RESEARCH PROJECT DEVELOPMENT

Developing a clear, concise statement of the research question that you wish to answer and setting a clear intention for how you wish to solve it are foundational to developing a fundable project. In this document, you will find a series of initial questions to ask regarding both general project formulation and study design:

Research question(s):

* Can you state the question(s) to be answered briefly and concisely?
* Is your question one for which you can identify a potential source of funding?
    (1) What organization(s) are calling for proposals in your area of interest?
    (2) Do you know an experienced investigator(s) who may have similar interests or can you find one?

Specific Aim(s):

*Prepare a brief statement of how you will attempt to answer the question(s):
    (1) Which subjects?
    (2) What will be measured?
    (3) What experimental procedure will you use for measurement?
    (4) Will your study involve systematic treatment of human or animal subjects?
* Identify what is the "primary aim," which is a "secondary aim" and which are "exploratory aims."
* For each of the aims, what are the main outcomes that you hope to observe? It can be helpful to write your outcomes, just as you wrote your aims.

Background and significance:

*Why is this question(s) important enough to deserve investigation and funding?
    For clinical questions:
        Who does the problem effect?
        What does it cost?
        If the questions are answered what would be the impact on clinical practice?
    If this is a mechanistic question:
        What therapeutic or disease process is the mechanism relevant to?
        What is already known about the mechanism?
        If the questions were answered how would that advance our understanding of the therapeutic or disease process?
    If this is a health utilization question:
        What new information will be generated?
        How might that new information effect teaching, practice or professional development of SI?

*What research has already been done that is relevant to the question?
*What research is there on the intervention and the measures that you propose to use?

The following outline is a guide for designing clinical trials:

Study design:

*Write a brief statement which answers the following questions:

(1) Will subjects be divided into two or more groups that will be treated differently?

(2) What will be the time frame of treatment for each group?

(3) What data will be collected from each subject

(4) When will data be taken? How frequently and how many times?

* Build a study flow diagram - this is a block diagram showing flow of study subjects from recruitment through to the last data collection point.

Subjects, recruitment, screening, enrollment, treatment assignment.

*Who will be the subjects? For humans, what type of person are you seeking?

(1) e.g. Foot pain and no foot pain? Shoulder pain and no shoulder pain?

(2) Specific disease or disorders?

(3) How will they be recruited and contacted?

*What will be the participation criteria?

(1) Who will you include?

(2) Who will you exclude?

(3) How will you screen them to determine eligibility to participate? Questionnaire?

*How and who will handle the enrollment process?

(1) Will they be remunerated for participation?

(2) If there is more than one treatment group, how will participants be allocated to the interventions/treatments being compared? For example, you might randomly assign enrollees

*Who performs treatment assignment?

* Are some investigators blind to treatment assignment?

Intervention:

* What treatments, interventions or experimental procedures will be used?

* Define the treatment, intervention or experiment specifically enough that it could be reproduced by another; include specification of any equipment used.

* Who will deliver or implement the intervention?

(1) What are minimum qualifications for individuals implementing intervention?

(2) Do they require training specific to the study prior to giving intervention?

(3) Who will train?

* What is the schedule for treatment?

(1) How frequently?

(2) What is duration of individual treatment?

(3) What is the duration of series of treatments?

Outcomes:

* What data will be collected? At what point in the study flow?

* What questionnaires or instruments will be used?
    (1) How do you know that questionnaires produce data that is valid and reliable?
    (2) If you are using data collection instruments that have not previously been studied for reliability and validity, describe plans to pre-test your questionnaire.
* Who will collect each type of data?
    (1) Will they be blind to treatment allocation?
* Who will record and store data? How?
* Who will monitor data for quality and security?

Analysis:
* Sample sizes; how did you decide how many subjects to include?
* How will randomization sequences be generated?
* What tests for significance of primary, secondary, exploratory outcomes?
    * intent-to-treat? what method for treating missing endpoints?
* Are analysts blind to treatment assignment?

Subject safety:
* What are the risks of participating in this research?
* What measures will be taken to minimize risk?
* How will safety be monitored?
    (1) Collection of safety data?
    (2) Assessing significance of safety data?
    (3) Which oversight bodies will be utilized:
        (a)Independent Monitor
        (b) IRB
        (c) Data Safety Monitoring board
        (d) Funding agency
* How will serious adverse events be treated?

The following outline is a guide for designing case series reviews:

Study design:
*How are the cases available?
*Are you proposing a retrospective review of existing records?
    (1) Where do the records originate from?
    (2) Who wrote them?
    (3) How have they been stored?
* Are you proposing a prospective series review of ongoing cases.
    (1) Who writes the records?
    (2) How are they stored?
*How are cases selected from among those available?
    (1) Will all available cases be included?
    (2) Will cases be selected at random?
    (3) Will a particular type of case be selected?
*What are primary, secondary and exploratory outcomes expected from review of these

cases?
* What outcome data is available in the records?
*Build a study flow diagram – this is a block diagram showing study flow, beginning with selection of cases, continuing through data extraction and ending with analysis of outcomes.

Case selection, records management:
* Will selection of cases be random or will all cases within a calendar period be taken?
*Are cases screened against entry criteria?
(1) For example, are you looking at characteristics of subjects - age, BMI, diagnosis?
(2) Likewise, what are exclusionary criteria?
* How will personally identifying data for each subject be deleted?
(1) Who will take care of personal data deletion?
(2) Are there any other concerns regarding identity being discerned?
* How and by whom are the records stored?

Data extraction:
* What data is extracted?
* Who does the extraction?
(1) Are extractors blind to certain information in the cases?
(2) If there are multiple extractors, how are disagreements resolved?

Data quality:
* How and where are research copies of case stored?
* Who monitors integrity of the research copies, and of the extracted data?

Analysis:
* Sample sizes; how do you justify how many cases are included?
* Generation of randomization sequences if used
* Outcomes
(1) What tests for significance of primary, secondary, exploratory outcomes?
(2) What was the intended goals of the treatment?
(3) What method will be used to treat missing endpoints?
* Are analysts blind to some recorded information?

Animal study design guidelines to be added in the future.
Mary has contact….