

WRITING A RESEARCH PROPOSAL

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Preliminary Questions

- **What is the specific question?**
- **Is the idea novel?**
- **Do your resources (i.e. facilities, equipment personnel, patient population, time, motivation) make this a realistic project for your centre at this time?**
- **Is the answer of sufficient importance?**
- **What funding agency is most appropriate?**

Initial Steps

- Do a thorough literature search
- Visit “Research Roadmap” at dept Ob/Gyn homepage
<http://meds.queensu.ca/medicine/obgyn/research/course2004.htm>
- Enlist support of Supervisor / Mentor and Collaborators
- Meet to devise a research protocol

Remember

Win - Win

- **When you approach prospective collaborators remember that their enthusiasm will be proportional to their anticipated gain (mentorship, authorship, equipment, resources)**

The Mentor

Role

- Role Model
- Support and Encouragement
 - moral
 - financial
 - resources

Your Mentor's Rewards

- Your successes
- Your efforts lead to presentation or publication (co- authorship)



Collaborators

Roles

- Share work
- Provide essential
 - Knowledge
 - Skills
 - Resources



Collaborators' Rewards

- Funding or equipment
- Co-authorship

Who are the reviewers for your grant application?

- 1) Relaxed knowledgeable government employees**
- 2) Professional grant reviewers hired by CIHR or other granting agencies**
- 3) Busy clinicians who have just finished a long day at the office**

**You must convince the reviewers that
your research is important!**



**On second thought, I will approve your application
for funding of the optical heat-ray research**

The Title

➤ Make it specific and captivating

“An alternative means to detect osteoporosis”

VS.

“Osteoporosis : A rapid inexpensive office screening test for early detection ”

Hypothesis

- **Should be clearly stated in one or two sentences**
- **Do not make reviewers look for it**

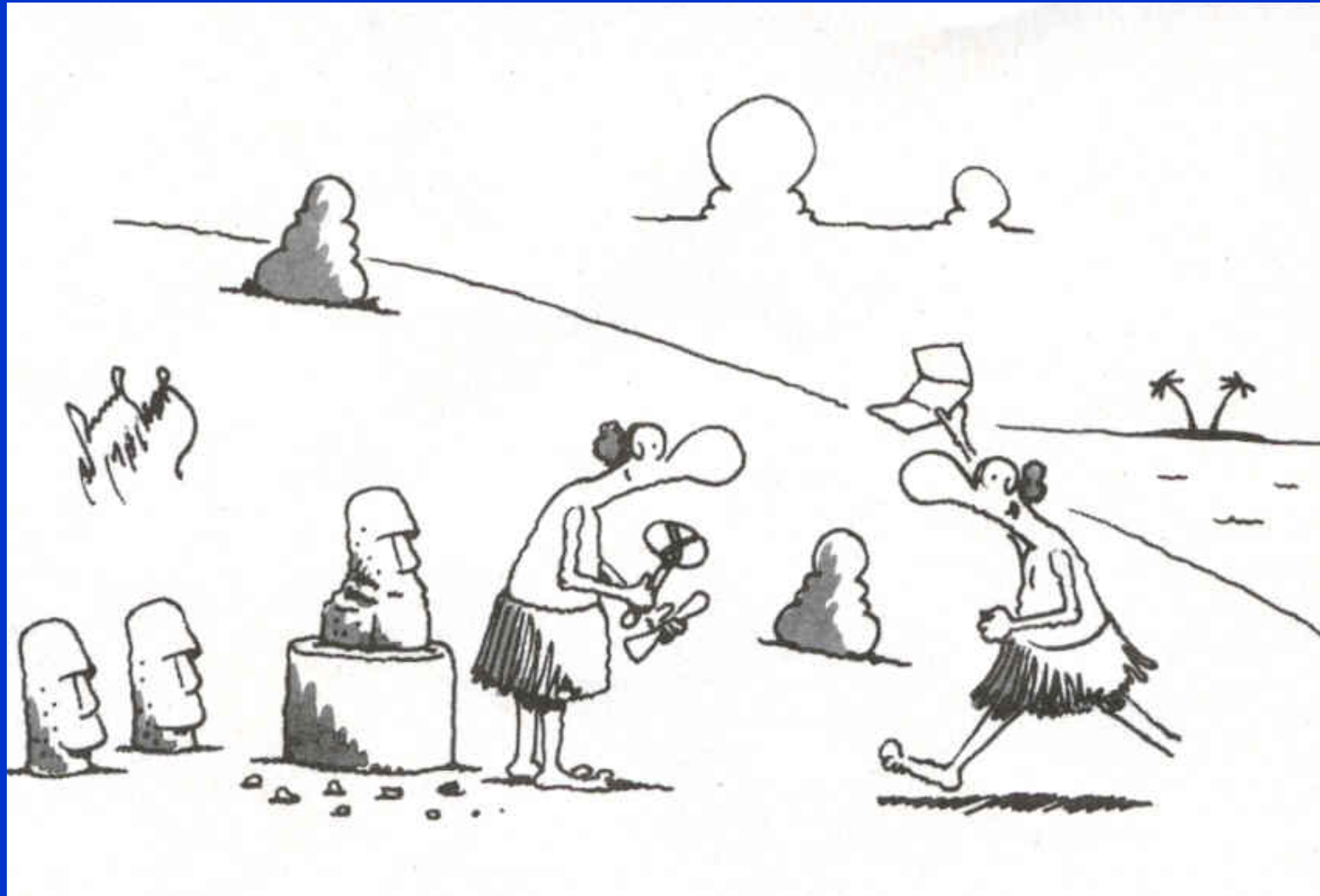
Objective

- **Define one or two specific objectives**
- **Do not try to answer too many questions**
 - **(most important problems are answered one question at a time)**

Background

- **Your opportunity to convince the reviewers that you are up-to-date and conversant in your field of enquiry**
- **Concise, thorough, well referenced review**
- **Preliminary data may strengthen your proposal**
- **Should lead to the logical conclusion that your proposed question needs to be answered !!!**

Preliminary data often allow you to take a little idea and get funding to turn it into a big project



Good news!
The tourist board approved our funding

References

- **Include full reference**
 - **Author, title, vol., pages, year**
- **Reviewers have been chosen for their critical thinking ability and will seldom accept a statement contrary to their own perception without determining your source of information**

Research Design

Describe

- **Facilities and resources**
- **Study population**
- **Methodology**
- **Sample size determination**
- **Data management**
- **Statistical analysis**

Budget

- **Must be reasonable, itemized, justified**
- **Document expenses with copies of proposed charges, maintenance contracts, etc.**
- **Give degree of overlap with other grants (either submitted or funded)**



For any aspect of the proposal that you can not accomplish by yourself you must establish the fact that you have the necessary collaborations to succeed

- **Establish collaborators' experience and credibility with letters of support and CVs**

Your Curriculum Vitae (CV)

- **Should emphasize the training and experience of investigators**
- **Should not be embellished (peer reviewed publications important)**
- **When you first create a CV have another researcher critically review your method**

Ethics Review and Consent

Needed for human clinical research

OR

Research employing human tissues

“The institution within which the researcher works has the major responsibility to ensure that the research meets the ethical standards of society”

MRC Guidelines on REBs

REB Structure and Composition

Eg.

Lay Member

Epidemiologists

Ethicist

Statisticians

Theologians

Medical staff members

Sociologists

**Applied health
professionals**

Consensus development (minority opinions)

**Report to Senior Administration of Hospital /
University**

Factors In Ethics Review

- **Scientific and ethical review should be married**
- **Subject recruitment must not interfere with other doctor -patient relationships**
- **Sample size is critical for statistical validity**
- **Informed choice**
- **Compensation vs. coercion**

Consent Form I

- Lay language
- Reason for the study
- What specifically is being tested
- Why was the subject selected
- What exactly is required of participants

Consent Form II

- **Potential risks / potential benefits**
- **Anonymity**
- **Right to decline or withdraw**
- **Who to contact if concerns**
- **Copy for patient**

Special Ethical Concerns

- **Pediatric / Incompetent patient**
- **Epidemiological studies (data bank origin)**
- **Proxy consents (i.e. confused AIDS patient)**
- **Studies in pregnant women**
- **Fetal tissue use**
- **Multi – centre drug trials**

Summary Page :

sets the stage for a positive review

- **Summarize** hypothesis, objectives, methodology and data analysis concisely on one page – Most reviewers begin with such a capsule summary
- Tell them the **impact / significance** of your proposal as they are usually asked to evaluate this

Simple but often overlooked errors in grant preparation

- Do not exceed allowable **page limits**
- Limit **appendices** to essential documents
- Use bold **easy to read type**
- **Typos and grammatical errors** indicate sloppy preparation or inattention to detail which may reflect upon the investigators' research skills
- Avoid **bad xerox copies**

*Proof read carefully to
see if you any words out*

Anonymous

Font size too small

Regular exercise is reported to reduce the severity of PMS for several hours following activity but clearly is not a cure-all for PMS unless the level of exercise is sufficient to induce amenorrhea.

Dietary changes that have been reported to alleviate PMS are reduction in caffeine (known to be a stimulant contributing to anxiety and sleep disturbance), alcohol, as well as salt and refined carbohydrates. A small snack mid-morning and mid-afternoon may minimize the impact of impaired cellular glucose uptake in women with PMS.

Clearly the degree of medical intervention needs to be tailored to the severity of symptoms. Where symptoms are multiple but of moderate severity a range of non specific treatment options are available.

Vitamin B6 100 mg daily has been shown to alleviate premenstrual symptomatology in many (but not all) controlled clinical trials. At these doses there need not be concern about peripheral neuropathy that has been reported with higher daily doses of vitamin B6/ Non steroidal anti-inflammatory drugs, such as mefenamic acid, taken in a dosage of 500 mg t.i.d. in the premenstrual and menstrual week, have been shown to reduce premenstrual and menstrual symptomatology. Danazol 200 mg daily throughout the month has been shown to reduce both menstrual bleeding and premenstrual symptomatology whereas luteal phase danazol may be effective for premenstrual mastalgia. Simple supplementation with calcium carbonate has been reported to alleviate premenstrual symptomatology slightly more than placebo and may be a simple, inexpensive intervention where symptoms are mild.

Oral contraceptive could be considered individuals who require contraception, particularly if dysmenorrhea or heavy menstrual flow are major contributors to the overall summations of symptomatology. Women presenting with severe PMS on the oral contraceptive pill should probably consider a trial of an alternative form of contraception since the contraceptive steroids may accentuate PMS in some individuals.

Where specific symptoms predominate, symptom specific therapies may be appropriate. For severe anxiety or sleep disturbance alprazolam 0.25 mg b.i.d. or triazolam 0.25 mg qhs respectively may be helpful. Estrogen withdrawal has been linked to menstrually-related migraines and estrogen supplementation with a 100 ug transdermal estrogen patch or the acute administration of 1 mg estradiol sublingually at the time of migraine aura may be helpful to avert menstrual migraine.

Women with significant edema of their extremities who do not benefit by a reduction in salt or refined carbohydrates may benefit from a potassium-sparing diuretic such as spironolactone 100 mg daily.

Bad Xeroxing Job

...response of men and women to the
Case histories have provided insight into subgr
An unusual cluster of events may spark suspicion
a therapy is harmful to a subgroup of people.
example, the surprising occurrence of vaginal ca
in a group of young women led to the implicatio
diethylstilbestrol as the causative agent in the da
ters of women who had taken the drug during p
nancy.²⁷

More formal approaches to observational stu
include many epidemiologic methods, the phase
postmarketing study, and outcomes research.²⁸
pharmaceutical industry is currently studying new
approaches designed to expedite and improve the res
of drug-development activities. Such approaches
include pharmacokinetic screens and the use of su
rate end points for pharmacodynamic measures.
Other approach is meta-analysis, a set of technic
or combining data from various studies.²⁹ Data fr
various demographic subgroups can be pooled ac
many studies to provide more information on tre
ment effect than is available from a single trial.

An armamentarium of methods to learn about s
group responses to therapy is available and must
sed. Research designs and analytic techniques m
e appropriate to the specific questions being ask
and data must be collected that will ultimately be u
l in sorting out the relations between sex, hormo
atus, and response to therapy. A global soluti
ch as the one proposed in the NIH Revitalizati
ct, cannot provide the answers to complex and v
d questions about the effects of therapy on wome
In summary, neither adherence to quotas in t
mposition of a study cohort nor the irrational exc
on of a subgroup of people can be supported scient
ully. Determining the number of women to be i
ided in a trial should reflect reasonable hypothes
out the relation of treatment efficacy to sex, n
bal rules about the composition of study cohort

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Reference numbers cut off during xeroxing

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