**Checklist and Instructions For Applications: NINDS R25 Clinical Trials Methodology Course 2017 Cohort**

Do not use less than 11 point font. Do not adjust the margins. All text (including references) should be included within the specified page limitations. Please edit the header above to include your name, email address and institution. When you have completed the application, please delete the instruction text from this page so that the first page of your application is Part 1. When your application is completed please send it as an email attachment (either Word or PDF) to ninds-ctmc-info@umich.edu . Due date is February 28, 2017 at midnight, Pacific Time.

Part 1: Participant information form (Limit 1 page): Please provide responses to the questions on page 2 of these instructions.

Part 2: Statement of Scientific Area (Limit 1 page including references)

The goal of the course is to help you develop a rigorous and thoughtful scientific protocol. In the text box provided, discuss the area of study where you will develop a clinical research trial proposal. The most highly weighted criterion is a research project that delivers some intervention (drug, device, diagnostic, behavioral) to patients in a prospective way. Describe potential scientific questions and briefly inventory areas of important scientific uncertainty in the field. This intervention should have a good basis in biology (or theory, for behavioral interventions). The best designs for this course will seek to confirm important pre-clinical estimations of dose, mechanism, or target acquisition. The goal is to learn whether and how a follow up trial should be conducted. Provide a general description of what sort of trial design you think might be appropriate. Please consider the NINDS Transparency in Reporting Guidelines when drafting this section. <http://www.ninds.nih.gov/funding/transparency_in_reporting_guidance.pdf>.

Part 3: Potential Funding Sources (Limit 1 page)

The second most highly weighted criterion is the review committee’s estimated likelihood that the clinical trial that you are designing will actually enroll patients. Projects that use existing resources (e.g. study coordinators from local infrastructure, PI protected time for research, etc) will receive the highest priority for participation in this course. In the text box provided, please describe at least three specific, potential areas of funding to conduct the clinical trial protocol which you develop as part of the R25 course. Include web links to funding announcements as appropriate. Discuss why your potential project might be desirable to the funder. An example of a specific funding source would be NINDS: Dissemination and Implementation Research in Health (<http://grants.nih.gov/grants/guide/pa-files/PAR-10-039.html>) or American Heart Association Fellow to Faculty award. Local pilot mechanisms through CTSAs, along with foundation mechanisms are encouraged. You should review funding histories or NIH project reporter to assess whether clinical trials in this area are ongoing or within funding priorities of these potential sources.

Part 4: Biosketches (Limit 5 pages each)

Please follow the instructions for the 2015 NIH biosketch format and append into your application. <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html> Please provide a biosketch for yourself and your mentor. The third most highly weighted criterion is a dedicated mentor at your home institution that can help facilitate the project’s success. The mentor personal statement should describe the mentorship plan and who will help them implement the project. If you are applying with a biostatistician, you must also submit a biosketch with their personal statement relevant to the proposed project.

Part 5: Chair’s Letter (Department Chair or Division Chief – Limit 2 pages)

* Describe the applicant’s research training, experience, and potential for a successful clinical research career;
* Outline the applicant’s current competing responsibilities and availability of protected research time for the two years after the clinical trials course;
* Describe the resources are currently available (contingent on IRB approval) for the applicant to conduct a clinical trial (study coordinators, project management, data management, lab processing, etc.);

**Part 1: Participant Information Form**

**Participant Information:**

Project Title:

Name:

Degree(s):

Email:

Title:

Department/Division:

Institution:

**Mentor Information:**

Name:

Degree(s):

Email:

Title:

Department/Division:

Institution:

Please indicate if you have designed interventional clinical trials before and are interested in more work with clinical trial simulation and potentially innovative adaptive designs:

Yes / No

If you have selected yes, please find a biostatistician collaborator who is also interested in attending this course. There will be parallel sessions in clinical trial simulation and labs to design simulations and trials during the residential course. The biostatistician applicant will not be required to attend CTMC sessions focused on introductory biostatistics that are intended for the clinicians taking the course. New assistant professors in biostatistics or potentially post-docs working in clinical research would be ideal candidates. Ideally, the biostatistician would be someone from your institution. They must be available to attend the residential course.

Name of biostatistical collaborator:

Department:

Degree:

Title: