



2026 Application Instructions

Deadline for 2026 Applications: January 21, 2026, at 11:59pm Pacific Standard Time

Combine all required application materials into a single PDF document using the [linked template](#). You may download the [template](#) and edit it directly.

Upload the complete application using the following portal:

<https://redcapsurvey.healthsystem.virginia.edu/surveys/?s=LME7T8KTLN4JYJ9F>

Before applying, you must agree to the following course requirements:

1. **An ongoing time commitment from you.** This includes:
 - Virtual webinars and small group meetings from March – August
 - In-person attendance at the Residential Meeting in Indianapolis, IN on June 15-18 (travel within the U.S. is covered by the program). Attendance at the in-person course is a required condition of your acceptance to the course.
 - Trainee orientation is scheduled for Friday, March 13, 2026, from 12-1:30pm Eastern Time. Attendance is highly encouraged but a recording will be available, if necessary.
 - Additional preparation and time are expected throughout the course to achieve progress on your clinical trial development.
2. **Ongoing support from your mentor.** Your mentor must be committed to a long-term mentorship throughout the course and as you perform your clinical trial. This may include a virtual, 15-minute meeting between you and/or your mentor and the selection committee during the application review period.

Types of Proposals/CTMC Tracks:

- **Clinical Trial:** As defined by NIH, a clinical trial is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
 - **Single-center Trials (Foundation Track):** Single-center, early phase are the most common and preferred type of trials accepted into the course.
 - **Multi-center Trials (Advanced Track):** Proposals for large, multi-center trials will be considered for the advanced track. The multi-center proposals should ideally be aligned with the focus areas of one of the established NINDS clinical research networks ([NeuroNEXT](#), [StrokeNet](#), [SIREN](#)). If you are considering another network, please reach out to ninds.ctmc@virginia.edu to confirm that your trial would be a fit for the course.
 - **Biomarker Study:** Clinical studies investigating biomarkers with a close relationship to therapeutics may be considered. “Biomarker” is defined by this course as a measurable quantity, previously identified and specific to the individual patient at a specific time. Your application should clarify the intended use of the biomarker and include supporting references related to the proposed biomarker to be used. Applications proposing a single biomarker that is identified a priori will be considered. Studies intended to evaluate a variety of new biomarkers will NOT be considered.

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- **Biostatistics Track:** The biostatistics track is an opportunity for early-career biostatisticians to get hands-on experience developing clinical trials across a range of neurological disease-areas and design types. Please contact us at ninds.ctmc@virginia.edu to learn more about the biostatistics track.

Application Notes & Requirements

- **Formatting:** Font size must be 11-point or larger. Page margins must be at least 0.5in. All text (including references) should be included within the specific page limitations. URLs are permitted where requested. Name your file “*LastName_FirstName_Year*”
- **Accessibility:** We are committed to training individuals from all backgrounds in compliance with all federal regulations. Please contact us at ninds.ctmc@virginia.edu with any questions or concerns.
- **Resubmissions:** For those who have previously applied, one additional page (titled *Revised Application*) is permitted to describe the changes you have made to your application based on feedback and progress since the prior application. Place the additional page as the first page of your compiled PDF, prior to Part 1A.
- **Multiple investigator applications:** While most applications are expected from individual investigators, coordinated applications from multidisciplinary teams of investigators with complementary expertise working on a single project will also be considered (2-3 people maximum – e.g., clinician and statistician and/or engineer). If selected, ALL team investigators are required to participate fully in ALL course activities. Each team member should submit a separate application, but parts 1 and 2 (see below) should be the same.
- **Common pitfalls to avoid:**
 - Unrealistic study in scale or translation of science
 - Underpowered efficacy studies
 - Lack of availability of drug and/or technology to be utilized, and uncertainty that it is practical and safe for humans
 - No clinical trials are allowed in NINDS R21 planning grants. You should consider Clinical and Translational Science Awards (CTSA) or foundation research grants to obtain pilot data
 - Implementation studies without patient centered outcomes
 - Unclear evidence that the applicant is the scientific leader of their project (e.g., residents or fellows). See [FAQs](#) for more information.
 - Unclear local mentorship and/or insufficient protected time for course activities

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Application: Descriptions of Required Sections

Do not include the section descriptions/instructions text in your submission. You may use [this template](#) to populate your answers.

Part 1a: Statement of Scientific Area and Key Information (*Limit 1 page including references*)

The goal of the course is to help you develop a rigorous and thoughtful scientific protocol for a research project that delivers an intervention (drug, device, diagnostic, behavioral) to participants in a prospective way. This should be a protocol that you are planning to submit for funding and actually carry-out as the trial leader. Discuss the area of study where you will develop a clinical research trial proposal. 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). Provide a general description of what sort of trial design you think might be appropriate. Provide a critical summary of the existing preclinical or prior clinical work that supports the evaluation of this therapy. Specifically address the rigor and reproducibility of the methods of preclinical experiments that justify implementing your proposal in a clinical trial.

Consider the [NINDS Rigorous Study Design and Transparent Reporting](#) when drafting this section and discuss the scientific premise underlying your idea.

Part 1b: Summary of Research Question (*Limit 1 page*)

In addition to the text provided in 1A, please answer the following questions (even if the answer was previously described). Be specific and concise. For the primary goal, do not state “establish safety.” It is well known that most safety outcomes occur relatively infrequently, and small sample size studies will not reduce uncertainty about these. If establishing safety is a goal, “establish that the symptomatic intracerebral hemorrhage rate is not likely to be greater than 20%” would be responsive. Please see example hypothetical answers below.

1. Indicate the target condition:
2. Indicate the specific phenotype, if applicable:
3. State in one sentence what the main goal of the current clinical trial or study will be:
4. Describe the biological rationale (and relevant preclinical evidence) for the study concept:
5. State the primary clinical endpoint:
6. Estimate the general scale of the sample size you believe is needed (range is preferred):
7. If this study is successful, what would the next study look like:
8. State how findings from this line of work would change practice:
9. If performing a biomarker study, describe the biomarker and how it would interact with the treatment or inform a clinical trial design:

Hypothetical answers (using TBI as an example):

1. *Traumatic brain injury*
2. *Comatose patients without space occupying extra-axial hemorrhage (such as epidural or subdural hematoma); parenchymal and subarachnoid hemorrhage included.*
3. *To determine if agent X reduces cerebral edema in acute TBI*

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4. *In a pig model of TBI with blinded outcome assessment, edema progression was reduced 20% when animals with controlled cortical impact were treated with agent X versus placebo (vehicle).*
5. *Cerebral edema at day 7 measured quantitatively using ADC mapping on MRI*
6. *20-50 patients*
7. *Reducing post TBI cerebral edema would demonstrate proof of concept for agent X. This would provide motivation for a larger clinical study to establish dosing, schedule, and inclusion criteria. If agent X is shown to reduce TBI associated cerebral edema and reduce neurological disability, we would start using it to improve health.*
8. *We plan to develop companion biomarker Z and will determine how well the longitudinal dynamics of this biomarker track imaging evidence of brain edema (quantitative ADC on MRI); this approach was promising in an animal study.*

Part 2: Potential Funding Sources (Limit 1 page)

Feasibility is a key component of your application (i.e., the review committee's estimated likelihood that your clinical trial will actually enroll patients). Your application can be strengthened by making use of existing institutional resources (e.g., study coordinators from local infrastructure, PI protected time for research, etc.). Describe specific opportunities for potential funding to conduct your clinical trial, as well as a projected timeline to submit your final grant application. Include web links to funding announcements. Discuss why your project might be desirable to the funder. Examples of specific funding sources for early phase trials include: local pilot mechanisms including through CTSAs, foundations; NINDS or other NIH ICs – find relevant PARs that accept early clinical trials; or American Heart Association Fellow to Faculty award. For multi-center trials, please review the NINDS network ([NeuroNEXT](#), [StrokeNet](#), [SIREN](#)) funding announcements to ensure your design would be within scope. You should review funding histories or NIH RePORTER to assess whether clinical trials in this area are ongoing or within funding priorities of these potential sources.

Part 3: Team Members (Limit 1 page)

List the members of your team (mentor, coordinator, biostatistician, data management, engineer, etc.), provide their email addresses, and briefly describe their roles in your proposed project and their expertise. These members may be invited to your small group meetings to participate in protocol development discussions (though their attendance is not required). Provide a brief paragraph summarizing how you will organize and interact with the team.

Part 4a: Your Biosketch (Limit 5 pages)

Provide your biosketch in NIH format (<https://grants.nih.gov/grants/forms/biosketch.htm>). Please ensure that you have edited your personal statement to address your motivation for applying to the course, delineate previous clinical research experience, and describe how you think this course will help your future career.

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Part 4b: Mentor's Letter (Limit 2 pages)

A dedicated mentor, preferably at your home institution, who can facilitate your success leading the project is a required component of your application. The mentor's letter should summarize how their research interests overlap with your project and describe their mentorship plan (how often you meet, how you work together, how the mentor will help you implement the project).

IMPORTANT: Please make certain you have a mentor that can devote time and attention to support you through the course and as you perform your clinical trial. If your mentor is not at your home institution, they should explain your relationship and how you will navigate being at separate institutions.

Part 5: Department Chair's Letter (Limit 2 pages)

Please have your department chair provide a letter of support addressing the following:

- Describe the applicant's research training, experience, and potential for a successful career in clinical research
- Outline the applicant's current competing responsibilities and availability of protected research time during the course and for two years afterwards
- Describe the resources that are currently available for the applicant to conduct a clinical trial (study coordinators, project management, data management, lab processing, etc.)

Part 6: Other materials (Optional; limit 1 page)

For projects with plans to use an investigational compound or device, provide evidence of the availability of that compound or device to you for this potential clinical trial. You may provide URLs if applicable to demonstrate availability. For all projects, please include any other materials that are important for the review committee to consider with your application.

Link to editable application template: https://docs.google.com/document/d/1Q0CsJzvB3Wr-0aotVamiwVl_YN89GGMM/edit?usp=sharing&oid=105386546157328792489&rtpof=true&sd=true