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| **Project Information** |
| PI Name: Click or tap here to enter text. | PI Department/Division: Click or tap here to enter text. |
| Phone Number: Click or tap here to enter text. | Email Address: Click or tap here to enter text. |
| PI Employer: 󠆼[ ]  Einstein 󠆼[ ]  Montefiore |
| Project Sponsor: Click or tap here to enter text. |
| Sponsor Protocol Number: Click or tap here to enter text. |
| Sponsor Study Title: Click or tap here to enter text. |
| External Collaborating Institutions: (List all sites and vendors with which Einstein/Montefiore will need a contract) Click or tap here to enter text. |
| **Recruitment – Consider how many patients in your practice area meet the inclusion criteria.** |
| The PI named above has how many existing open trials? Click or tap here to enter text. |
| Does the PI have access to appropriate patient population for recruitment? 󠆼[ ]  Yes 󠆼[ ]  NoIf yes:* How will PI identify and recruit subjects? Click or tap here to enter text.
* Will referrals from colleagues be needed? 󠆼 [ ]  Yes 󠆼[ ]  No
 |
| Is subject accrual feasible within the stated protocol timeframe? 󠆼[ ]  Yes 󠆼[ ]  No How many subjects does the PI anticipate enrolling in the first year? Click or tap here to enter text. |
| Are there existing open trials competing to enroll the same subject population? 󠆼[ ]  Yes [ ]  NoIs there a plan to address competing recruitment goals? 󠆼[ ]  Yes 󠆼[ ]  No |
| Will subjects be compensated for their time and effort: 󠆼[ ]  Yes [ ]  No |
| **Equipment – Identify whether new equipment will be needed to successfully implement this protocol.** |
| Will equipment specific to the research protocol need to be purchased or provided by the sponsor? Specify equipment, name of vendor/supplier/estimated cost.Click or tap here to enter text. |
| **Staff Resources – Consider your access to appropriate personnel to execute this study.** |
| Does the PI have the necessary research regulatory and research coordinator staff to successfully manage recruitment/retention/sponsor reporting/BRANY CTMS, Velos, EPIC documentation, research test ordering, regulatory requirements, data entry, charge reviews?  󠆼[ ] Yes 󠆼[ ]  No What FTE/effort be required to devote to study? Click or tap here to enter text.Nursing, Coordinator, PI |
| **Research Data – Evaluate whether you have secure mechanisms to secure and transmit research data and specimens.** |
| Where and how will research data be stored? (Name of software, name/location of server) HIPAA Compliant? 󠆼[ ]  Yes 󠆼[ ]  NoClick or tap here to enter text. |
| How will research data be shared with sponsor or collaborating institutions? (Name of software, describe mechanism, etc.)  Click or tap here to enter text. HIPAA Compliant? 󠆼[ ]  Yes 󠆼[ ]  No |
| Will you be using Redcap? 󠆼[ ]  Yes 󠆼[ ]  No |
| **Cancer Center** |
| Does this study involve cancer patients and require PRMC approval? 󠆼[ ] Yes 󠆼[ ]  No |
| **Ancillary Resources – Consider your partnerships with ancillary departments necessary to complete this study.** |
| Have other departments, clinics, or ancillary services that may be impacted by, or provide services for, the research been informed and agreed to support the conduct of the study? Check all that apply: Pharmacy? 󠆼[ ]  Yes 󠆼[ ]  No  Will study drug be provided by the sponsor? 󠆼[ ]  Yes 󠆼[ ]  NoPathology? 󠆼[ ]  Yes 󠆼[ ]  NoRadiology?󠆼[ ] Yes 󠆼[ ]  No Which of the following are required: 󠆼[ ]  MRI 󠆼[ ]  CT 󠆼[ ]  PET 󠆼[ ]  XRAY 󠆼[ ]  Other: Click or tap here to enter text.Nuclear Medicine?󠆼[ ]  Yes 󠆼[ ]  NoOther: \_\_Click or tap here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Subject Testing – Are there any tests or procedures being conducted for Research Purposes Only** |
| Will research subjects require any medical test or procedure for research purposes only? 󠆼[x]  Yes 󠆼[ ]  NoIf Yes, list tests/procedures for research purposes only: Click or tap here to enter text.  |
| For subjects enrolled in this protocol, within this study, will there be procedures and tests performed for: (Check one) Standard of Care only: 󠆼[ ]  Yes 󠆼[ ]  No Research purposes only: 󠆼[ ]  Yes 󠆼[ ]  No Mixed of Standard of Care and Research : 󠆼[ ]  Yes 󠆼[ ]  No  |
| **Logistics of the Study – Consider the detailed coordination of each study visit.** |
| Where will subjects enrolled in the study be seen? (Location of recruitment, procedures, etc.)Click or tap here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Specimen Collection – Consider how you will collect specimens from research subjects and how they will be processed.**  |
| Will any specimens need to be shipped to the sponsor’s central lab? 󠆼[ ]  Yes 󠆼[ ]  No* Does Montefiore need to process specimens before shipping? 󠆼[ ]  Yes 󠆼[ ]  No
* If yes, who will be do the processing and where? Click or tap here to enter text.
 |
| Does the PI need to store specimens on site? 󠆼[ ]  Yes 󠆼[ ]  NoWhere will specimens be stored? \_Click or tap here to enter text.\_ |
| Does PI need access to special freezers or incubators? 󠆼[ ]  Yes 󠆼[ ]  No |
| Will the PI be using resources of the CRC? 󠆼[ ]  Yes 󠆼[ ]  No |
| Will specimen banking require using resources of Einstein or Montefiore’s central biorepository? 󠆼[ ]  Yes 󠆼[ ]  No |

Signature below indicates completion of feasibility review for the study noted above. Approved: [ ]  Yes 󠆼[ ]  No

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Principal Investigator Signature (**If applicable, attached fully executed Non-Disclosure Agreement)**

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Chair or Designee Signature