



Wie schreibe ich einen Forschungsantrag
How to write a protocol

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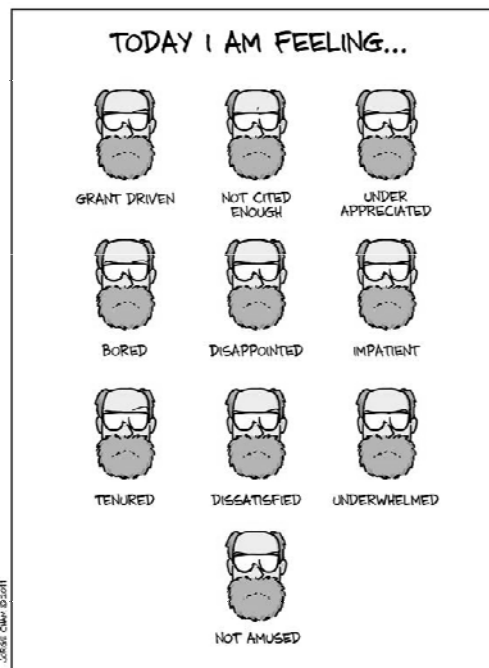
<http://www.skillsandethics.org/about/>

After attending this course you should ...

- ▶ Have an idea why grants are written
- ▶ Know which information you should have before starting
- ▶ Know the development process of a grant
- ▶ Be able to start ...

▶ 2

WS 2011/12



▶ 3

▶ 4

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Frame of mind

Preparing a grant protocol...

allows you to focus on something beautiful: your future

gives you the chance to get feedback from colleagues and reviewers

provides you with text for future publications

is an opportunity



Outline

- ▶ Developing the concept: ask the right question
- ▶ Who is going to pay? The grant agencies
- ▶ Ensure collaboration and support
- ▶ Presentation of the proposal
- ▶ Discuss your prior work/Pilot study?
- ▶ Technical questions: Preparing, submitting, responding

1. Developing the concept: ask the right question

- ▶ Is the concept strong enough?
- ▶ Does the study fill a gap in knowledge?
- ▶ Is it important? (to whom?)
 - ▶ Burden of illness
 - ▶ The research community
 - ▶ Costs of research vs. Benefits
 - ▶ Research fashion



2. Who is going to pay? Types of grant agencies

- ▶ Local, community, intramural
- ▶ Industry, pharmaceutical companies
- ▶ Foundations
- ▶ National organizations
- ▶ International organizations

2. Who is going to pay? The grant agencies

- ▶ <http://www.foerderdatenbank.de/Foerder-DB/Navigation/Foerderrecherche/inhaltsverzeichnis.html>
- ▶ <http://www.dfg.de/foerderung/programme/index.html>
- ▶ <http://www.bmbf.de/de/1398.php>
- ▶ http://www.stifterverband.org/stiftungen_und_stifter/stiftungen_suche/index.html
- ▶ <http://cordis.europa.eu/fp7/dc/index.cfm>
- ▶ <http://ec.europa.eu/research/participants/portal/page/calls>
- ▶ http://grants.nih.gov/grants/funding/funding_program.htm

More about funding sources

- ▶ Objectives of the funding agency?
- ▶ Instructions of the funding agency?
- ▶ Communicate with program staff:
 - ▶ Topic relevant to the agency?
 - ▶ Instructions for grant application
 - ▶ Evaluation criteria
 - ▶ Percentage of funded proposals
 - ▶ Level of funding, maximum grant sum
 - ▶ Two-level submission? Screening procedure? Letter of intent necessary?

3. Ensure collaboration and support

- ▶ Inform supervisor, chair of department, contact person of institution
- ▶ Finance?
- ▶ Secretary?
- ▶ Someone to read your proposal and give advice?
- ▶ Collaborators you want to involve?
- ▶ Do you need letters of intent? Statements from the ethics review board?

4. Presentation of the proposal: outline

- ▶ Title: a statement of your long term goals
- ▶ Abstract: simple, accurate, interesting, contains key words
- ▶ Research plan
 - ▶ Objectives (5%)
 - ▶ Background & Significance (10-15%)
 - ▶ Pilot Data
 - ▶ Methods/Approach (55-60%)
- ▶ Budget

4. Presentation of the proposal: Background

- ▶ We have a problem
- ▶ It is an important problem
- ▶ Here is what has been done to address the problem
- ▶ Here is the key issue that remains unanswered
- ▶ This is our objective

Fear of heights is considered a variant of specific phobias according to the Diagnostic and Statistical Manual of Mental Disorders [1]. A prospective study reported the prevalence of fear of heights to be 4.9% [2]. There is, however, a continuum extending from acrophobia to stimulus-dependent height intolerance (also called height vertigo), which does not fulfill the diagnostic criteria of a specific phobia [3]. The prevalence of this individual susceptibility has not yet been determined, although its disabling impact on daily life and sport activities is obviously

▶ A

4. Presentation of the proposal: Objectives

- ▶ Most important section!
- ▶ Well focused, fully conceptualized, realistic
- ▶ Not overly ambitious

“The proposed study will test the hypothesis that the **efficacy for reducing illicit drug use and improving buprenorphine adherence** of physician management (PM) plus cognitive-behavior therapy (CBT) is greater than PM alone during the initial 12 weeks of maintenance treatment, and during 12 weeks of followup.”

- ▶ Write the specific aims

Inouye SK, Fiellin F. 2005

... specific aims ...

4. Presentation of the proposal: Methods

- ▶ At least 50% of page allowance
- ▶ Specific sections
 - ▶ Design and setting: Methods for randomization, representative sample enrolled? How is bias handled if not?
 - ▶ Study sample: justify exclusion criteria
 - ▶ Availability of participants
 - ▶ Data collection procedure
 - ▶ Outcomes/measures
 - ▶ Intervention strategy – what happens to controls?
 - ▶ Data analysis, sample size calculation

5. Discuss your prior work/Pilot study

- ▶ Show why you and your group are the right persons to do this
- ▶ „*You need accomplishment to obtain grant funding, but you need grant funding to accomplish anything*“ (D. Sackett)
- ▶ Small grants for feasibility studies (local, intramural, community, foundations)
- ▶ Proof of successful collaboration (e.g. ...)

6. Technical questions: Preparing

▶ A

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- ▶ Outline, write, edit
- ▶ Write the entire draft before editing
- ▶ Understand the reviewers' perspective
 - ▶ They might not have in-depth experience in your field
 - ▶ They will be reviewing in a few hours
 - ▶ The proposal should be self-contained
 - ▶ Check out the review criteria (if they are available)
- ▶ Get the required approvals **in time**

6. Technical questions: Submitting

- ▶ Obtain optimal assignment (talk to program staff)
- ▶ Deadlines (postmarked or arrival date? Flexibility?)
- ▶ Online submission – cave:
 - ▶ Computer breakdown
 - ▶ Overflow
- ▶ Is supplemental material accepted?
- ▶ Ensure receipt

6. Technical questions: Reviewing

- ▶ Lack of significance to the scientific issue being addressed. Lack of original or new ideas.
- ▶ Proposal of an unrealistically large amount of work (i.e., an over ambitious research plan).
- ▶ Project too diffuse or superficial or lacks focus. Proposed project a fishing expedition lacking solid scientific basis (i.e., no basic scientific question being addressed).
- ▶ Studies based on a shaky hypothesis or on shaky data, or alternative hypotheses not considered.
- ▶ Proposed experiments simply descriptive and do not test a specific hypothesis. The proposal is technology driven rather than hypothesis driven (i.e., a method in search of a problem).
- ▶ Insufficient methodological detail to convince reviewers the investigator knows what he or she is doing (no recognition of potential problems and pitfalls).
- ▶ Most experiments depend on success of an initial proposed experiment (so all remaining experiments may be worthless if the first is not successful).
- ▶ The proposal lacks critical literature references causing reviewers to think that the applicant either does not know the literature or has purposely neglected critical published material.

6. Technical questions: Respond to review

- ▶ Lower budget? Rescale objectives
- ▶ Talk to program officer at funding agency
- ▶ Supplement material?
- ▶ Revise based on review and resubmit
- ▶ Provide rationale for not making all requested changes (politely & tactfully ...)
- ▶ Do NOT criticize the reviewers



Last remarks: get credit

- ▶ Written agreements on credit
- ▶ Written agreements on authorship

Ressources

- ▶ <http://www.skillsandethics.org/resources/handout/>
- ▶ Devine, EB. The art of obtaining grants. *Am J Health-Syst Pharm* 2009;66:580-587.
- ▶ Inouye SK and Fiellin F. An evidence-based guide to writing grant proposals for clinical research. *Ann Intern Med* 2005;142:274-282
- ▶ Guyatt, G. Preparing a research protocol to improve its chances for success. In: Haynes RB, Sackett DL, Guyatt GH, Tugwell P, (eds.) *Clinical Epidemiology*. Philadelphia: Lipincott³ p. 429-439
- ▶ http://www.ninds.nih.gov/funding/write_grant_doc.htm