IMMUNOLOGY 607 GRANT WRITING, SPRING 2020

Tuesdays, 2:00 – 4:00 pm

Course Director: Ivan Maillard, MD, PhD

Location: Stellar-Chance 204 (Large Group Meetings only)

FACULTY

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COURSE GOALS & DESCRIPTION

There are several objectives for this course: First, we will introduce the basic principles of grant writing. In this regard, a primary objective of the course is to teach you how to describe your ideas and experimental objectives in a clear and concise manner within the standard NIH grant format. To accomplish this, you will be required to write an NIH F30 (combined degree) or F31 (straight PhD) grant proposal based on your own laboratory thesis project. Second, we will provide insights into how NIH grants are processed and reviewed. To this end, you will participate in three mock study sections, in which you will evaluate and score actual grants. Investigators here at Penn wrote the proposals that you will review during the first two sessions. You and your colleagues will write the proposals to be reviewed for the final session.

Grant proposal: Details on the content of the F30/31 proposal are given below, and will be discussed at length in class and during workshops. Your final proposal will be graded for overall ability to express your experimental objectives in a clear, concise, and potentially fundable manner.

Mock study sections 1 and 2: You will be given several grant proposals written by students or faculty here at Penn. Everyone must read each grant and be prepared to discuss its strengths and weaknesses. In addition, some of you will be assigned as reviewers for one of these proposals. One week later the entire class will meet to discuss the strengths and weaknesses of each proposal in a study section type meeting. The main objectives of this exercise are to introduce you to the proposal format and the study section "culture," and to provide you with some examples of what makes a good, as well as a not so good, proposal. Afterwards, when possible you will receive the actual summary statement for these grants written by reviewers of an NIH study section. For each grant, the primary reviewer will provide a brief and succinct description of the proposal to the other members of the panel (class) such that others can ask key questions that everyone will use in formulating a final opinion about the proposal. The primary reviewer should discuss the overall strengths and weaknesses of the proposal, and be prepared to answer questions from other class members regarding the proposal. The secondary reviewer will then state whether he/she agrees with the assessments made by the primary reviewer, and add any additional insights that will help others generate a final score. After the primary and secondary reviewer's comments, the proposal will be open for discussion by other members of the study section. Students will not be asked to provide written critiques of these proposals.

Mock study section 3: After submitting your F30/31 to the course director, copies of all students' grants will be given to each class member. You will be assigned as a primary and secondary reviewer on two of your colleague's grants. As a primary and secondary reviewer for a given grant, you will be required to write a critique of the grant that discusses the strengths and weaknesses of the proposal. These critiques should follow the general format of an NIH summary statement (see above). **All written**

critiques are due the morning of this mock study section. As before, the entire class will also meet to discuss and assign scores to each proposal. The primary reviewer will provide a brief and succinct description of the proposal to the other members of the panel (class) such that others can ask key questions that everyone will use in formulating priority scores for each grant. The primary reviewer should discuss the overall strengths and weaknesses of the proposal, and be prepared to answer questions from other class members regarding the proposal. The secondary reviewer will then state whether he/she agrees with the assessments made by the primary reviewer, and add any additional insights that will help others generate a final score. After the primary and secondary reviewer's comments, the proposal will be open for discussion by other members of the study section. Finally, everyone will generate a priority score based on the information given, and we will move on to the next grant. Students will be graded on their written critiques and overall participation in this facet of the course.

Writing your grant. Similar to manuscripts, grants are usually written in phases with one or more drafts for each section. For this course you will be asked to submit the first draft for each section at the dates specified in the SCHEDULE listed below. To submit your work, you will need to create a pdf file of your work, then upload this file on the Blackboard web site. The faculty leader for your assigned subgroup will then evaluate the first draft for each section of your grant, and then we will meet in small groups (WORKSHOPS) to discuss how you might improve your work.

Purpose of workshops. As you will see below, we have scheduled several small group meetings or workshops throughout the course. Each of these occurs one week after the first draft for each section of your grant is due. These meetings will consist of 2-4 students plus one faculty member, and will provide the means for each of you to get direct one-on-one feedback on your work at that time. All members of a given workshop should read their colleagues proposals during the week leading up to each workshop and be prepared to offer criticism and advice on how to improve the proposal.

GRADING: There will be no exams. Your grade will be derived from the quality of the grant that you write, the quality of your written critiques of others' grants, and your ability to explain your thoughts and reasoning during all three study sections. A breakdown of the grading strategy is provided below.

Written grant proposal 100 Study sections I-II (participation) 20 Study section III (participation) 30 Written critiques of others' grants 50
MAX POSSIBLE TOTAL POINTS 200
MAX POSSIBLE FINAL SCORE 100 (200/2)

The following "straight scale" grading system will be used to generate final grades:

>97 = A+, 93-96 = A, 90-2 = A-
87-89 = B+, 83-86 = B, 80-85 = B-
77-79 = C+, 73-76 = C, 70-72 = C-
<70 = D
<60 = F

SCHEDULE

Date	Large group meetings	WORKSHOPS	*Drafts due*
Jan 14	Elements of an F30/31		
Jan 21			*Specific aims*
Jan 28		Specific aims	*[receive grants for review]*
Feb 4	Mock study section #1		
Feb 11			*Significance + Revised Aims*
Feb 18		Significance + Revised Aims	
Feb 25	Mock study section #2		*Aim 1 Approach + Revisions*
Mar 3		Aim 1 Approach + Revisions	
Mar 10			*Full Research Training Plan + Revisions*
Mar 17		Full Research Training Plan + Revisions	
Mar 24			*Training components*
Mar 31		Training components	
Apr 7			*complete proposal*
Apr 14		complete proposal	
Apr 21			*Final F30/31 due to IM*
Apr 28	Mock study section #3		*All critiques due to IM*

Elements of an F31

The **Research Training Plan** portion of an F30/31 is limited to **7 pages** and consists of four sections: **Specific Aims, Significance, Innovation,** and **Approach**. See pages I-83 to I-102 of the SF424 Guidelines for a table outlining all components of an F31 application.

Specific Aims (1 page)

- State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
- List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

The specific aims page should state the problem at hand, its significance, and a description of how you will solve the problem. Avoid the use of jargon in the Aims page. It is generally agreed that the specific aims is the most important part of the grant - it sets the tone for the remainder of the grant and should provide the reviewer with a good idea of what you want to do and how, in general terms, you plan to do it. Use an introductory paragraph stating the problem to be addressed and why it is an important problem? Give the big picture. What unique insights or abilities do you have regarding this problem and how will you utilize this unique advantage? What is the overall hypothesis to be tested? This should be stated explicitly in a sentence that guides the entire proposal. Following the introductory paragraph, provide a listing of 2-4 specific aims that will collectively test the general hypothesis. Each of these can contain a brief but specific description of what you will do to accomplish your objectives.

Research Strategy (6 pages)

a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

b) Innovation

Unlike an R01, F30/31 fellowship applications should not include an Innovation section unless specified in the FOA.

c) Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.

- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.
- If research on Human Embryonic Stem Cells (hESCs) is proposed but an approved cell line from the NIH hESC Registry cannot be identified, provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

Additional components of the F31 application

In addition to the **Research Training Plan**, there are over 25 additional components that need to be prepared for an actual F31 application, most of which are listed and defined below. You will need to work with your PI and grants admin. staff to complete most of these other components. See pages I-83 to I-102 of the SF424 Guidelines for a table outlining all components of an F31 application.

The additional components that you will write as part of this class are the ***Project Summary/Abstract*** **and** ***Goals for Fellowship Training and Career*****.**

Fellowship Biosketch - see page I-73 of the SF424 Guidelines for instructions.

Project Summary/Abstract - meant to serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research training program design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text.

Project Narrative - using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

Respective Contributions - Describe the collaborative process between you and your sponsor/co-sponsor in the development, review, and editing of this research training plan. Discuss the respective roles in accomplishing the proposed research. Limit one page.

Selection of Sponsor and Institution - Describe the rationale/justification for the selection of the sponsor and institution. Explain why the sponsor, co-sponsor (if any), and institution were selected to accomplish the research training goals. If the proposed research training is to take place at a site other than the sponsoring organization, provide an explanation here (e.g., NIH-based students). Limit one page.

Responsible Conduct of Research - NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. NIH recognizes that instruction in responsible conduct of research occurs formally and informally in educational settings and that informal instruction occurs throughout the research training experience. The guidance provided below is directed at formal instruction in responsible conduct of research and describes the accumulated experiences and the best practices of the scientific community over the past two decades.

A. Format: Substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs (see below), or unusual and well-justified circumstances.

B. Subject Matter: While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:

a) conflict of interest (personal, professional, and financial)
b) policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
c) mentor/mentee responsibilities and relationships
d) collaborative research including collaborations with industry
e) peer review
f) data acquisition and laboratory tools (management, sharing and ownership)
g) research misconduct and policies for handling misconduct
h) responsible authorship and publication
i) the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all of the above topics.

C. Faculty Participation: Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.

D. Duration of Instruction: Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

E. Frequency of Instruction: Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual fellows/scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Senior fellows and career award recipients (including F33, K02, K05, and K24 awardees) may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the trainee, fellow or career award recipient is not actually supported by an NIH grant. This instruction can be documented as described below.

In keeping with the individual nature of these programs, fellows and scholars, along with their institutions and sponsors/mentors, are encouraged to tailor instruction in responsible conduct of

research to the needs of the individual. Thus, instruction may go beyond formal institutional courses and provide opportunities for the individual to develop their own scholarly understanding of the ethical issues associated with their research activities and their impact on society. An individualized plan would be appropriate in the rare instances where an institution does not have an established formal mechanism for such instruction. Limit one page.

Goals for Fellowship Training and Career - The fellowship applicant must describe his/her overall career goals, and explain how the proposed research training will enable the attainment of these goals. Identify the skills, theories, conceptual approaches, etc. to be learned or enhanced during the award. Limit one page.

Activities Planned Under This Award - The fellowship applicant must describe by year the activities (research, coursework, etc.) he/she will be involved in under the proposed award and estimate the percentage of time to be devoted to each activity, based on a normal working day for a full-time fellow as defined by the sponsoring institution. The percentage should total 100 for each year. Also, briefly explain activities other than research and relate them to the proposed research training. Include any courses that you plan to take to support the research training experience. Predoctoral fellowships (F31) may reflect up to six years if allowed by the applicable FOA. Limit one page.

Doctoral Dissertation and Research Experience - Summarize your research experience in chronological order. Advanced graduate students, who have (or will have) completed their comprehensive examinations by the time of award must also include a narrative of their doctoral dissertation (may be preliminary). If you have no research experience, list other scientific experience. Do not list academic courses. In summarizing their research experience, Postdoctoral and Senior Fellowship applicants should include the areas studied and conclusions drawn. Limit two pages.

Sponsor and Co-Sponsor Information - Work with your PI to complete the items listed below as comprehensively as possible so that a meaningful evaluation of the training environment can be made by the reviewers. Limit six pages.

a) Research Support Available - In a table, list all current and pending research and research training support specifically available to the applicant for this particular training experience. Include funding source, complete identifying number, title of the research or training program, and name of the principal investigator, dates, and amount of the award. Include this information for any co-sponsor as well.
b) Sponsor's/Co-Sponsor's Previous Fellows/Trainees - Give the total number of predoctoral and postdoctoral individuals previously sponsored. Select up to five that are representative and, for those five, provide their present employing organizations and position titles or occupations. Include this information for any co-sponsor as well.
c) Training Plan, Environment, Research Facilities - Describe the research training plan that you have developed specifically for the Fellowship applicant. Include items such as classes, seminars, and opportunities for interaction with other groups and scientists. Describe the research environment and available research facilities and equipment. Indicate the relationship of the proposed research training to the applicant's career goals. Describe the skills and techniques that the applicant will learn. Relate these to the applicant's career goals.
d) Number of Fellows/Trainees to be Supervised During the Fellowship - Indicate whether pre- or postdoctoral. Include this information for any co-sponsor as well.
e) Applicant's Qualifications and Potential for a Research Career - Describe how the Fellowship applicant is suited for this research training opportunity based on his/her academic record and research experience level, including how the research training plan, and your own expertise as the sponsor will assist in producing an independent researcher.

GLOSSARY

CSR, center for scientific review: The branch of the NIH assigned the task of reviewing all scientific proposals.
Direct costs: The fraction of a total grant budget that can be used by the principle investigator to perform the proposed studies. Also see indirect costs. Maximum direct costs for an R01 are usually $250,000/year and a given R01 covers no more than 5 years.
Effort: All budgets require that the per-cent effort, the fraction of a person's total time, be specified for all relevant personnel.
IACUC: A detailed animal use protocol that must be submitted and approved by an institutional regulatory affairs department before a grant can be funded.
Indirect costs: The fraction of a total grant budget that is not available to the principle investigator. Instead, this money goes to the investigator's institution and is used for general "overhead".
Modular budgeting: A relatively new NIH policy states that all budgets are to be rounded up in intervals of $25,000. For example, if your detailed annual budget were $205,000, the modular budget for that year would be $225,000. Despite this policy, most institutions (including PENN) require a detailed itemized budget plan be submitted to institutional officials (with the grant) before they will sign the grant face page.
Percentile ranking: After receiving a priority score, a grant is ranked with all grants reviewed by a given study section over the past year. The resulting ranking is expressed as a percentile ranging from 1 (best possible ranking) to 100. Institutional program officials use this number in decisions about which grants will actually be paid. See pay-line.
Pay-line: The cut-off for grant payment decisions based on the percentile ranking. Different NIH institutes have varying amounts of money; therefore the pay-line varies for each institute. For instance, last year's pay-line at NCI was 14 but at NIAID it was 12. This means that a grant receiving a percentile ranking of 13 would stand a good chance of getting paid by NCI but not by NIAID.
Priority score: A raw number score given to a grant at study section. Scores range from 10 (best possible score) to 50. Typically (these days), scores between 10-17 stand a reasonable chance of getting funded.
Program administrator: NIH institutional staff. Make decisions about which grants are to be funded. Also make policy decisions about special funding initiatives (see PA, RFA).
PA, program announcement: NIH institutional announcements describing a desire of the institute to fund grants addressing a particular problem. PA's typically ask for applications over a defined period of time. For example, the Aging Institute currently has a PA for applications dealing with stem cell defects and aging and NIAID recently announced several PA's dealing with bioterrorism.
Program grant: A collection of R01's, usually from the same research institute, that share a common theme. Program grants provide a means to fund core resource laboratories such as the Penn Cancer Center Flow Cytometry Core Laboratory in the John Morgan Building.
RFA, Request for applications: Similar to a PA except these tend to be a one-time event.
FOA, **Funding opportunity announcement**: the umbrella term for PA, RFA, etc.
R01: Typical 5-year grant proposal.
R03: "Pilot" grant proposal for a limited amount of funds and designed to allow investigators to investigate a new idea for which there is limiting supporting data.
R21: Two-year grant proposal to investigate risky but potentially high impact research projects.
SRA, scientific review administrator: CSR staff personnel assigned the task of running a given study section. These people have the often-difficult task of recruiting scientists with the appropriate expertise to review grants at study section.
Summary Statement: About 6-weeks after a grant receives a priority score and percentile ranking, the applicant receives a summary statement consisting of written critiques from the primary and secondary reviewers and budgetary recommendations. The summary statement can be used both by the applicant if a revised application is indicated, and by program administrators in making funding decisions.
Study section: A scientific review committee specializing in a particular field. Study sections review and assign priority scores for all assigned grants and are typically composed of the SRA, a chairperson,

and 10-15 experts in the field that critique the grants to which they have been specifically assigned and vote on a priority score for every grant assigned to that study section. All study section members, with the exception of the SRA, are typically faculty members at non- government research institutions (such as Penn) who volunteer their efforts to the grant review process.

Triage: Unofficial term for when a study section decides NOT to discuss a particular grant and put it up for a full score, which the NIH refers to as 'not discussed - ND'. In real life, most study sections will not score (triage) roughly 50% of their assigned proposals. Such a decision is usually based on the argument that the proposal in question falls in the bottom 50% of all proposals to be reviewed.