# IAED IRB LogoStudy/Protocol Proposal Submission Form

# Board (IORG0005364/IRB #00006450)

## Principal Investigator: [Name]

## Institution: [Institution]

## Study/Protocol Title:

[Title]

## Co-Investigators and affiliations:

[Co-Investigators]

[Affiliations]

## Is this a multi-site study? A multi-site study is generally a study that involves one or more institutions in which one site takes a lead role in the research study. (e.g., sharing data to support a research study)

Yes / No: [Answer]

## Are there any collaborating institution(s)? A collaborating institution is generally an institution that cooperates equally on a research endeavor with one or more institutions (e.g., each site conducts the research study at their agency).

Yes / No: [Answer]

## Is there any funding for this study? (Training Grant, Program Project Grant, Federally Sponsored Project, Industry Sponsored Clinical Trial).

Yes / No: [Answer]

***Has a statistician been involved in the research design of the study?***

Yes / No: [Answer]

# BACKGROUND

## Purpose (Briefly describe the purpose of this protocol. Describe how the research will contribute to generalize knowledge)

[Enter study purpose]

## Study description

*Type of Study* (e.g. observational, double-blind randomized controlled trial)[Type of study]

### *Study hypothesis*

[Hypothesis]

### *Study objective(s)*

[Objectives]

### *Study primary and secondary endpoints* (describe the outcome measure of the study).

[Enter primary/secondary endpoints]

### *Inclusion / Exclusion Criteria*

[Enter Inclusion/Exclusion criteria]

### *Ethical considerations*

#### Individual informed consent processes:

[Answer]

#### What are the direct/indirect benefits and risks/costs of the study for those involved?

[Answer]

#### Dissemination/Feedback of information/finding:

[Answer]

#### Animal Subjects:

[Answer]

#### *Benefits* (describe expected direct/indirect benefits to participants/investigators)

[Answer]

# STUDY DESIGN (describe the procedures/methods used to conduct this research study).

## Research procedures and methods

[Answer]

## B. List research related procedures that are not standard of care for these patients.

[Answer]

## C. Describe the characteristics of the patients and recruitment methods (i.e. age, gender, race)

[Answer]

## D. Describe statistical analysis methods to prove the study hypothesis.

### *Primary & secondary endpoints and objectives.*

[Answer]

### *(ii) Data management* (describe data collection, processing, quality assurance and security procedures)

[Answer]

### *(iii) Sample size estimation* (include factors considered in determining appropriate sample size)

[Answer]

# If this is a clinical trial, using an experimental drug and/or device, or an approved drug and/or device used for an unapproved purpose, briefly describe the drug and/or device.

[Answer]

# Additional Information- any pertinent information to highlight or simply refer to proposal.

[Answer]