



*Fast Forward*

## **Fast Forward Proposal Guidelines - 2018**

NOTE: A grants management system (MS Grants) has been implemented for preparation and submission of research proposals to the National MS Society. MS Grants can be found at <https://nmss.fluxx.io>

Use this Fast Forward proposal template as a guide for preparing your application. All applications must be submitted online; refer to instructions in the Fast Forward Request for Proposals to submit your application.

## **EXECUTIVE SUMMARY**

**Page Maximum: 2 single-spaced pages**

**Use at least an 11-point font.**

**Include the following sections:**

1. Overview of Product and Description of Proposed Plan
2. Proposed Plan Objectives
3. Scientific Rationale for relevance to MS
4. Commercialization Potential (How does the proposed therapeutic or diagnostic product compete with or complement existing products)
  - a. Market: (Summarize how your approach addresses current unmet medical needs in MS. Describe any established market precedence for commercialization of the product or platform technology relevant to your plan.
  - b. Key Technical and Commercial Risks: (Describe the key technical and commercial risks involved in the development of the technology and how you propose to mitigate these risks.
  - c. Commercial Strategy and Exits: (Briefly describe how this effort will be commercialized. What are the expected outcomes? Describe your expectations for the potential exit-points.

## **SCIENTIFIC SUMMARY**

**Page Maximum: 1 single-spaced page**

**Use at least an 11-point font.**

Please provide a **non-confidential** summary of the proposed research. This information may be used for public dissemination if funded. Limit your summary to 500 words or less. If special characters or symbols such as Greek letters are used, they should be spelled out (e.g., "alpha", "beta", etc.).



**PROPOSED AIMS, EXPERIMENTAL DESIGN AND DEVELOPMENT PLAN**

**Page Maximum: 10 single-spaced pages**

**Use at least an 11-point font.**

**NOTE:** Any charts, diagrams and figures **MUST** be submitted as a PDF attachment.

**Include the following sections:**

1. Proposed Aims: (Limit 1 page. Please list numerically)
  
2. Background: (Preliminary scientific, preclinical and clinical data)
  
3. Experimental Design and Methods: (Experimental design should provide detailed procedures and experimental methodology that serves to address the feasibility of the proposed plan. Indicate which assays are validated, planned or established, or will be outsourced. Where appropriate, include possible outcomes, potential challenges and alternative approaches. Clinical design reports, data reviews and protocols may be attached in the Appendix at the back).
  
4. Development and Regulatory Plan: (Include a projected timeline with key scientific and development milestones. Illustrate through use of a flowchart, Gantt chart, or table – see table below)

Key Milestones		
Development Activity / Milestone	Projected Time for Completion	Projected budget (for meeting milestone)



**HUMAN SUBJECTS AND/OR VERTEBRATE ANIMALS**

If documents concerning these assurances need to be included, such as Institutional Review Board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) approval memos, they must be included along with any letters uploaded in PDF format as part of the application. If your proposed research involves human subjects, you must provide a signed and dated approval letter from the IRB or equivalent appropriate committee of your institution as part of the single PDF file uploaded in the Letters section. If approval is pending, indicate that the project has been submitted to the committee for review in the Human Subjects section. Payment for a successful application will not begin until such signed and dated approval is received, reviewed and approved by the Society. If a clinical trial is proposed, please include a clinical protocol or summary as an attachment in the Appendix section.

**MANAGEMENT AND RESEARCH TEAM**

List the names, affiliations, roles and responsibilities of all professional personnel involved in this plan. Include any information that will help establish the competence of the research team to pursue the proposed plan.

Name/Title	Company/Institution	Designated Role/Responsibility*

\*Additional details may be provided as necessary.

**Do you anticipate outsourcing or subcontracting any of the work to be performed under this research/clinical program? If so, name the person or people and their affiliated institution or company.**



**BIOGRAPHICAL SKETCH – (NIH Biosketch Format suggested) 2 pages maximum**

A possible format is provided below. You may however, use any format to summarize the following information for the key scientific personnel and other significant contributors listed. Each biosketch may be uploaded as a PDF.

OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

**BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED TWO PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login, if applicable):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY

- A. Personal Statement
- B. Positions and Honors
- C. Contributions to Science
- D. Additional Information: Research Support and/or Scholastic Performance

Please list other Positions, Honors, publications and skills/experience that relate to the proposed project.



**BUDGET (Use the budget template provided below as a guide to populate fields within the online application)**

- Budget: include a detailed budget and proposed use of funds for the entire funding period.

DETAILED BUDGET FOR ENTIRE FUNDING PROPOSAL PERIOD						
					Fringe	
Subtotals						
Consultant Costs						
Contract Services ( <i>itemize vendor and tasks</i> )						
Supplies ( <i>itemize by category</i> )						
Travel						
Other Expenses ( <i>itemize by category</i> )						
Total Budget						

## **OTHER FUNDING**

Please indicate how the company has raised funding to date to support the organization's activities. Please list current, pending and other sources of funding support on hand at the start of the plan (i.e. private investments, collaborative partnerships, grant support for the lead investigator and all other personnel involved in the plan). If funding requested for this program exceeds \$300,000, please indicate from which sources additional funding will be secured.

## **APPENDIX**

Appendix materials may be attached. Use the Appendix for common items such as relevant publications, press releases, clinical study protocols, clinical design reports, clinical data reviews, investigator's brochures, regulatory documents and letters of support or collaboration.

## **INTELLECTUAL PROPERTY**

Provide a comprehensive overview of all patents or licensed technologies relevant to the subject matter of this proposal. List any granted patents and patent applications relevant to the program. Additional IP information may be requested if reviewers seek further clarity.

- List any existing patents or patent applications owned or in-licensed by you and/or your Institution or Company relevant to the subject matter of this proposal.
- List any patents or patent applications related to those listed above that are currently owned by or licensed to another Institution or Company because of transfer from your present Institution or Company.
- Include structures, sequences or related chemical matter in this section. Please note if structures, sequences or related chemical matter are listed in patents.