows that you are familiar with current work in field**
- ▶ **Don't just read abstracts - read entire manuscript (abstracts may be incomplete or misleading)**

▶ **Need to include:**

- **Full title of paper**
- **Names of all authors**
- **Book or journal, volume number, page numbers and year of publication**

▶ **Check to make sure complete correspondence**

- **Every citation in text is in list**
- **Every citation in list mentioned in text**

# H. Consortium/Contractual Arrangements

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- ▶ **Involves two or more institutions and investigations**
- ▶ **Detail the arrangement between you and collaborating organization - - programmatic, fiscal and administrative**
- ▶ **Be clear that the consortium arrangement satisfies a specific need and supports research otherwise impossible to complete**
- ▶ **If the contracted work is a significant portion (i.e., majority) of the overall project, you will need to explain why the monies should be granted to you and not the other investigator. If not obvious, assure reviewer that you will have a major role in the project.**

- ▶ **State that the administrative personnel of each organization are aware of the Public Health Service (PHS) consortium grant policy and are prepared to establish the necessary interinstitutional agreements consistent with that policy.**
- ▶ **Provide copies of written agreements or letters (signed by PI and authorized official of collaborating organization)**

# I. Consultants

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- ▶ **List all consultants and collaborators, whether or not you are paying them**
- ▶ **Here is where you put letter from each person, confirming his/her role in project**
- ▶ **Don't forget to put biographical sketches with the others**

# Appendices

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## ▶ Samples:

- Questionnaires
- Relevant manuscripts ( $\leq 10$  reprints, accepted papers, abstracts)
- Established experimental protocol

## ▶ Make sure that:

- Publication is of good quality (don't hand draw figure)
- Mentioned in text
- Important contribution

- ▶ **Don't use it as an extension of the 25 page limit**
- ▶ **Keep in mind that only assigned readers will get the appendices - need to submit 5 copies**
- ▶ **Nice to add cover sheet to each appendix summarizing content and reason for its inclusion**

# Common Mistakes and More Tips on Abstract

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- ▶ **Too much background**
- ▶ **Add a statistic re: significance of problem**
- ▶ **Lack of specificity in methods**
  - **Study design**
  - **Numbers of participants**
  - **No statement of how exposures or outcomes will be ascertained**
  - **Analysis not driven by aims**