The full application should be formatted in Arial 11pt font and single-spaced with 1" margins. It should contain the following sections:

1. Cover Page (1 page):
    - Number and title of the funding opportunity
    - Project title
    - SPARC Funding Priority being addressed
    - Project lead(s) first and last name(s), title(s), email address(es), and phone number(s)
    - Type of applicant (see the "Detailed Eligibility Requirements" section of OTA-20-004)
    - Name of the applicant's organization and department
    - Authorized Organizational Representative (AOR) first and last name, email address, and phone number (only applies to organizational applicants)
    - Name(s), email address(es), and organizational affiliation(s) for other key personnel
    - Period of support requested and estimated total costs (direct + indirect)
    - Answers to the following questions:
        - **Are Human Subjects Involved**: Answer "Yes" or "No"
        - **Are Vertebrate Animals Used**: Answer "Yes" or "No"
        - **Are Biohazardous Materials Used**: Answer "Yes" or "No"
        - **Are Select Agents Used**: Answer "Yes" or "No"
        - **Are Human Embryonic Stem Cells Used**: Answer "Yes" or "No"
2. Project Overview (1 page)
    - Provide an outline of the project. Indicate the objective of the project and how the outcomes will impact neuromodulation therapy development within the next 1–4 years. Provide a summary of major tasks to be accomplished and their timeline. State what the deliverables of the project will be.
    - Include a hyperlink to a completed "Ten Simple Rules for Model Credibility" online form.
        - Planning for evaluation with the Ten Simple Rules creates a path to credibility within the intended context of use, fostering confidence, adoption and re-use for an analytical tool.
        - Follow these instructions to obtain an IMAG wiki account and complete the online form:
            1. Sign up for an IMAG wiki account if you don't already have one: https://www.imagwiki.nibib.nih.gov/user/register. Choose the "To edit the wiki as a Resource credibility" option when signing up.
            2. Once your account has been created, log in to the wiki and complete the Resource Credibility Assessment form: https://www.imagwiki.nibib.nih.gov/node/add/resource_credibility_assessment.
            3. Once you save the form, it will be assigned a unique URL. Copy that URL from browser address bar into your application. Your form will only be visible to those who have the URL.
3. Project Plan (up to 12 pages, including figures and references):
    - Rationale
        - Briefly describe the relevant major knowledge gaps and/or barriers that the project will address.
        - Compare the models/simulations to be developed against the existing state-of-the-art.
        - Indicate how the project will impact neuromodulation therapy development within the next 1–4 years for diseases and conditions that impact the stomach,

colon, lungs, heart, or lower urinary tract. (Proposed projects should have a goal to inform therapy development in a manner that can begin to be tested clinically within 4 years of the project commencing. Projects are not expected to perform clinical validation on their own. However, knowledge or predictions that result from a project should take a form that enables them to be tested in a clinical setting by others.)

- Preliminary Data
  - Indicate precisely which existing experimental data will be utilized and how. Include digital object identifiers (DOIs) if applicable.
  - Describe any preliminary work that has been performed to demonstrate feasibility of the project.
- Development Plan
  - Describe in detail the approach and methodology to develop the models and/or simulations, keeping in mind that the project should employ a model-driven design strategy. Explain how model reproducibility approaches will be incorporated in the project, and how uncertainty quantification will be addressed in the model development process.
  - Explicitly address how the proposed simulations:
    1. Will be personalizable (i.e., designed to allow for user-defined input parameters that correspond to variables that could be assessed in individual humans as part of near-future clinical care or clinical research).
    2. Will be interoperable (i.e., do not run in isolation but rather are capable of coupling to other simulations within the o^2S^2PARC platform).
    3. Will be extensible by others.
    4. Will account for variability and uncertainty across species, individuals, and sexes. (Provide justification if any of these criteria cannot be met.)
    5. Will account for off-target effects. (Provide justification if off-target effects cannot be accounted for.)
  - Indicate what new experimental data will be generated, if any, and why. Generation of new data is allowable, but applications should justify why new data are needed. Examples could include measurements of parameters not reported in previous literature or performing experiments to validate the models, for example, by confirmation of model predictions.
  - Describe how the model would be validated. Though full model validation may be outside the scope of this award, describe the animal experiment(s) and/or human study(s) that could evaluate the validity of the model.
- Risk Analysis
  - Provide a description of potential pitfalls and limitations, and approaches to retire and/or mitigate them.
- Tasks, Milestones, Benchmarks, Deliverables, and Timeline
  - Identify the major tasks. For each major task, define: 1) a set of milestones with benchmarks at 3-month intervals, and 2) the deliverables. Benchmarks should include quantifiable criteria for success (i.e., go/no-go) and should aggressively address major risks in the first year of the project. The timeline must include targets for transfer of models/simulations to o^2S^2PARC. The table below is an example of one way in which this information may be submitted:

	Description	Year 1				Year 2				Total Cost (Direct + Indirect)
Task 1	Brief description, milestones, benchmarks, and deliverables									
Task 2	Brief description & milestones/deliverables									
Task 3	Brief description & milestones/deliverables									
Task 4	Brief description & milestones/deliverables									

- Investigators
  - Identify project lead(s) and other personnel. Specify specific roles, relevant expertise, and contribution levels for each person. Describe past collaborations between the key personnel, if any. If the project is to be carried out in more than one department or institution, identify what parts of the project will take place at each organization and which senior/key individuals will be responsible for each portion.
  - For Multiple PD/PI applications, indicate who the Contact PI is and attach a separate Leadership Plan to the application (does not count against the 12-page limit).
- References

4. Resource Sharing Plan (1 page)
   - Describe how the project will integrate with the o^{2}S^{2}PARC online computational platform. State what technical assistance and support the project will require from the IT'IS Foundation, if any. In cases where significant levels of effort (beyond technical support) are requested from the IT'IS Foundation, describe the work to be performed by the IT'IS Foundation.
   - Indicate what software and programming language(s) will be used. SPARC strongly recommends leveraging free and open-source software when possible. Provide justification if using any proprietary software.
   - Indicate what software license(s) will govern the models and simulations developed in the project. SPARC strongly recommends open-source development under the Apache 2.0 or MIT licenses. Provide justification if proposing closed-source development or a different software license.
   - Indicate how the project will comply with the SPARC Material Sharing Policy.
5. Budget and Budget Justification (limit 1 page per institution)
   - Provide the expected cost for each of the following categories: personnel, materials & supplies, equipment, travel, subawards, other direct costs, and total costs (with indirect costs included). Provide a budget justification for all years of the project. For subawards with budgets greater than $100,000, provide details of cost breakdown.
   - The budget should include travel costs for attending annual meetings of the SPARC Consortium (these annual meetings are expected to be held in Bethesda, Maryland).
   - Institutions with an established Facilities and Administrative (F&A) rate should use the approved rate to calculate indirect costs. Indirect costs on foreign awards will be reimbursed at a rate of 8% of total direct costs, less tuition and related fees, equipment, and subawards in excess of $25,000. Any applicant that has not negotiated an indirect

cost rate may elect to propose a rate as a percentage of modified total direct costs for NIH review and consideration.

6. Letters of Support (up to 3 letters, not required)
    - Letters of support from potential end users of the models/simulations are encouraged.
    - In cases where significant levels of effort (beyond technical support) are requested from the IT'IS Foundation, attach a letter of support from the IT'IS Foundation. (A letter from the IT'IS Foundation does not count against the 3-letter limit.) When only basic assistance/support is required, a letter of support from the IT'IS Foundation should not be included.
7. A copy of the Invitation to Submit a full proposal in response to the previously submitted Concept Letter.