CEME Resident Research Award Application

Fully completed and signed Applications *must be submitted electronically* to ceme@nova.edu. All applicants will be notified of the award in approximately 4 weeks after submission. In the event a grant is awarded to support this application, a final report and presentation of research findings are required at either the NSU-KPCOM Annual Residency Fair or CEME Scientific Research Poster Competition. Also, the applicant and mentor agree to adhere to all award conditions specified by CEME as outlined in the guidelines which accompany this application.

CHART REVIEW STUDIES ONLY

Title of Proposed Study:

Principal Investigator:
(*List PI's name, degree, position, affiliation, address, telephone, e-mail)*

Co-Investigators:
(*List PI's name, degree, position, affiliation, address, telephone, e-mail)*

Research Faculty Mentor:
(*List mentor's name, degree, position, affiliation, address, telephone, e-mail)*

Study Site(s): (*List all sites involved)*

Protocol Version: (*1.0)*

Protocol Date: (*month/day/year)*

PRINCIPAL INVESTIGATOR ASSURANCE:

I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I certify that individuals or entities named herein are aware of their planned or potential involvement. I agree to accept responsibility for the scientific conduct of the project.

_____ _____

Resident Investigator ***Date***

1. STUDY OBJECTIVES/HYPOTHESIS

Primary Objectives

(The overall objective(s) must have scientific merit, provides some meaningful information to help guide clinical practice, etc.)

Preferably, the primary objective should address a specific hypothesis. IF so, then state the hypotheses in quantifiable terms.

Secondary Objectives

Secondary objectives may or may not be hypothesis-driven, may include secondary outcomes, and general non-experimental objectives (e.g. to develop a registry, to collect natural history data).

2. RATIONALE/BACKGROUND

Rationale

This section is based on your objective(s). How are the possible answers to the objective(s) explained and defended? What are assumptions and relationships? What are the working hypotheses? Justification of your conducting this study based on existing knowledge and your research question. Describe the disease including incidence. Provide a summary of previous pre-clinical studies, relevant clinical studies, or any epidemiological data if available include references with citations from the literature. In the last paragraph state the main purpose of the study summarizing all the information provided in your background section.

3. STUDY DESIGN

Briefly describe the study design and indicate, in general terms, how the design will fulfill the intent of the study.

4. TARGET STUDY POPLUATION SPECIFICS

Briefly describe the number and type (patient population).

Inclusion Criteria

- *List the disease or disorder under study*
- *How will it be documented, i.e. diagnostic methods, criteria for classification, etc.*

- *Demographic characteristics (e.g., gender, age) as applicable*

Exclusion Criteria

- *List specific clinical contraindications.*
- *Specify any specific grades of signs/symptoms.*

5. DATA COLLECTION

Data Collection Procedures

- *Describe the method for identifying candidates for the study*
- *Describe the procedure for obtaining data*
- *Describe the type of data to be collected and timeframe, i.e., lab tests, procedure outcome, length of stay, etc. Attach a sample of the database elements to be collected or Data Collection Form. Please be certain any Form contains page numbers and a place for the person collecting the information to sign and date.*

Records to be kept

Indicate what information will be retained for each subject and by whom. Describe methods for maintaining confidentiality of subject records.

Secure Storage of Data

Briefly describe clinical site responsibilities in data collection and management.

Quality Assurance

Due to the type of study, no ongoing monitoring will be necessary.

Note:

For exempt research: Keep only the search criteria for identifying records to be used so the search could be repeated for Quality Assurance Purposes.

For expedited research: If any type of a subject log is maintained after the data has been recorded, please ensure that a waiver of consent and HIPAA waiver have been obtained. The subject log must only contain minimal subject information. Do not retain direct identifiers such as name and date of birth.

6. STUDY DURATION/STUDY TIMELINE

Briefly state the stages of your study for example,
Stage 1, review of medical records ----4-6 months
Stage 2, data collection and data analysis
Stage 3, presentation and publication…

Include a projected start date.
Provide the *total length of time and include an approximate end date of the study.*

It is convenient for the reviewer to see the events of the study schedule or duration in the form of a flow chart.

7. STATISTICAL CONSIDERATIONS

Measures *(i.e., response (measure of interest) explanatory (factor potentially associated with measure of interest), other (demographics etc.)*

- *Primary measure (including definition, data type and range of values)*
- *Secondary measure(s)*

General Design Issues

Describe general design issues including:

- *Primary and secondary objective(s) and how they relate to the choice of primary and secondary measures most appropriate for your study design.*
- *The validity and reliability of the primary and secondary measures when available;*
- *Details of why certain design features were chosen (e.g., how the length of the evaluation period was chosen);*

Sample size determination

What sample size will you be able to get and if your suggested sample size sufficient for your primary objective? Include the number of charts you are planning to review. For multi-center studies, include the total number of sites expected and the total number of subjects to be included across all sites. Provide the rationale for the sample size.

Data Analyses

List the statistical methods to be used to address the primary and secondary objectives. Specify any confounding variables for which it is anticipated adjustment will be made. Explain how missing data and outliers, will be handled in the analyses.

8. BUDGET

The purpose of the budget and justification section is to present and justify all expenses required to achieve project aims and objectives. Provide a breakdown of the estimated project and/or dissemination costs (includes poster printing, conference registration and travel expenses, open access journal manuscript printing fees), consultants, and other direct expenses.

9. HUMAN SUBJECTS

Institutional Review Board (IRB) Review and Informed Consent

This protocol, and any subsequent modifications, must be reviewed and approved by the IRB at the Nova Southeastern University.

10. PUBLICATION OF RESEARCH FINDINGS

List any meetings or conferences where you will be presenting the data and the results of your study. Please provide timeline for finalizing manuscript and when and where you plan to submit for publication.

11. REFERENCES

Provide the citations/bibliography for all publications and presentations referenced in the text of the protocol. Each reference must include names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application. For tip sheet on AMA style referencing, see: http://library.nymc.edu/informatics/amastyle.cfm

12. ATTACHMENT(S)

Data Collection Form or Database Elements