Albert Einstein College of Medicine

Cayuse Supplemental Form (v.5.0)

ALL SECTIONS MUST BE COMPLETED AT THE TIME OF ROUTING FOR NEW OR COMPETING RENEWAL APPLICATIONS

To ensure regulatory and institutional approval, please complete the questions below on **ALL** 4 pages.

PI: Megan Darrell **Cayuse Proposal Number:** 25-0649

For more information, visit the following websites:
IRB: https://www.einsteinmed.edu/administration/human-research-affairs/
IACUC: https://www.einsteinmed.edu/administration/animal-care-use-committee/
EH&S : https://www.einsteinmed.edu/administration/environmental-health-safety/

Input Applicable EHS #: ☐
Input Applicable DOR #: ☐

ANIMAL SUBJECTS:

If you answered **Yes** to the question, "Does this research involve ANIMAL SUBJECTS?" Complete the following:

A. Which species of animal will be used? ☐;
B. Do you have an IACUC- approved Animal Use Protocol that includes the animal experiments and/or animal use activities described in this grant application? Yes ☐ No ☐
   a. If Yes, please provide:
      i. IACUC-approved Animal Use Protocol Number(s): ; ☐
      ii. Latest IACUC approval date(s): ☐ ; ☐
      iii. IACUC Proposal PI Name: ☐
   b. If No, please note:
      i. IACUC approval is required prior to start of all work. Grant agencies require proof of IACUC approval to release funds.
      ii. IACUC approval requires that we evaluate concordance between the grant and the protocol. Please contact IACUC at Just-In-Time to immediately start the process.
      iii. If inter-institutional animal work is proposed, an MOU between collaborating PHS- Assured institutions is required.

If animal work is conceptualized outside of Einstein and will be performed at Einstein, an MOU without PHS - Assurance will be required.

HUMAN SUBJECTS:

Please indicate if the following apply to this grant:

A. Obtaining, using, studying, or analyzing information or biospecimens through intervention or interaction with living individuals: Yes ☑ No ☐
B. Development of an *in vitro diagnostic* using identifiable OR deidentified human specimens: Yes ☐ No ☑
C. Obtaining, using, studying, analyzing or generating identifiable private information (Personally identifiable information (PII) (including access to Protected Health Information (PHI) or medical records) or identifiable biospecimens (including use of discarded clinical specimens): Yes ☑ No ☐
D. Collection, use, receipt or shipping of embryonic stem cells or fetal tissue: Yes ☐ No ☑

IRB ORGANIZATION:

If Yes is checked to any question under the HUMAN SUBJECTS section above, please answer the following:

A. If this is a single site study, it is occurring at Einstein [✔] Montefiore Medical Center [ ]
Montefiore Medical Center includes Moses, Weiler, Wakefield, CHAM, MMG sites.

B. Name the site if any other Montefiore Health System institutions (outside Montefiore Medical Center) are participating in this research. Examples of non-MMC entities include White Plains Hospital, Montefiore Einstein Advanced Care, and Burke Rehabilitation Hospital, Montefiore New Rochelle, Nyack, Mt. Vernon, etc.

C. Name the site if any external institution is participating in this research (including Yeshiva University.

_____

D. If this is a multi-site study, is each site using a different IRB (multiple IRBs being used) or are all sites using a single IRB (sIRB)? (sIRB is required for federally-funded.) Multiple [ ] Single [ ]

E. If multiple sites are using a Single IRB, *is Einstein serving as the single IRB for all sites*?
Yes [ ] No [ ]

a. If Yes, an IRB Reliance Request form is needed **at least 10 business days prior** to the grant deadline.

i. Following review of the request form the Einstein IRB will provide:

1. Single IRB fees that must be included in the budget as a direct cost item
2. **A Single IRB Letter of Support (LOS) that must be attached in Cayuse SP**

ii. Please contact the Einstein IRB with any single IRB related questions at singleirb@einsteinmed.edu.

F. If multiple sites are using a Single IRB that is NOT the Einstein IRB, *which IRB is being used*?

_____

a. An IRB Reliance Request form is needed **at least 10 business days prior** to the grant deadline. The IRB will provide:

i. A Single IRB LOS agreeing to cede to the designated IRB upon Notice of Award (NOA). **The LOS must be attached in Cayuse SP.**

b. Have you included the external IRB's fees in the budget as a direct cost item? These fees must be provided by the designated Lead IRB. How much will they bill us? _____

c. Please contact the Einstein IRB with any single IRB-related questions at singleirb@einsteinmed.edu.

G. Does the participant population include prisoners? Yes [ ] No [✔]
If Yes, you must contact the Office of Human Research Affairs (OHRA) and budget for BRANY.
Does this study investigate a condition experienced by individuals in an emergency setting where there's no opportunity to obtain consent from each individual's legally authorized representative? Yes [ ] No [ ]
If Yes, you must contact the OHRA. For more information on requirements please refer to the following guidance: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed- consent-requirements/ index.html.

MATERIALS FROM OUTSIDE ORGANIZATIONS:

Will you need to access materials (specimens, animals, samples, datasets) from outside organizations that are NOT covered under a purchase or procurement agreement? Yes [ ] No [✔]

If you answered Yes above, complete the following:

A. If transfer of materials is with an academic institution or non-profit organization, did you submit the request through the MTAShare Portal? Yes [ ] No [ ]

B. If Yes, when [ ]

C. If transfer of materials is with an industry partner/sponsor AND involves human specimens or human datasets, did you submit the request through the *Einstein/Montefiore Research Agreement Request Portal*? Yes [ ] No [ ]

D. If Yes, when [ ]

For all complex transfers of materials (bi-directional or multi-party), contact the Office of Biotechnology and

Business Development for next steps (MTA@einsteinmed.edu)

CONFLICT OF INTEREST:
Do all investigators have current (i.e. submitted within the past 6 months) Einstein COI disclosures on file (please email COI@einsteinmed.edu if unsure)? Yes ☑ No ☐
If No, please submit updated COI disclosures at https://einstein.coiriskmanager.com
Reminder: COI disclosures must be submitted every 6 months to avoid delays in funding. For more information on Einstein's COI disclosure policies, refer to the Comprehensive Conflict of Interest Policy. Please contact COI@einsteinmed.edu with any questions.

RedCAP PORTAL:
Do you plan to use RedCAP resources? Yes ☑ No ☐
If Yes, include $1,000 per research protocol in the budget as a direct cost to the grant in year 1. (If there are multiple protocols associated with this grant, use a multiple of $1,000).

SHARED FACILITIES & CORE:
Do you plan to use any shared facilities or research cores? Yes ☐ No ☑
If yes, please estimate cost for budgets using pricing for desired services listed in iLab or contact the core for pricing.

CLINICAL RESOURCES:
Will this study involve prospectively consenting participants at a Montefiore Medical Center or Albert Einstein College of Medicine facility? Yes ☑ No ☐
Will billable clinical services be conducted SOLELY for research purposes at Montefiore/Einstein including but not limited to specimen processing by the Pathology Department? Yes ☐ No ☑
If Yes, please list the full procedure description and CPT code below (MRI Chest w/o & w/dye 71552):

Full Procedure Description	CPT Code
n/a (consenting only, no billable service)	n/a (consenting only, no

If you answered Yes to any question in the CLINICAL RESOURCES section, please add the Office of Clinical Trials (OCT) to the routing chain. Kindly, *allow two weeks for review and approval*.

PHARMACY RESOURCES:

A. Will you be using an investigational product, drug, biologic (FDA-approved or non-approved, Standard of Care drug or controlled substance) or a device for drug administration as part of the project? Yes ☐ No ☑
B. Will the study require pharmacy involvement (drug procurement, storage, accountability, randomization & blinding / preparation & dispensing)? Yes ☐ No ☑
C. Will the study require pharmacy involvement at multiple sites? Yes ☐ No ☑
D. Are you considering requesting a storage waiver? Yes ☐ No ☑

If you answered Yes to any of the above, pharmacy review of the protocol prior to contract negotiation will be required. Please email research pharmacy at least 2 weeks prior to deadline or contract negotiations for approval:
Non-Oncology services: Clemencia Solorzano csolorza@montefiore.org
Oncology services: Roy Browne RBROWNE@montefiore.org and Pragna Patel PPATEL@montefiore.org

BUDGET

1. If anyone named on the budget is not on Einstein payroll, please explain with a note in Cayuse SP.
2. If anyone named on the budget is on the Montefiore payroll, please include a list of personnel in the note section of Cayuse SP and identify institutional affiliation (Montefiore and Einstein). Include Montefiore ORSP in the routing chain.
3. If a budgeted base salary is materially different from the EPAF amount, please explain this in a note in Cayuse SP.
4. Single IRB fees must be included as direct costs in the budget. Please contact the lead IRB to obtain the exact dollar amount.
5. Please ensure budget reflects costs associated with the husbandry per diem rates for animals.

FOREIGN SUBAWARD

Does your research involve the inclusion of a foreign subaward? Yes ☐ No ☑

If you answered yes, you must obtain a signed Letter of Support (LOS) from the subsite with specific language to meet the compliance requirement of NOT-OD-23-182. See below:

We confirm that all appropriate programmatic and administrative personnel involved in this application are aware of the prime awarding agency's policies, agree to accept the obligation to comply with award terms, conditions, and certifications, and are prepared to establish the necessary inter-institutional agreement consistent with those policies.

As outlined in NOT-OD-23-182, we will provide access to copies of all lab notebooks, all data, and all documentation that support the research outcomes to the primary recipient no less than once per year, in alignment with the timing requirements for Research Progress Report submission.

DATA MANAGEMENT AND SHARING (DMS) PLAN & COST (NOT-OD-23-161):

Does your research generate data that must be shared according to the NIH Data Management and Sharing Policy? Yes ☐ No ☑

A. If Yes, attach a document in Cayuse 424 Other Plan (s) section of the PHS 398 form. Name the document **"Data Management and Sharing Plan."**
   1. **Effective** for applications submitted for **due dates on or after October 5, 2023**, NIH will require applicants **to specify estimated "DMS cost"** details within the **"Budget Justification"** attachment of the **R&R Budget Form** or "**Additional Narrative Justification"** attachment of the **PHS398 Modular Budget Form**, pursuant to the instructions.
   2. While the single cost line item is no longer required, "**DMS costs" must be requested in the appropriate cost category**, e.g. **personnel**, **equipment**, **supplies**, and **other expenses**, following the instructions for the funding opportunity.

B. Not all funding mechanisms require the DMSP (i.e. NIH F mechanism, subawards, foundations). Please read the NOFO closely for NIH. If the funding mechanism does not require a DMSP please leave a comment in the notes section of Cayuse SP. For additional information please click here.