Albert Einstein College of Medicine
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Montefiore

Harold and Muriel Block Institute for Clinical and Translational Research

Catalytic Seed Grant (CSG) – Required Information

THE CSG APPLICATION MUST BE COMPLETED AT TIME OF SUBMISSION. YOU CAN NOT SAVE AND RETURN AT A LATER DATE/TIME.

*required fields

General Information

- *First name
- *Last name
- *Phone Number
- *Email address
- *Institute, Department, Division
- *eRA Commons eRA Commons
- *Project Title
- Is this a substudy? If yes, parent study title, PI of parent study, PI's academic title
- *Key Personnel
- *IRB/IACUC #
- *IRB Title
- *Select category/consultation:
  - Learning Healthcare System Science Projects Consultation
  - Life Span Research and/or Studies in Special Populations Consultation
  - Projects that Build on Currently-Funded Extramural Career Development Awards
- *Is there a community engagement component?
- *Is this study collecting genomic data?
- *Is this study exempt from Federal Regulations? If yes, exemption number
- *Clinical Trial Questionnaire:
  - Does this study involve human participants?
  - Are the participants prospectively assigned to an intervention?
  - Is the study designed to evaluate the effect of the intervention on the participants?
  - Is the effect that will be evaluated a health-related biomedical or behavioral outcome?
- Provide the ClinicalTrials.gov identifier (e.g. NCT00000000) for this trial.

- *Provide a brief (≤ 500 words) summary of the specific aspects of the proposed study that will be supported by NCATS funds
- If the proposed research is considered an amendment or is a sub-study/ ancillary study to an IRB-approved parent protocol, provide a summary of the parent protocol with an explanation of how the proposed study connects to it.

Documents Needed for Submission (Include footer that provides identifiers ex: DSMP, Page 2, LastName)

- *IRB approval or exemption letter
- *NIH formatted Biosketch for PI and key personnel Download the Form
- *IRB approved protocol
- *Informed Consent document(s) (includes assent, parental permission, waiver, or verbal documents)
- *Line item budget. Core Director signature(s) required for the proposed core services requested. Download the Form
- *Protection of Human Subjects (describe the risk, protections, benefits and importance of the knowledge to be gained)
- *Eligibility Criteria
- *Inclusion plans for women, minorities and children
- *Recruitment and Retention Plan
- *Recruitment Status
- *Study timeline
- *Enrollment of first subject and Inclusion Enrollment Report Download the Form
- *Data and Safety Monitoring Plan
- *Overall Structure of the Study Team
- *Human Subjects Research Education (CITI) CITI Instructions: Log in to http://citiprogram.org/ and enter your username and password; click on Albert Einstein College of Medicine, Inc. Courses; under "Completion Record" click on "Print-View-Share"; click on the link to share the Completion Certificate (not the Completion Report); download certificate and save as a PDF
- Good Clinical Practice (CITI)
- Does the research include an investigational new drug (IND) or device exemption (IDE)?
    - If the research includes an IND or IDE, provide the following documentation: The IND number or letter from the FDA that the study is IND-exempt (drug) or a letter from the IRB if an investigational device is involved.
    - The approved product label, the investigator brochure, or description of the device, as applicable.
- Additional information will be requested if this Human Subjects Research meets the NIH definition of a clinical trial (answered "yes" to all four questions on previous page).