VetClin 576 Introduction to Veterinary Clinical Research (2 credits) 2014 Syllabus

Designing, executing, analyzing and reporting clinical research fundamental to practicing evidence-based medicine.

JM Gay DVM PhD DACVPM 1.1 1/14

Objective:

The purpose is to develop your understanding of clinical research fundamentals and to coach you through developing a strong research grant proposal for research that you will carry out under the guidance of your faculty advisor as a component of your WSU program.

You are expected to obtain your advisor’s guidance and approval throughout the proposal development process. The second to the last week of the semester, you will submit this proposal to the VCS Research Committee for their evaluation of funding worthiness. This evaluation is the primary component of your grade. Because this scoring is not a ranking, they could score every proposal as either fundable, not fundable for minor reasons, or not fundable for major.

This proposal may be either for VCS intramural funding or for extramural funding but must meet the budget and format requirements of the funding source. During the class, you will gain perspective through providing critical reviews of classmates’ précis and proposal drafts as well as receiving the same.

Class Goals: At the end of this class you will:

- Understand the components and flow of the scientific research cycle
- Use resources supporting literature searches (e.g. Web of Science, PubMed through WSU Griffin) efficiently and be aware of bibliographic software (e.g. EndNote, Mendeley, RefWorks, Zotero) options
- Develop a strong research question, construct directly testable hypotheses for addressing it, and strong justification for your approach.
- Select suitable a study design to address the question, appropriately incorporating key design components (e.g., randomizing, allocating, blinding, blocking, controlling, replicating) into the design and avoiding major design and analysis flaws
- Apply relevant consensus reporting statements, such as ARRIVE, CONSORT, MIBBI, MOOSE, PRISMA, REFLECT, STARD, or STROBE – NIH Research Reporting Guidelines and Initiatives
- Incorporate relevant validated clinical and laboratory standard methods and standard materials, such as those of ATCC, AOAC, CLSI, or OIE, into your research designs
- Be aware of background information on common laboratory techniques, processes, and protocols, such as D Freifelder’s Physical Biochemistry, the Oxford IRL Practical Approach Series, Springer Protocols, and on-line resources such as ProtocolMonkey and Protocol Online (use with due caution, of course)
- Concisely write and edit in an active, lucid, and compelling style to construct an appealing proposal meeting the requirements of the funding source
- Be aware of the important groups supporting institutional research (e.g., WSU OGRD, IACUC, IBC, IRB, OCV), their services (e.g. identifying funding sources), their requirements (e.g. administrator signatures, budgets, REX forms, ASAF forms, IRB forms) and their timelines for processing and approval (days)
- Construct sufficiently logical, well referenced, well written, well presented research grant proposals for strongly evaluating important questions with a high likelihood of success
Course on-line materials:

- Veterinary Clinical Research Links and Resources
  [http://www.vetmed.wsu.edu/courses-jmgay/ClinicalResearchIntro.htm](http://www.vetmed.wsu.edu/courses-jmgay/ClinicalResearchIntro.htm)

- Current Class materials (developed as class progresses)


Instructor: John Gay, DVM (WSU 78), PhD (U Minn 88 - epidemiology), DACVPM (1996)

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Office hours – arranged if necessary. Otherwise, my door is usually open and you are welcome if it is.


A quick way to find my home page is to do a Google search for “WSU jmgay”

**Philosophy:** This is an applied “hands-on” class flexible to your needs. Because your programs put heavy demands on your scarce time, I’m happy to modify the class and schedule to meet your needs. I provide handouts and links to materials to improve your understanding of fundamental research components, such as experimental design, and to improve your efficiency in critical processes, such as concise, active writing. If the class is not meeting your needs or other conflicts arise, please tell me, the sooner the better.

**Meeting time and place:**

Tuesday 7-9 AM ADBF 2018 (ADBF 1020D when 2020 is otherwise reserved, a computer lab as necessary and otherwise as arranged). If you cannot attend class because of an urgent case, please let one of your classmates know.

As part the schedule below, you may elect to meet as small groups as part of reviewing your classmate’s précis and proposal drafts. To accommodate your schedules, some of these may be at other than scheduled class times.

**Grading:** Grades are based three criteria – VCS Research Committee classification of proposal fundability, meeting in-class deadlines, and class participation

A – **Proposal classified as fundable by VCS Research Committee**, all deadlines met, full participation (e.g., thorough, thoughtful, useful critical reviews provided to your peers).

B – Missing one of the above, such as proposal strong in all but one aspect, missing one deadline by < 24 hours, or performing one weak, uncritical review

C – Proposal classified as weak by VCS Research Committee, missing deadline by > 24 hours, missing 2+ deadlines, performing poor reviews

(+)- Upward modifier for exemplary performance otherwise

(-) – Downward modifier for further performance weaknesses

Historically the VCS Research Committee classifies between approximately one fourth and a half of the 12 to 20 proposals submitted annually as fundable; the balance having one or more errors or problems precluding funding. **Writing a fundable proposal is a hard task!**
Four Strongly Suggested Books: (Amazon links provided for example only and not as a recommended source)

- **A book on clinical research** – three suggestions, the last being most comprehensive:

- **A book on experimental design** – two suggestions:

- **A book on scientific writing** – two suggestions:

- **A broad coverage, in depth biostatistics book for reference** - five suggestions:
  - van Belle et al. (2004). *Biostatistics: A methodology for the health sciences*, 2nd ed - Amazon $137

- (On the cheap)
  - Brused Books – used statistics books
  - Pezzullo (2013). *Biostatistics for Dummies*, - Amazon $18

Suggested statistical analysis and graphics program:

“R” is a free, open source, programmable statistics program widely adopted for teaching statistics, doing data analysis, and constructing presentation-ready graphs. Already very powerful and continually being updated by statistics experts, it has a huge amount of on-line information. Its great advantages are that it does not have annual licensing fees, you can immediately download and run it on any computer connected to the internet, you can continue to use it where ever you go, and documentable, reproducible analyses are easily redone.

- CRAN Home Page [http://cran.r-project.org/](http://cran.r-project.org/)
- download R for Windows from [http://cran.fhcrc.org/](http://cran.fhcrc.org/)

Introductory R books: (don’t overlook the huge mass of on-line introductory guides, blogs, and so on, such as Applied Epidemiology Using R (288 pg [pdf](#)), Quick-R, Short R intro [pdf](#), Simple R [pdf](#),)

- Gardener (2012). *Beginning R* – Amazon $21
- Meys & de Vries (2012). *R for Dummies* – Amazon $20
Proposed Schedule:

Précis and Proposal Draft Due Dates: Constructing a fundable proposal is a difficult task that requires repeated careful thought, multiple critical reviews, and continual re-writing. For major proposals to federal agencies, grant writing experts recommend planning on 9 months of work prior to the submission date. Because most busy residents put off writing to the bitter end, which almost guarantees failure, this class is structured to move you through the grant writing process. Every bolded line is a due date for either a draft or a review. If the following due dates conflict with your participation in national conferences or other trips, please let your peers and I know in advance.

Week 1:
- Begin précis (concise 2 page research proposal summary)
- Read assigned readings on selecting a research question, view NIH videos

Week 2: (Monday - MLK Holiday)
- Begin literature review
- Develop study design, reading material relevant to that design

Week 3:
- Thur, Jan 30: Authors give first précis draft to peer review group

Week 4:
- Thur, Feb 6: Reviewers provide first précis draft peer review to author

Week 5:

Week 6: (Monday – Presidents’ Holiday)
- Thur, Feb 20: Authors give completed précis to peer review group

Week 7:
- Thur, Feb 27: Reviewers provide peer review of completed précis to author
- Begin drafting proposal

Week 8:

Week 9:
Spring Break – Mar 17-21

Week 10:
- Mon, Mar 24: Authors give first proposal draft and précis to peer review group

Week 11:
- Mon, Mar 31: Reviewers provide first peer review of proposal draft to author

Week 12:
- Mon, Apr 7: Authors give second proposal draft and précis to peer review group

Week 13:
- Mon, Apr 14: Reviewers provide second peer review of proposal to author

Week 14:
- Thur, April 24: Final Grant Proposal due to VCS Research Committee

Week 15: