Break it Down to Build it Better

Part II

Tips and techniques not found in grant writing guides
<table>
<thead>
<tr>
<th>Important versus Urgent</th>
<th>Important</th>
<th>Urgent</th>
<th>Not Urgent</th>
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<tr>
<td>Important and urgent</td>
<td>- Crises</td>
<td>- Preparation and prevention</td>
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<tr>
<td></td>
<td>- Pressing problems</td>
<td>- Values clarification</td>
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<td></td>
<td>- Deadline-driven projects, meetings, preparations</td>
<td>- Planning</td>
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<td></td>
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<td>- Relationship building</td>
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<td>- Empowerment</td>
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<tr>
<td>Important but not urgent</td>
<td>- Interruptions, some phone calls</td>
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<td>- Some mail, reports</td>
<td>- Trivia, busywork</td>
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<td>- Some meetings</td>
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<td>- Many proximate, pressing matters</td>
<td>- Time wasters</td>
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<td>- “Escape” activities</td>
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</table>

First Things First by Steven R. Covey, 1994
Workshop Agenda

• Review of timelines and discussion of Item 2 on prework
• Specific Aims page
• Flow Diagrams
• Develop flow diagrams for your proposed study
• Variations of flow diagrams
• Organizing your Research Strategy
• Study timelines
• Lunch
• Personnel Planning
  – What it is
  – Examples
• Work on personnel planning/budget (Budget/resources checklist)
• Tables and Figures
• Writing from the reader’s perspective—Edge review video and discussion
• Workshop evaluation (Plus/Delta)
Review of timelines and prework
Specific Aims
Specific Aims

• Vital part of the proposal
• Reviewers need to like your idea by the time they finish reading your aims
• Aims page provides an overview of entire project
• Needs to persuade reviewers that your project is important, that yours is the right team to do it, and that it will advance the state of the science
• Must be carefully written, clear, and concise

## Powerful Aims Grid

I have conducted a literature review and can document this aim:

<table>
<thead>
<tr>
<th>Example: Makes substantive advances in study design (separate from population, measurement approaches, length of follow-up, and setting)</th>
<th>AIM 1</th>
<th>AIM 2</th>
<th>AIM 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
<td>No</td>
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</table>

1. Is entirely novel; the association of the exposure with the outcome have never been studied.

2. Makes substantive advances in study design (separate from population, measurement approaches, length of follow-up, and setting)

3. Addresses an association that has not previously been studied in this population and there are substantive reasons for research focused on this population.

4. Advances the approach for measurement of key exposure(s).

5. Advances the approach for measurement of outcome(s).

6. Advances the approach for measurement of key covariates, confounders, or effect modifiers.

7. Applies a more appropriate or advanced approach to data analysis and modeling.

8. Will achieve superior power (compared to prior studies) for assessing a primary association (exposure to outcome).

9. Will achieve superior power/precision for assessing other associations (effect modification, prediction, etc.).

10. Makes other meaningful improvements to the current state of knowledge (please explain in annotation, e.g. longer follow-up, more complete retention of subjects, important novel setting, etc.).
Flow Diagrams
Flow Diagrams

• Combination of techniques borrowed from process engineering and Information Technology
• Uses standard set of 6 symbols to capture the flow of a study (plus 1 optional)
• Why do flow diagrams?
  – Linear, step-by-step logic; helps organize thinking
  – Identifies areas needing clarification
  – Serve as framework for budget development
  – Provide framework for writing narrative (good clue as to how to organize your research strategy section)
  – May or may not use in the proposal (the thought process is the most important element)
Flow Diagram Symbols

- Event, activity, or outcome
- Connector
- Decision point: Yes or No
- List or document
- Outcome Measure (optional)
- End point

Indicates direction of flow
Examples of Flow Diagrams
Project Overview

NC-DPH Community Oral Health Focus Group Project

Pre-Phase I

Final report issued July 2007

Phase I

Questionnaire design and validation

Enroll 600 women

Complete and analyze minimum of 500 questionnaires

Propose multiple intervention strategies

Phase II

Use stakeholder groups to determine top two

Develop detailed interventions, pilot and evaluate

Phase III

Final recommendations
Subclinical Hypothyroidism and Risk for MI and Stroke (ancillary study to WHI observational study using stored specimens)

WHI Observational cohort

Incident MI Cases (800)

Incident Stroke Cases (750)

Controls Subcohort 3,200

Serum sent to ancillary study site

Test TSH levels

Within normal limits?

Test Free T4 and TpoAB levels

Within normal levels?

Record data

Ancillary site sends data to CCC

CCC integrates into ancillary studies database

CCC pulls variables as requested by ancillary study site

CCC sends integrated data set to ancillary site

Ancillary site conducts analyses and publishes manuscripts

Ancillary site sends ancillary site data files containing requested variables

Ancillary site adds data from their TSH testing

Ancillary site sends integrated data set to CCC

Ancillary site conducts analyses and publishes manuscripts

CCC sends de-coder list that links serum barcode with study ID to ancillary site
Validation of Enzymatic Cell Separation using Laser Capture Microdissection so that you can use resultant cells for later studies

Laser Capture Microdissection

Freeze tissue in cryomolds

Fix tissue in formalin

Dissect cryostat sections

Enzymatic digestion process

Cells separated

Stroma

Epithelium

Freeze viable cells for future use

Store

Measure whatever

Store

Measure whatever

Compare using appropriate methods

Freeze viable cells for future use
Acquire animals

Animals arrive

Acceptable? no → What now?

Acceptable? yes → Animals caged; given food and water

Experimental groups

Knockout Strain A (8-10 per group)

- Control diet
- Chow diet
- Ethanol diet

Wild type (8-10 per group)

- Control diet
- Chow diet
- Ethanol diet

Feed diet for 3 months

Animals sacrificed; livers harvested

Livers fixed in formalin and embedded in paraffin

Livers sectioned and stained

Conduct whatever tests

Data stored for analysis

Knockout Strain A (8-10 per group)

Wild type (8-10 per group)
Developing your flow diagrams
Hybrids of flow diagrams and other cartoons
Randomized Non-inferiority Clinical Trial of Drug X versus Drug Y for Condition A Complicating Pregnancy

**Recruitment and Enrollment**

**Eligibility Criteria**
- Condition A
  - Blood level of Y < some value
  - No contraindications to Drug X
  - 6th to 19th weeks

**Dietary Counseling**
- Supplies for self-monitoring provided
- Self-monitoring taught

**Routine Prenatal Care**
- Study visit with each clinic visit to assess tolerability, side effects, blood levels, Maternal blood draw at XX weeks

**Randomization Process**
- 2:1 Drug X to Drug Y

**Drug X Group**
- Total of XX women enrolled

**Drug Y Group**

**Outcome Measures**

**Primary**
- Noninferiority of Drug X versus Drug Y comparing % LGA

**Secondary**
1) Maternal weight gain between enrollment and XX weeks; maternal weight retention at X weeks postpartum
2) Neonatal anthropometrics
3) Maternal and fetal inflammation

**Delivery**
- Umbilical cord blood
- Neonatal information
- Neonatal exam and anthropometrics

**Post Partum Follow-Up**
- Maternal weight
- Infant exam and anthropometrics
- 2 YEAR FOLLOW-UP Maternal weight
- Infant/child anthropometrics
Figure 2. Information Flow and Process for Responding to a TORFP

**Feasibility**
- Preliminary look at available population (Carolina Data Warehouse for Health [CDW-H], review of clinics, etc.)
- Combine availability with participant burden of specific protocol
- Use Matrix A to estimate degree of recruitment and retention difficulty
- Estimate attrition
- Estimate participant reimbursement

**Technical and Business Proposals**
- TASK ORDER ARRIVES
  - UNC CCTN team establishes common understanding of protocol
  - Deconstruct protocol into participant visits, activities per visit, labs, etc.
  - Total staff time required (Sum)
  - Estimate non-clinic related staff time required
  - Associate clinical visits and activities with staff time
  - Yes
  - Associate activities with costs, etc.
  - Generate activity-based budget
  - Review budget and finalize
  - Yes
  - Protocol final
  - Protocol finalization process

**CRMS**
- UNC CLINICAL RESEARCH MANAGEMENT SYSTEM (CRMS)
- Associate activities with costs, etc.
- Generate activity-based budget
- Review budget and finalize
- No
- Protocol final
- Protocol finalization process

**IRB**
- UNC IRB submission process
- Review
- Approved?
- Yes
- Study initiation
- No

* See Abbreviations Table at beginning of document
Recruit

Enroll

Randomize

Intervention arm

Usual care arm

Data collection at months 0, 3, 6, 12: weight, HOMA-IR, blood pressure, pregnancy status, measures of wellbeing, functioning, and behaviors

Months 1 - 6
Weight loss period

Months 7 - 12
Maintenance period

12-month internet program, videos, CHW* visits and telephone calls, ongoing follow-up visits and calls

Intervention arm

* CHW = Community Health Worker

* CHW = Community Health Worker

Figure 4. Intervention and Data Collection Points
Figure X. Flow of Study

- Pre-Pregnancy Intake Interview N=2,100
- Pregnancy Reported N=1,200
- Negative pregnancy test
- Positive pregnancy test
- Completing daily diary

Weeks gestation: -10 -8 -6 -4 -2 LMP 2 4 6 8 10 12 14 16 18 20 22 24 26 28

Birth
Gestational diabetes

Hyperglycemia, increased GWG

Short term adverse outcomes in infants (accelerated growth, infant adiposity)

Long term adverse outcomes in childhood (obesity and diabetes)

Predisposition to adult obesity

Pregnancy (Females)

Mothers

Subsequent pregnancy

Long-term adverse outcomes (obesity, T2DM)

Increasing BMI over time

Increased amounts of postpartum weight retention

Infants

START

Gestational diabetes
Figure 3. Schematic of XXXXXXX XXX XXXXXX intervention and assessment time points.

Legend:
- Home-based assessment
- Lactation Consultant visit
- Home visit with tailored visitation plan
- Telephone assessment
- Newsletter
- Texts-emails – 1 per week
Peer review of flow diagrams
Organizing your research strategy
Organizing your research strategy

• Look at your flow diagram(s)
• Did you do a separate flow diagram for each specific aim?
• If yes, consider organizing your research strategy by specific aim
• If no, and you did a single flow diagram for the entire study, consider organizing your research strategy by your study design as a whole
Organizing by Specific Aims

- Background and significance
- Preliminary research
- Innovation
- Approach
  - Specific Aim 1
    - Overview
    - Recruitment
    - Methods
    - Analysis plan (include power calculations)
  - Specific Aim 2
    - Overview
    - Recruitment
    - Methods
    - Analysis plan (include power calculation)
- Limitations and mitigation strategies
- Summary/future directions
Organizing by Specific Aims

• Significance
• Innovation
• Approach
  – Specific Aim 1
    • Introduction
    • Justification, feasibility, preliminary data
    • Research design (include power calculation)
    • Expected outcomes (or could be statistical analysis)
    • Potential problems and alternative strategies
  – Specific Aim 2
    • Introduction
    • Justification, feasibility, preliminary data
    • Research design (include power calculation)
    • Expected outcomes (or could be statistical analysis)
    • Potential problems and alternative strategies
• Summary and future directions
Organizing by study design as a whole

• Significance
• Innovation
• Approach
  – Preliminary studies
  – Research design and methods
    • Overview of study design
    • Data collection
    • Quality control procedures
    • Statistical analysis and power calculations
      – Aim 1
      – Aim 2
      – Aim 3
• Study timeline
• Study limitations and mitigation strategies
• Summary/future directions
Study timelines
### Figure 6: Study Name Study Timeline

<table>
<thead>
<tr>
<th>Study Activities</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finalize protocol, IRB revisions, CATI modification *</td>
<td>J-M</td>
<td>A-J</td>
<td>J-S</td>
<td>O-D</td>
<td>J-M</td>
</tr>
<tr>
<td>Web- &amp; phone-based development and testing †</td>
<td>A-J</td>
<td>J-S</td>
<td>O-D</td>
<td>J-M</td>
<td></td>
</tr>
<tr>
<td>Hire and train additional study staff</td>
<td>J-S</td>
<td>O-D</td>
<td>J-M</td>
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<tr>
<td>Develop additional pre-pregnant recruitment materials</td>
<td>O-D</td>
<td>J-M</td>
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</tr>
<tr>
<td>Active enrollment of participants</td>
<td>J-M</td>
<td>A-J</td>
<td>J-S</td>
<td>O-D</td>
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<td>Conduct baseline interviews and ultrasounds</td>
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<td>Conduct first trimester interviews (13 weeks)</td>
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<tr>
<td>Follow-up pregnancy outcomes &amp; abstract records</td>
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<tr>
<td>Clean and compile data</td>
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<tr>
<td>Analyze data</td>
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<tr>
<td>Prepare and disseminate results</td>
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* Activities to begin as soon as funding decision is announced.
† Beta-test scheduled for Summer 2005.
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<td>Hold Focus groups</td>
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<td>Develop questionnaires</td>
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<td>Recruit study population/administer questionnaire</td>
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<td>Data collection</td>
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<td>&quot;Tooth Day&quot; events</td>
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**Bold italics and X denote milestones**
<table>
<thead>
<tr>
<th>Establish study infrastructure</th>
<th>10-15 dyads per month, March 2011-2013</th>
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<tr>
<td>Data analysis</td>
<td>Intent-to-treat  Causal inference  Cost</td>
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<td>Manuscripts and follow-up grant</td>
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<tr>
<td>Dec 2010</td>
<td>Dec 2011  Dec 2012  Dec 2013</td>
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Tips for timelines

• Simple is better
• Plan time for study start-up
• Use a legend; label appropriately
• Refer to the figure number in the text and give some information about it
• Use gray scale and patterns; may or may not be printed in color by recipient
• Ensure your narrative matches the timeline
Develop your study timeline
Personnel planning
Flow diagram for example of personnel planning
(Study involving human subjects)

Approach potential participants and explain study

End

No

Interested?

Yes

End

No

Eligible?

Yes

Signed consent?

Yes

96 participants enrolled

Baseline interview Week 1

Interview 2 Week 4

Interview 3 Week 8

Interview 4 Week 12

End participant data collection

How many interviewers will you need over what time period?
Assumptions for example

• Assume you can enroll between 12 to 16 women a week
• Total of 96 participants, each with 4 interviews
• Each interview takes 2.25 hours
• 864 hours total, but how do the interviews and associated times distribute?
Example of personnel planning  
(Study involving human subjects)

<table>
<thead>
<tr>
<th>Activity</th>
<th>Month 11</th>
<th>Month 12</th>
<th>Month 13</th>
<th>Month 14</th>
<th>Month 15</th>
<th>Month 16</th>
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<tbody>
<tr>
<td></td>
<td>W1 W2 W3 W4</td>
<td>W1 W2 W3 W4</td>
<td>W1 W2 W3 W4</td>
<td>W1 W2 W3 W4</td>
<td>W1 W2 W3 W4</td>
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<td>12 16 12 16</td>
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<td>12 16 12 16</td>
<td>12 16 12 16</td>
<td>12 16 12 16</td>
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<td>12 16 12 16</td>
<td>12 16 12 16</td>
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<td>Total # interviews per week</td>
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<td>28 28 28 24</td>
<td>32 24 16 24</td>
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<tr>
<td>x 2.25 hours per interview</td>
<td>27 36 27 63</td>
<td>63 63 63 54</td>
<td>72 54 36 54</td>
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<td>36 27 36 27</td>
<td>36 27 36 27</td>
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</table>
How many lab personnel should you plan for?
Personnel planning
(Animal study)

Assumptions

Daily activities (7 days/week)
Feed, water, maintain takes 2 minutes per animal x 60 animals (in single cages) = 120 minutes/day or 2 hours/day, 7 days/week = 14 hours/week
Feed ethanol to 10 Knockout Strain takes 2 minutes per animal x 10 animals = 20 min/day x 7 days/week = 140 minutes/week or 2.3 hours/week
Feed ethanol to 10 Wild type takes 2 minutes per animal x 10 animals = 20 min/day x 7 days/week = 140 minutes/week or 2.3 hours/week

Weekly activities
Collect blood and urine samples takes 20 minutes per animal x 30 Knockout Strain 1 = 600 minutes/week or 10 hours/week
Collect blood and urine samples takes 20 minutes per animal x 30 Wild type = 600 minutes/week or 10 hours/week

One-time activity
Sacrifice and harvest takes 15 min/animal x 30 Knockout Strain 1 = 450 minutes or 7.5 hours total
Sacrifice and harvest takes 15 min/animal x 30 Knockout Strain 1 = 450 minutes or 7.5 hours total
Personnel planning  
(Animal study)

<table>
<thead>
<tr>
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<th>Month 4</th>
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<td>Wk6</td>
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<td></td>
<td>Wk17</td>
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<tr>
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Personnel Planning (Animal Study)

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<td>Wk2</td>
<td>Wk3</td>
<td>Wk4</td>
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<tr>
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<td>2.3</td>
<td>2.3</td>
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<td>2.3</td>
<td>2.3</td>
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<td>30 Wild type blood and urine</td>
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<td>Sacrifice and harvest</td>
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<td></td>
<td>7.5</td>
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Person hours/week | 26.3 | 38.6 | 38.6 | 38.6 | 38.6 | 38.6 | 38.6 | 38.6 | 38.6 | 19.8 | 7.5 |

<table>
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<tr>
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<td>Feed and maintain 7 days/week</td>
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<tr>
<td>Feed ethanol to 10 Wild type</td>
<td>2.3</td>
<td>2.3</td>
</tr>
<tr>
<td>30 Knockout Strain 2 blood and urine</td>
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</tr>
<tr>
<td>30 Wild type blood and urine</td>
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</tr>
<tr>
<td>Sacrifice and harvest</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Person hours/week | 46.1 | 43.8 | 38.6 | 38.6 | 38.6 | 38.6 | 38.6 | 38.6 | 38.6 |

Conduct experiments in series or in parallel?
Validation of Enzymatic Cell Separation using Laser Capture Microdissection so that you can use resultant cells for later studies

How many lab personnel should you plan for?

Tissue samples

Laser Capture Microdissection
- Freeze tissue in cryomolds
- Dissect cryostat sections

Enzymatic Cell Separation
- Fix tissue in formalin
- Enzymatic digestion process

Cells separated

Stroma
- Freeze viable cells for future use
- Store
- Measure whatever

Epithelium
- Freeze viable cells for future use
- Store
- Measure whatever

Compare using appropriate methods
Personnel planning
(Lab-based study)

Assumptions

50 tissue samples for the Laser Capture Microdissection (LCM) technique
50 tissue samples for the Enzymatic Cell Separation (ES) technique

Freeze tissue and dissect cryostat sections (LCM) takes 30 minutes total time x 50 samples = 1500 minutes or 25 hours
Fix tissue and conduct ES process takes 20 minutes x 50 samples = 1000 minutes or ~17 hours (16.6)

Measure A takes 10 min/sample x 100 samples = 1000 minutes or ~17 hours
Measure B takes 15 min/sample x 100 samples = 1500 minutes or 25 hours
Measure C takes 5 min/sample x 100 samples = 500 minutes or ~8 hours (8.3)
Separate viable cells from 100 samples and store takes 15 min/sample x 100 samples = 1500 minutes or 25 hours
# Personnel planning

## (Lab-based study)

<table>
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<tr>
<td>Fix and conduct ES</td>
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<td></td>
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<tr>
<td>Measure A (all 100 samples)</td>
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<td></td>
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<td>Measure B (all 100 samples)</td>
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<td></td>
</tr>
<tr>
<td>Measure C (all 100 samples)</td>
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<td></td>
<td></td>
<td></td>
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<td>Separate and store</td>
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<td></td>
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<tr>
<td>Analyze and compare</td>
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<td>33</td>
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<tr>
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<tr>
<td>Freeze and dissect</td>
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<tr>
<td>Fix and conduct ES</td>
<td>17</td>
<td></td>
<td></td>
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<td>Measure A (50 samples)</td>
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<td>Measure B (50 samples)</td>
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<td></td>
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<td>Measure C (50 samples)</td>
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<tr>
<td>Separate and store</td>
<td>12.5</td>
<td>12.5</td>
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<td></td>
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<tr>
<td>Analyze and compare</td>
<td>??</td>
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<td></td>
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<tr>
<td>Person hours/week</td>
<td>33.5</td>
<td>29</td>
<td>38</td>
<td>16.5</td>
</tr>
</tbody>
</table>
Subclinical Hypothyroidism and Risk for MI and Stroke (ancillary study to WHI observational study using stored specimens)
Personnel Planning
(Ancillary Study or Secondary Data Analysis)

Follow same approach as lab-based example
- Identify procedures
- Estimate number of minutes each procedure takes
- Multiply number of minutes by number of times that procedure will be done
- Divide by 60 to get hours
- Repeat for each different procedure
- Place in spreadsheet and calculate hours per week (or month)

Personnel implications
Programmer—how much time and when?
Statistician—how much time and when?
Who extracts the data?
At what cost?
Who builds and maintains the data dictionary?

- Learn the database
- Finalize/locate data you want
- Will you have to derive any variables?
- If so, how will you do this?
- Will you need to do any data cleaning?
- What and how?
- Extract the data
- Create Analysis data set
- Run analyses
- Interpret
Tips for personnel planning

• Most people underestimate time
• If your planning window is 3 months or more, use 4, 4, 5 weeks in a month
• 40 hours is typical work week; use no more 75% of that for planning (Why?)
• 2080 hours in a year; 1040 in a half-year; 520 in a quarter
• 160 in a month with 4 weeks; 200 in a month with 5 weeks
• Full time equivalent (FTE) is person who works 40 hours a week
• Need to consider skill sets required (can same person do everything?)
• For the budget justification, you will need to calculate calendar months for each person
Budget and resources checklist
Personnel planning for your study
Tables, graphs, and figures
Tables versus graphs

• Graphs
  – Immediate impact
  – Good for showing trends/patterns or highlighting differences between two sets of data

• Tables
  – More precise and exact
  – Use when individual or summarized values are more important than trends
Tables

• Can present qualitative or quantitative data
• Can contain words, symbols, numbers, or a combination
• Allow side-by-side comparison of data
• Good for presenting large amounts of information too cumbersome or confusing to place in main text
Tables should...

- Draw attention to the information and not the table itself
- Have clear and concise titles
- Stand alone without need for repeatedly referring to main text (but do refer to the table in your text)
- Contain data deserving to be in a table rather than in the main text
Table components

- Title
- Column headings
- Row headings (stubs)
- Data fields
- Footnotes
- Spanners (optional)
General rules for format and alignment

• Left justify row headers (stubs)
• In data fields, left justify words, right justify whole numbers
• Data fields with symbols such as decimals, plus/minus signs, slashes, hyphens, or parentheses should align in those elements
• Text in row headings that wraps to a second line should align with the top line of that row heading
Tips for tables

• Create a format for your tables and use it consistently
• Create each table as its own document; use placeholder in document, then copy and paste tables into main document
• Incorporate title and footnotes into table itself
• Number tables and figures independently, in the sequence in which they appear
• Do not split a table over two pages
• Keep your tables small
Reference for previous six slides

http://www.clinchem.org/cgi/collection/guidetowriting

http://www.ncsu.edu/labwrite/res/gh/gh-tables.html
# Examples of Tables

Table 3. Patient population served in 2009 and 2009 at UNC MFMU sites

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<td>61</td>
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<td>76</td>
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* Includes institution and all affiliated clinics and practices
** Includes military coverage
Examples of Tables

Table 1. UNCCH Clinical trials by phases FY 2010-2011-2012*

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</tr>
<tr>
<td>Phase IV</td>
<td>14</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Other</td>
<td>63</td>
<td>63</td>
<td>59</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>289</td>
<td>284</td>
<td>269</td>
</tr>
</tbody>
</table>

*Estimates based on available data
Figures

• Visual representations
  – Graphs, diagrams, photos, drawings, schematics, maps, etc.
• Refer to figures within the text
• Avoid using a sentence that gives the reader no information other than directing them to the figure
• Number tables and figures independently, in the sequence in which they appear
• Any figure should be sufficiently clear, well-labeled, and described by its legend to stand alone and be interpretable
• Strive for simplicity
• If using color, be sure everything is readable if printed in grayscale
• Incorporate the legend and footnotes into the figure itself if at all possible, particularly if using PowerPoint
• Construct each figure as its own document, use a place holder in text, then copy and paste
Figure 2. Prevalence of Preconception Risk Factors by Race and Ethnicity

- At-risk drinking
- Smoking
- Obesity
- Diabetes
- Frequent mental distress

AI/AN = American Indian/Alaskan Native
Example 2: Figure

Figure x. Major Anticipated Outcomes of the XXX Program

- **Increased number of investigators brought into environmental health**
  - Bring together investigators with expertise in environmental sciences and health with those from other disciplines

- **Engagement of communities in NC and Mexico**
  - The COTC core will work with the NC and Mexico communities to increase awareness of environmental issues of concern

- **Translation and dissemination of health promoting decision making**
  - Formation of outreach sessions and development of new materials for health-promoting decision making

- **Young scientist career development**
  - Increase junior investigator(s) connection to the environmental health science community through increased publications and scientific discussions
WHI-OS Participants
N = 93,676

Total Stroke Cases
N = 1,050

Total Cohort Members
N = 93,676

Exclusions:

<table>
<thead>
<tr>
<th>N</th>
<th>Exclusions</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>Blood sample unavailable</td>
<td>2,693</td>
</tr>
<tr>
<td>286</td>
<td>History of medication use that modify thyroid measures</td>
<td>24,629</td>
</tr>
<tr>
<td>8</td>
<td>History of MI or stroke</td>
<td>119</td>
</tr>
<tr>
<td>26</td>
<td>History of CABG/carotid endarterectomy</td>
<td>60</td>
</tr>
<tr>
<td>0</td>
<td>Race/ethnicity data incomplete</td>
<td>278</td>
</tr>
<tr>
<td>0</td>
<td>Did not participate after baseline</td>
<td>380</td>
</tr>
</tbody>
</table>

Eligible Cases
N = 675

Selected Cases
N = 675

Random selection

Selected Cohort
N = 3,200

Exclusions:

<table>
<thead>
<tr>
<th>N</th>
<th>Exclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>No lab measures</td>
</tr>
<tr>
<td>9</td>
<td>Overt thyroid Disease</td>
</tr>
<tr>
<td>16</td>
<td>Sub-clinical hyperthyroidism</td>
</tr>
<tr>
<td>6</td>
<td>Negative follow-up time</td>
</tr>
</tbody>
</table>

Final Case Group
N = 639

Final Cohort Group
N = 2,927
Example 4: Figure

Figure 3. Organizational Chart for Proposed CCTN Site

Leadership Team

Center for Women’s Health Research
Tracey Conrad, Business Coordinator
Carol Lorenz, Grant Manager

Gretchen Stuart, MD, MPHTM
Principal Investigator

Co-Investigator
Amy Bryant, MD, MPH

Project Coordinator
Suba Narasimhan, MPH

Research Assistant
TBN

Study Implementation Team

Pool of Research Assistants
ObGyn Perinatal Research Group
MFMU
TraCS
University Targeted Staffing

Consultants and Experts

Protocol Evaluation and Development Team

VANDERBILT UNIVERSITY MEDICAL CENTER

R session 2 v5.1
Common frustration with Power Point documents

Figure 3. Organizational Chart for Proposed UNC CCTN Site

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VANDERBILT UNIVERSITY MEDICAL CENTER

R session 2 v5.1
Writing from the reviewer’s perspective

• Science **must** be high quality
• Know your audience
• Much of the quality of a proposal pertains to the way you present your science
  – Write clearly and succinctly
  – Use active voice wherever possible
  – Provide context for the reader
  – Connect your ideas within sentences and paragraphs, then between paragraphs and sections
  – Present a logical argument
  – Do not make your reader “hunt” for information
  – Pay attention to formatting
  – Leave white space on the page
  – Insert tables and figures to break up dense text
An appropriate saying  
(attributed to various famous people)

• If you want me to talk for an hour, I’m ready now
• If you want me to talk for 30 minutes, I’ll need two days to prepare
• If you want me to talk for 10 minutes, I’ll need a week to prepare
• The same is true for writing clearly, logically, and succinctly; it takes time and thought
Resources

• Figures and tables
  – http://abacus.bates.edu/~ganderso/biology/resources/writing/HTWtablefigs.html
  – http://www.plosone.org/static/figureGuidelines.action

• Work breakdown
  – Gregory T. Haugan; Effective work breakdown structures. Vienna, Va; Management Concepts (2002)

• Project management (and other techniques)
  – http://www.mindtools.com/

• Writing effectively
  – Phillipa J. Benson and Susan C. Sliver, What Editors Want (2013)

• NIH Resource
  – Open Mike http://nexus.od.nih.gov/all/category/open-mike/ (updates on NIH extramural funding)
Brief evaluation
Plus/Delta
Thank you
and good luck
with your proposal writing