PhD Roadmap

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Qualifying Exam

	Revised
Objective	Test the readiness to conduct research (i.e., graduate level BME knowledge and research skills)
Format	Develop a research proposal (in NIH R21 or F31 format), and present it at the end of the exam. • The topic of the proposal will be relevant but not directly related to the PhD research of the student. • The topic (RFA) will be given by the adviser of the student, with approval of the Exam Committee. • The maximum duration of the exam will be one semester.
Exam Committee	The PhD Dissertation Committee (Excluding the Major Adviser) + one Graduate Program Committee member
Outcome	Pass or Fail*

* Student may retake the qualifying exam once.

1. Proposal Structure (for Student Only)

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

The required elements of your proposal include:

Project Summary/Abstract (1 Page)

Provide the overall goals for the entire application and indicate separately Specific Aims to be accomplished in your proposal.

Specific Aims (1 Page*):

Research Strategy (6 Pages*):

Organize the Project Narrative in the subsections identified below.

1) Background and Significance

Example

- *Define the cancer problem to be addressed, including type(s) of cancer targeted.*
- *Outline the proposed technology/assay/device/treatment and its potential to improve cancer treatment for people living in LMICs.*

2) Preliminary data

Example

- *Describe the technology/assay/device/treatment to be developed, as new or adapted from existing ones, which address diverse aspects of cancer detection/diagnosis (using imaging as well as non-imaging approaches) or cancer treatment and how the technology would be tested.*
- *Summarize preliminary data documenting the technology's potential to achieve both analytical and clinical sensitivity and specificity comparable to a currently used technology.*
- *Describe its potential for fast, low-cost, accurate detection, diagnosis, and/or treatment of a cancer treatable in a low resource setting.*

3) Research Plan

Develop research strategies to address the specific aims of the proposal. The strategies should contain designs of experiments, methods of data analysis, expected outcomes, and alternative approaches.

4) Milestones and timeline

A timeline (Gantt chart) including milestones is required. Milestones are goals that create go/no-go decision points in the project and must include clear and quantitative objective criteria for success. Provide appropriately detailed (quantitative) criteria by which milestone achievement will be assessed.

Bibliography & References Cited (No Page Limit)

Facilities & Other Resources (No Page Limit)

Equipment (No Page Limit)

Evaluation Process

1. Proposal Evaluation (Adopted from NIH Program Announcement)

The proposal will be judged by the following criteria:

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves clinical research, are the plans for 1) protection of human subjects from

research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Milestones

How well thought out is the overall plan for the progression from UH2 to the UH3 validation phase? Is the sequence of elements/steps in the phased UH2/UH3 project clearly defined, logical, and complete? Are milestones provided for the UH2 and UH3 phases properly objective and quantitative whenever appropriate? Are these milestones well aligned with the specific aims of each phase? How realistic are these milestones and associated timelines? Do the proposed milestones and timelines clearly identify benchmarks for successful completion of the UH2 phase that could serve as a decision point to advance studies to the UH3 phase?? Are other critical go/no go decision points and timelines well defined and appropriate? .

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Children

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of

children. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

2. Oral Presentation/Examination

The oral presentation/examination of the proposal should be scheduled by the student for any time in the designated exam period. The proposal should be submitted to the committee at least one week prior to the oral exam.

At the beginning of the Oral Presentation/Examination, the student shall make an uninterrupted 10-15 minute oral presentation describing the proposal. A PowerPoint presentation is appropriate during this initial period to display essential graphics, videos, etc. This is followed by the examination itself, which is free-flowing and at the discretion of the Qualifying Exam Committee.

The proposal provides a scaffold for the oral exam, but the oral exam itself focuses on determining whether the student has incorporated the fundamental knowledge needed for proceeding towards his/her future PhD research. The student must be able to demonstrate a broad understanding of the basic biomedical engineering principles relevant to the proposal. In addition to knowledge obtained from the coursework and relevant literature, students will also be tested for knowledge of experimental strategies and the ability to think on their feet and across the "pitfalls" (controls, alternative approaches, etc.). The primary focus of the oral presentation

should not be the preliminary data. It should focus on the background, experimental approaches, what you want to accomplish and how this fits in the “big picture.”

The oral presentation/examination is expected to run approximately 90 minutes. The use of a (blank) white board during the oral examination is appropriate. If necessary, the Chair may stop the exam for a brief discussion, or to allow the student to take a short break.

3. Grading

Following the exam, the Qualifying Exam Committee will vote: Pass, Retake, or Fail. The preliminary vote is anonymous, and is to be followed by an open discussion among the Committee members, and then a final vote.