

# FOR VIEWING PURPOSES ONLY

## Treatment Trial Application Instructions

**\* Signifies a required information, please do not hit next until you have completed all required fields**

### **\* Section One: Investigator's Information**

Name of proposed treatment trial

Primary Investigator's contact information (Page 1)

- Salutation
- First Name
- Middle Name
- Last (sur) Name
- Job Title
- Department
- Name of Institution
- Address Line 1
- Address Line 2
- City or Town
- State or Province
- Zip or Postal Code
- Country
- Telephone Number
- Fax Number
- PI's Email Address

Enter Degree(s), and attach a condensed CV (no more than 5 pages)

> hit "Save" and/or "Next"

Enter each Co-Investigator's contact information (Page 2)

- Salutation
- First Name
- Middle Name
- Last (sur) Name
- Name of Institution
- Co-PI's Email Address

Enter Degree(s), and attach a condensed CV (no more than 5 pages)

> hit "Save" and/or "Next"

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**\* Section Two: Treatment Trial Design Information (Page 3)**

Check all boxes that are appropriate

**Type of Trial (Check One)**

- Off-label Use of Existing Drug
- Natural Substances
- Investigational Compounds
- Head to Head Comparisons
- Nonpharmacological Interventions
- Confirmatory (multi-site) Studies

Indicate whether the study is a  Drug Trial or  Intervention

Indicate whether the study is an  Open Label or  Randomized Controlled Trial

If your study is an Open Label indicate whether it is:

Adjunctive

or

Monotherapy

Drug/Intervention: \_\_\_\_\_

Dosage: \_\_\_\_\_

If your study is a Randomized Controlled Trial indicate whether it is:

Adjunctive

or

Monotherapy

Drug/Intervention vs. Placebo

Drug/Intervention vs. Drug/Intervention

Drug/Intervention #1: \_\_\_\_\_

Dosage: \_\_\_\_\_

Drug/Intervention #2: \_\_\_\_\_

Dosage: \_\_\_\_\_

Parallel Group

Crossover

Double-Blind

Single-Blind

Enter the following:

Total sample size (type in number)

Study period for each subject (in days)

Duration of entire trial (in years)

List the sites where the project will be conducted.

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Outcome Measurements (Check all that apply)

- PANSS
- CGI
- BPRS
- HAM-D
- YMRS
- AIMS
- Simpson-Angus
- Others (type in any other measurements that will be used)

If you would like to submit additional information about the trial design, you can upload a Microsoft Word or PDF file (no more than 5 pages).

> hit "Save" and/or "Next"

### \* **Section Three: Proposal Summary** (Page 4)

Please provide a proposal that includes:

- a) the scientific rationale for the study, citing all relevant basic research and prior clinical experience with the drug
- b) a detailed study design
- c) a description of how the compounds tested will be obtained

You can either cut and paste the proposal summary (no more than 5 pages) into the text field or upload a Microsoft Word or PDF file.

> hit "Save" and/or "Next"

### \* **Section Four: Treatment Trial Budget Information** (Page 5)

Indirect costs may be included, up to 15% of total direct costs.

Select the budget category for each from a drop down list (Salary, Supplies, Equipment, Other), item name (i.e. PI salary) and enter the amount for each. The indirect costs should be listed in the "Other" budget category. Based on the expenditures that you enter, the system will automatically calculate the amount requested, cost per patient, and cost per patient day.

Please note: If approved, grant funding will occur as follows: 30% of funds will be released upon IRB approval and receipt of the required legal documents, 50% of funds will be released when half of the proposed sample is enrolled, and the remaining 20% of funds will be released when SMRI receives the final report.

> hit "Save" and/or "Next"

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### **Section Five: Sources of Funding** (Page 6)

List all sources of funds, pending and secured, related to the proposed research.

> hit “Save” and/or “Next”

### **Section Six: Investigators' Prior Grant Applications to SMRI** (Page 7)

Supply information on approved SMRI grants and un-funded SMRI grant applications for investigators listed in this application.

Grants Funded by SMRI:

List grant number, grant title, and investigator's name

Grant Applications to SMRI not funded (since March 1, 2001):

List year submitted, cycle (March or October), application title, and investigator's name

> hit “Save” and/or “Next”

### **\* Section Seven: Institutional Review Board Status** (Page 8)

Please check the appropriate box below. IRB approval of your proposed research application is not required before you submit the application. However, if your application is selected for funding, you must provide SMRI with a copy of the relevant approval letter before funding can be released.

Indicate status of IRB approval:

Received

Pending

Will apply if grant application is approved for funding

### **\* Section Eight: References**

If you would like to submit references (Bibliography/Citations that support your protocol) for SMRI to consider, you may upload a Microsoft Word or PDF file (no more than 5 pages).

> hit “Save Application” to save the application and edit/submit at a later time.

> hit “Submit Application” to submit your application. Please note that once you have submitted your application, you cannot make any changes.