## PART A

##### RESEARCH APPLICATION – BASIC INFORMATION

This application is submitted for:  **Full Board Review**

**Expedited Review (Requires submission of Part M)**

## A1. TITLE OF PROPOSAL

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| --- |
| Tech Enabled Clinical Care (TECC) |

**SHORT TITLE** (*50 characters – must contain keywords for identifying protocol*)

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| --- |
| Tech Enabled Clinical Care (TECC) |

**PROVIDE A BRIEF SUMMARY** (1*50 characters – must be in laymen terms)*

|  |
| --- |
| This protocol is designed to assess how eight weeks of outpatient mental healthcare for BIDMC patients (who are referred by primary care at BIDMC) can help reduce symptoms of anxiety and depression. These eight weeks of care are unique in that although the eight one-hour therapy-based visits will follow the clinical standard of care, between visits we will ask patients to use a smartphone app to augment care. Of note, there will be no interaction or monitoring of smartphone data between sessions. The question is to assess if this augmentation can help improve speed of recovery. The goal is to recruit 50 patients total |

**A2. PRINCIPAL INVESTIGATOR (PI)**

|  |  |  |
| --- | --- | --- |
| Principal Investigator: **John Torous** | | |
| Department: Psychiatry | Division: | |
| P.I.'s Chief of Department or Division (*if applicable*): **William Greenberg** | | |
| P.I. Internal BIDMC Mailing Address: **RW056B** | | |
| P.I. E-Mail Address: **jtorus@bidmc.harvard.edu** | | |
| P.I.’s Telephone: 510-684-6827 | P.I.’s Pager: NA | Fax: NA |

**A3. BASIC STUDY TYPE AND DESIGN INFORMATION**

|  |
| --- |
| Study Type:  ***(check all that apply)***  Therapeutic  Diagnostic  Epidemiologic\ Observational  Health Services\ Health Care Operations  Physiologic  Genetic Research  Behavioral  Quality Improvement  Educational Research  Medical Record Review  Specimen/Data Repository  Registry  Use of discarded/excess specimens  Other*(explain):* |

**A4. Please check all of the following that apply to this research**

|  |
| --- |
| This protocol will require assistance from nursing personnel *(****REQUIRED: Complete PART C and obtain signature****)*  This protocol will be conducted in the Clinical Research Center *(****REQUIRED: Complete PART C and obtain signature)*** |
| This protocol involves the use of a drug, biologic, nutritional supplement, herbal or homeopathic  medicine, medical food, medical gas, inhalation therapy, topical cream, chemical or other  compound that will be administered as the object of the protocol or because it is relevant to the  aims of the research protocol. (***REQUIRED: Complete Questions A14, A15 & PART E and obtain signature*** *)* |
| This protocol involves a medical device that will be used, administered, implanted, or applied to the  subjects, as the object of the protocol or is relevant to the objectives of the protocol. This includes  investigational devices classified as both significant risk and non significant risk as well as IDE Exempt and FDA  approved/marketed devices. (***REQUIRED: Complete Questions A14, A15 & PART G****)*  This protocol involves X-ray or Radioactive agent (***REQUIRED: Complete PART F and obtain signature*** *)* |
|  |
| This protocol involves laboratory testing: in-house or outside provider (***REQUIRED: Complete PART H and obtain signature)*** |
| This protocol involves transfusion medicine products and services (***REQUIRED: Complete PART H and obtain signature)*** |
|  |
| This protocol involves Infectious agents–see **Part J** for examples (***REQUIRED: Complete PART J and***  ***obtain signature)*** |
| This protocol involves Genetic Research (***REQUIRED: Complete PART K )*** |
| This protocol involves Hazardous Biological Agents – see **Part L** for examples - (***REQUIRED: Complete***  ***PART L)*** |
| This protocol involves Radiology including clinical and/or research (***REQUIRED: Complete PART R and***  ***obtain signature)*** |
|  |
| This protocol will be conducted outside of the United States (***REQUIRED: Complete PART I; THE CCI REQUIRES LOCAL IRB APPROVAL BE OBTAINED PRIOR TO ACTIVATION)*** |
|  |

**A5. REQUIRED ATTACHMENTS**

**\*\*\*Please check all attachments included in this submission to the CCI\*\*\***

**Refer to the following forms on the CCI portal for submission instructions:**

**Overview of Forms and the Instructions for Submitting New Research Applications**

|  |
| --- |
| Scientific Review  Research Staffing Form  Part B  Consent/Assent Form (with key information summary)  Waiver of Authorization  Part P  Sponsor Protocol  Investigational Brochure  Federal/Foundation Grant (i.e. NIH, NSF)  Recruitment Material/Scripts  Interview Guides  Focus Group Guides  Psychological/personality tests  Subject Diaries  Subject Instructions  Questionnaires  Other [Worksheets to be completed by patients via the mindLAMP app over the course of the study |

## A6. INSTITUTION(S) WHERE STUDY WILL BE CONDUCTED

## \*\*PART B must specify the location(s) where the study will be conducted\*\*

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| --- |
| 1. For subjects consented/enrolled at BIDMC, will any study visits or procedures be conducted at an institution outside of BIDMC?  Yes  No   Specify the institution (s): |
| B. Is this a multi-site study?  Yes  No  Specify the number of other sites, if known: |
| C. Is the BIDMC the coordinating site?  Yes  No |
| D. Is the BIDMC PI the lead PI of the multi-site study?  Yes  No  If this study is initiated by the BIDMC investigator or if BIDMC is the prime recipient of a federal grant, please list each site and for each site provide the following information, name and location of site, whether or not the site has an IRB, contact information for the site and if the site has an IRB, whether the IRB has approved the research or plans to ask to rely on the CCI for IRB review.    Please note that all requests to rely on the CCI for review must be discussed with the CCI Director of Operations prior to discussion with the other site.   |  |  |  |  | | --- | --- | --- | --- | | Site: | IRB | IRB Contact Information | IRB Approval Status | |  | Yes  No |  | Yes  No  Pending  Seeks to Rely on the CCI | |  | Yes  No |  | Yes  No  Pending  Seeks to Rely on the CCI | |  | Yes  No |  | Yes  No  Pending  Seeks to Rely on the CCI | |  | Yes  No |  | Yes  No  Pending  Seeks to Rely on the CCI | |

**A7. SPONSOR/FUNDING SOURCE**

**\*\*\*Section A7 and Billing Compliance Assessment must be completed for all research studies,**

**even if no funding is available\*\*\***

**If no funding is available for the study, please provide an explanation as required in the first box**

**below and then skip to section A8. Note the PI must contact Clinical Trial Office as review of the study**

**may be required.**

**Complete the remainder of section A7 (A thru G) for all sponsored and/or funded research**

**studies.**

**For applications involving federal or foundation funding, Department of Health and**

**Human Services (HHS) requires under regulation 45 CFR 46.103 (f) that each application or**

**proposal for HHS-supported human subject research be reviewed and approved by the IRB.**

|  |
| --- |
| **No** funding is available – provide explanation of how research can be done without funding and then skip to section A8 ***(If not funded, contact the Clinical Trials Office at (617) 667-4443 or CTO@bidmc.harvard.edu for possible review*)**  Please provide explanation: Dr. Torous start-up funds |
| **Yes**, monetary and/or non-monetary (i.e., in kind) funding:  Industry  Federal  Foundation  Internal  Free Drug or No Cost Loan of Device |
| **Billing Compliance Assessment**   1. Will any charges, items, and/or services be billed to insurance?  Yes  No 2. Does the trial have therapeutic intent (i.e. not designed exclusively to test the toxicity or disease pathophysiology)?   Yes  No   1. Will the trial enroll patients with a diagnosed disease, ie. not a Phase I study enrolling only healthy volunteers? (Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.)   Yes  No   1. Is the principal purpose of the study to test whether the intervention potentially improves the participant’s health outcome?  Yes  No   ***(Please complete A thru G below*)** |

1. **Funding or Supporting Information** *(check the appropriate box)*

|  |  |
| --- | --- |
|  | Industry initiated, and supported research  Funding entity *(please specify)*: |
|  | Investigator initiated, externally supported research  Funding entity *(please specify)*: |
|  | Investigator initiated, internally supported research  Internal funding source *(please specify)*: Dr. Torous’ startup funds |

1. **Review/Approval of Funding Agreement and Budget**

**For both industry and internally funded research, as well as in kind support such as free drug or no cost loan of device, the BIDMC Clinical Trials Office (x7-4443 or CTO@bidmc.harvard.edu) should review/approve the funding agreement and budget.**

**For all other externally funded research please contact the Research Administrator or Research Administrative Director for your department for review/approval of the funding agreement/application and budget.**

|  |  |  |
| --- | --- | --- |
| Which BIDMC research administrative office did you contact for review and approval of your funding agreement and budget? | | |
|  | **Contact Name** | **Date** |
| Clinical Trial Office (complete section A7.C) |  |  |
| Research Administrator *or*  Research Administrative Director |  |  |

1. **Clinical Trials Office**

|  |
| --- |
| The contract and budget are under review. |
| The contract and budget have been reviewed and fully executed/approved. |
| Internally supported, review not required. |
| Other (please specify in the comment section below). |

**Comments**

|  |
| --- |
| This is not grant or industry funded. |

1. **Funding or Support Details**

|  |
| --- |
| List dollars requested/approved: $0 |
| Describe any non-monetary support that will be provided and **the source** of such support (e.g. free medication, research drug, device, material gifts, and who will provide): NA |
| This research study involves:  one site only/BIDMC Locations  multiple sites |
| For federal grants: Is BIDMC the awardee institution?  Yes  No  If **No,** who is awardee institution*?*  If **Yes,** attach a completed, signed copy of the HHS/NIH application.  ***Note: The CCI cannot grant final approval until the grant application has been reviewed***  Is this study funded by the Department of Defense (DoD) or a component of the DoD  Yes  No  If **Yes,** complete **A7. G**. |

1. **Discrepancies**

|  |
| --- |
| Are there any discrepancies including administrative (e.g. title, Principal Investigator) or procedural between the CCI application and the HHS/NIH application?  Yes  No  If **yes,** specify and explain all differences: |

1. **HHS/NIH Application Details**

|  |
| --- |
| List the GEMS #, if applicable: |
| Assigned HHS/NIH grant #: |
| Grant application submission date: |
| Grant application status:  Funded   Pending (priority score/percentile is “fundable”) |

1. **Department of Defense (if not linked to the DOD, you may omit this section)**

|  |
| --- |
| How is your project linked to the Department of Defense? (check off all that apply)  **Information about DoD policies and regulations may be found in the CCI Policy and Procedure Manual,**  **Appendix J.**  The project is funded by DoD or one of its components (e.g., Department of Army, Navy, etc)  The project involves cooperation or collaboration with DoD  The project uses DoD property, facilities or assets  The subject population will be DoD personnel (whether military or civilian) |
| **If any portion of your study involves surveys or interviews of DoD personnel, additional DoD policies may apply. Refer to the CCI Policy and Procedure Manual, Appendix J** |
| **If this study involves greater than minimal risk, an independent medical monitor must be appointed by name**.  Physicians, dentists, psychologists, nurses or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual subject/patient management and safety may be the medical monitor. The monitor must also be independent of the study team and should possess sufficient information and professional experience to serve as the subject/patient advocate.  Depending on the nature of the study, the medical monitor may be assigned to assess one or more of the following phases of the research project: subject recruitment, subject enrollment, data collection, or data storage and analysis. At the discretion of the IRB, the medical monitor may be assigned to discuss research progress with the lead researcher, interview subjects, consult on individual cases, or evaluate adverse events reports.  I have designated a Monitor  I have attached the Monitor's *curriculum vitae*  I have attached a letter from the Monitor accepting the role  I have named the Monitor and described his/her role in the following:  Part B.3.A  Part P  In the Confidentiality section of the ICF (if the Monitor will have access to individually identifiable data)  The Medical Monitor has completed COI |
| **Protections for Military Personnel**  N/A DoD personnel (military or civilian are not a target population  I will ascertain that an individual's decision about participation has not been influenced by unit officers or senior noncommissioned officers (NCOs)  I will exclude unit officers and senior NCOs from recruitment/consent sessions for units under their command  I will offer separate recruitment/consent sessions for officers and NCOs excluded from sessions held for their units  An ombudsman not connected to the research or to the unit shall be present to monitor group recruitment briefings  I am implementing the following protections not specified above: |
| **NOTE: The DoD prohibits research involving prisoners of war (any person captured, detained, held or otherwise under the control of DoD personnel (military or civilian, or contractor employee) except DoD personnel held for law enforcement purposes.** |
| **NOTE:**  **The Principal Investigator is responsible for consulting with the DoD component and informing the IRB of any additional requirements.** |

**A8. SUBJECT INFORMATION**

1. **Research involves enrolling, reviewing records or obtaining discarded specimens from the following:**

|  |  |  |
| --- | --- | --- |
| **Outpatients** |  | **Fetuses \*\*\*** |
| **Inpatient** |  | **Newborns/Infants\*\*\*** |
| **Students** |  | **Children (2-12)\*\*\*** |
| **Adults (18-65)**  **Adults (65+)**  **Healthy Volunteers** |  | **Adolescents (13-17)\*\*\*** |
|  |  | **Pregnant Women \*\*\***  **Cognitive/Mentally Impaired\*\*\***  **Employees/Staff\*\*\***  **\*\*\*Research Involves Vulnerable Population, Refer to Appendix D of CCI Policy** |
| **If subjects are *Students*, are they enrolled at Harvard Medical School?  Yes  No** | | |  | **Cognitive/Mentally Impaired** |
| **If subjects are *Employees*, are they currently under PI.’s or CoPI’s supervision?  Yes  No**  **It is the policy at BIDMC that employees or trainees may not be enrolled in a study that is being conducted by someone who is in a supervisory/managerial position over them. That is, someone who has direct or indirect input into evaluating that employee. This policy would not apply to “treatment oriented” protocols with a potential to benefit the subject.**  **Questions regarding the application of this policy or requests for exceptions to this policy should be directed to the Director of CCI Operations.** | | |

**Investigators who wish to enroll a prisoner(s) must contact the CCI Director of Operations prior to submission of a research application. The CCI cannot review research which involves a prisoner population as the Committee does not currently have prisoner representative.**

**If enrolling children under the age of 18, please select appropriate risk level:**

no more than minimal risk. Consent from one parent is sufficient**.** [46.404/ 50.51](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.404)

greater than minimal risk but presenting the prospect of direct benefit to the individual subjects, Consent from one parent is sufficient**.** [46.405/ 50.52](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.405)

greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, Consent must be obtained from both parents if they have custody and are reasonably available**.** [46.406/ 50.53](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.406)

research not otherwise approvable that presents an opportunity to understand, prevent, or alleviate a serious problem that affects the health or welfare of children. Consent must be obtained from both parents if they have custody and are reasonably available. [46.407/ 50.54](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.407)

the children are wards of the state or any other agency, institution, or entity.46.409/ 50.56

**Full guidance on enrollment and consent/assent of children can be found in the CCI Policy and Procedure Manual, Appendix D**

**\*\* Protocols limited to review of patient health records and/or research with discarded**

**specimens already in existence at the time of CCI submission should skip to section A10**

**Consent / Authorization.**

1. **Disease**

|  |
| --- |
| Is there a **primary disease or target population** for which this research has been designed?  Yes  No  If ***Yes***, specify:  Depression and anxiety |

1. **Estimated Number of Subjects**

|  |
| --- |
| How many subjects will participate in this study at BIDMC? 50  **(Participation is defined as subjects who will have consented to be in the study including those who may screen out, withdraw or be found ineligible for participation after consenting)** |
| If a multi-site study, how many subjects will be needed at all sites? |

1. **Subjects Sex**

|  |
| --- |
| Male  Female |
| Are women of childbearing potential eligible?  Yes  No  If **not,** justification for this exclusion must be provided in Part B3 C. |

1. **Language Proficiency**

|  |
| --- |
| Will non-English speaking subjects be enrolled in this protocol?  Yes  No |
| If **yes**, what language(s) do you anticipate subjects may have as a primary language? |
| If **yes**, what are the plans for providing the subject with a written translation of the consent form and other study materials and to ensure that all study interaction will be in a language understandable to the subject? |

**\*\*\*Please refer to the CCI portal for guidance on the Consent Process for Non-English Speaking Participant\*\*\***

1. **Subject Compensation (Compensation is payment for participation)**

|  |
| --- |
| Will there be any compensation to the subjects?  Yes  No  If **yes**, specify:  1. Amount and for what:  2. Time(*s*) of payment: |

1. **Subject reimbursement (reimbursement is payment of expenses incurred by the subject as evidenced by receipts.)**

Will there be any reimbursement to the subjects?  Yes  No

1. Amount and for what:

1. **Incidental Finding**

Is there a possibility of clinically significant incidental findings being discovered during research procedure? **Incidental findings may include discovery of genetic mutations, abnormal results following an MRI of a healthy control, or indications of subject depression following review of quality of life assessments**

Yes  No

If yes, describe potential incidental findings: During these 8 weeks of mental health treatment, we may uncover a diagnosis or certain type of pattern that requires more care than we can offer in this protocol. We will let the primary care team and patient know. They can then refer the patient to the right care at BIDMC.

If yes, outline the plan for communicating the incidental findings (i.e. contacting the subjects primary care

provider, referral, etc.): Email to BIDMC primary care clinician.

**A9. RECRUITMENT AND SCREENING METHODS/PROCEDURES**

**Note the Part B must clearly outline all recruitment methods.**

1. **Recruiting Research Subjects Who Are Patients and for Whom Protected Health Information Will Be Accessed**

|  |
| --- |
| **ONLY** Screening/Recruiting Own Patients **(*If ONLY screening/recruiting own patients, do not submit HIPAA Waiver of Authorization Form*.)** |

**Check off any methods below that will be utilized to recruit research subjects and submit a HIPAA Waiver Application.**

|  |
| --- |
| Conversation with treating Healthcare Provider about individually identified patients |
| Conversations with prospective research subjects |
| Medical Records review |
| Review of Clinical Query2 |
| Review of data repositories |
| Review of appointment logs |
| Review of procedure posting books |
| Review of rounding lists |
| Review of other lists. Please specify: |
| Other Please specify: |

1. **Recruiting Research Subjects for Whom Protected Health Information Will NOT Be Accessed**

|  |
| --- |
| Please briefly describe how research subjects will be identified (e.g. local community, educational program lists, staff schedules): They will be referred by primary care |

1. **Recruitment Tools**

|  |
| --- |
| Submit written materials for the following types of recruitment methods.  Advertisements/Recruiting Flyers (include copies of all advertisements/recruiting flyers) |
| Trial X *(complete* ***Form S****)* |
| Letters (indicate how many different letter(s) will used and include copies of the letter(s) 1 |
| Targeted Emails (indicate how list will be generated)  Social Networking Websites (indicate what websites and include copy of the website posting and text) |
| Telephone Calls  Pre-screening script/questionnaire – *May require HIPAA Waiver of Authorization* |
| Other – Please explain: |

**A10. CONSENT/AUTHORIZATION PROCEDURES**

1. **Consent**

|  |
| --- |
| **Select all that apply:**  **Written informed consent/assent will be obtained for all subjects. 🡨(for all clinical patients)**  **\*\*Note a verbal pre-screening script must be included in the submission. Refer to CCI Guidance on Pre-Screening Potential Participants During Recruitment.**  **Request a waiver of documentation of informed consent/assent (i.e. study will use verbal consent process).**  If yes, please indicate reason for waiver of documentation:  The research is not FDA regulated and that the only record linking the Human Subject and the Research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each Human Subject must be asked whether the Human Subject wants documentation linking the Human Subject with the Research, and the Human Subject's wishes will govern; **or**  That the Research presents no more than minimal risk of harm to Human Subjects and involves no procedures for which written consent is normally required outside of the Research context; **or**  Subjects that are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subject and provided there is an appropriate mechanism for documenting that informed consent was obtained. *Provide details of consent process in Part B, B.6.*    Provide description of subject population and reason for waiver of documentation: primary care  **If waiver/of documentation is requested, provide explanation regarding why this waiver is necessary**. Primary care clinician will be asked to fill out a simple, anonymous, and non-PHI survey.  **\*\*Note the verbal consent/script must be included in submission. If requesting Waiver of Documentation of Informed Consent, you must also request Waiver of Authorization (Section B)**    **Waiver/alteration of informed consent is requested. (No consent will be obtained or an essential element will be altered.)**  All of the following must be true:  The Research involves no more than minimal risk to the Human Subjects;  The waiver or alteration will not adversely affect the rights and welfare of the Human Subjects;  The Research could not practicably be carried out without the waiver or alteration;  If the research involves using identifiable private information or biospecimens, the research could not practicably be carried out *without* using such information in an identifiable format; **and**  Whenever appropriate, the Human Subjects will be provided with additional pertinent information after participation  **If waiver/alteration of informed consent is requested, provide explanation regarding why this waiver is necessary**. To screen clinical patients for the research  **\*\*\* If requesting Waiver of Informed Consent, you must also request Waiver of Authorization (Section B)**  **Indicate the number of consent forms to be used in this study and identify their purpose:** 1 for clinical parients  *(e.g. healthy control, volunteer, patient volunteer, multi-lingual)* |

**Consent will be obtained:** **Consent to be obtained from:**

|  |  |
| --- | --- |
| Immediately prior to study | Patient/Subjects |
| 1-24 hours prior to study | Parent(s)  One Parent Both Parents |
| up to 1 week prior to study | Legally Authorized Representative (LAR)  Explain why use of an LAR would be necessary |
| greater than 1 week prior to study | **(Note: The Part B must contain a detailed justification for obtaining consent from a Legally Authorized Representative and the process used to determine whether an individual is capable of providing assent.)** |

1. **Authorization**

|  |
| --- |
| Waiver of authorization to use/disclose Protected Health Information is requested.  ***Please complete and attach the Waiver of Authorization*** |
| Written authorization to use/disclose a subject’s Protected Health Information will be obtained. |
| Permission to do research **ONLY** on deceased individuals.  ***Please complete and attach the HIPAA Permission to do Research on Deceased Individuals Form*.** |
| Not Applicable. The study will not involve the **use or disclosure** of Protected Health Information. |

**a11. Use of Medical Records**

**A. Basic information**

Will the patient medical record be accessed for the purpose of this protocol?

Yes  No

If No, skip to A12.

How long will the study access the medical record for the purpose of this protocol?

FROM: TO:

Will psychiatric records be accessed?  Yes  No

**In accordance with Massachusetts state law, psychiatric records may only be reviewed upon receipt of express written consent from the subject to disclose.**

Describe the patient related information to be studied: diagnosis or stage, age group, surgical or medical, particular service or division, inpatients or outpatients, etc.):

How many records do you estimate you will access at BIDMC for this study? **(Please note: this number includes every record you will screen. This number may be larger than the number of records you need to complete the data analysis)**

0 - 500

501 - 1000

1001 - 2000

Greater than 2000

How many records will be accessed at sites other than BIDMC?

|  |
| --- |
| Will identifiers, such as medical record number, be recorded and maintained or associated (e.g. via a coding system) with the data?  Yes  No  If YES, do you plan to contact patients?  Yes  No  If YES, explain why: |
| Describe the measures that will be taken to protect the confidentiality of identifiable patient data? |

**B. Source of Patient Related Information**

|  |
| --- |
| Indicate all records/databases which will be accessed:  Patient Medical Record  Hospital Administrative / Billing Records  Film/ X-ray/ Images  Clinical Query 2  Repository, specify:  Quality Improvement Records  Other, specify: |

**A12. BIOLOGICAL SPECIMEN Collection**

**A. Basic Information**

Will ANY biological samples (i.e. blood, tissue, urine, etc.) be collected prospectively from research subjects for the purpose of this research?

Yes  No **If No, skip to C. If Yes, skip to B.**

Will fetal tissue/samples be collected?  Yes  No

What types of samples will be collected from research subjects?

**B. Blood Collection**

Will the study collect blood prospectively from research subjects for the purpose of this research?

Yes  No

**If No, skip to C.**

Select the method(s) of blood collection.

Venipuncture at time of clinically indicated procedure

Venipuncture at time specifically for research

Heel/ finger/ ear sticks

From catheter or indwelling line

Other

If Other, specify:

Specify how many times blood will be collected from the subject?

What is the maximum blood volume (in mls.) collected from a subject at one time?

**\*\* If the study is obtaining 200 mL of blood or more at one time from an adult, the PI must review the CCI’s Blood Volume Safety Guidelines and ensure additional precautions are in place.**

Blood collection location:

Will you be collecting blood in a BIDMC phlebotomy station or on the Clinical Research Center?

Yes  No

If no, describe location:

**C. Discarded Specimen**

|  |
| --- |
| Will the study involve the use of discarded specimens? Yes No  **The CCI uses the term “discarded specimens” to describe the remaining portion of a biological specimen obtained for clinical or diagnostic purposes that is no longer needed for its original purpose and that would otherwise be discarded.**  If yes, describe how discarded biological specimens will be collected for this research?    **If No, skip to A13** |
| At the time of this submission, do all the specimens already exist (already stored or "on the shelf")?  Yes No, specimens will be prospectively collected?  For specimens collected prospectively, complete to Part H. |
| What type of samples are you collecting? (lung tissue, fluids, blood etc.)?  Will fetal tissue/samples be collected? Yes No |
| Does this research require more of the sample than is ordinarily discarded? Yes No  If Yes, explain: |
| Approximately how many specimens are needed for the study? |
| Specimens will be obtained from the following time period**:** FROM:       TO: |
| Source of Specimens:  BIDMC Pathology  Repository (specify):  Previously collected for another research study  Other (specify): |
| What is the duration of the study? |
| Will identifiers, such as medical record number, be recorded and maintained or associated (e.g. via a coding system) with the data?  Yes  No  If ***YES***, do you plan to contact patients?  Yes  No  If ***YES*,** explain why: |
| Where will the specimens be stored?  What will be done with specimens when study is complete? |
| Will specimens be used or sold in order to develop a commercial product?  Yes  No  If yes, explain: |

**A13. DATA/SPECIMEN USE**

|  |
| --- |
| Does this protocol involve the establishment of a specimen/data repository or registry?  **\*\* The CCI uses the term “repository/registry” to describe the collection, storage and later distribution of data and/or specimens for some future purpose. Refer to the Research Repository guidance on the CCI portal.**  Yes  No  If yes, specify where this repository will be located? If it is at another site, provide information about the location, agency, etc.  Briefly describe the purpose of the specimen/data repository or registry? |
| Will any data or specimens collected for this research protocol be sent or stored outside of BIDMC?  Yes  No  **If yes please explain in the Part B:**   * **what data or specimens will be sent or stored outside of BIDMC** * **how data/specimens will be coded** * **the process for transferring data/samples outside of BIDMC** |

## A14. DRUG, BIOLOGIC OR DEVICE- USE OF PLACEBO

|  |
| --- |
| Will a subject receive a placebo, pseudo-placebo, or other treatment in place of a medication that is currently FDA approved as standard of care for the condition that is being studied? Will they receive less than what is considered standard of care? **If there is currently nothing approved to treat the condition under study that this does not apply and no should be checked.**  Yes  No  If ***Yes***, specify rationale for use of placebo control: |
| Will any subjects in this study receive a sham device or other treatment that is considered less effective for the condition under study than the best current therapeutic method?  Yes  No  If ***Yes***, specify rationale for use of placebo control: |

## A15. CLINICALTRIALS.GOV REGISTRATION

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| --- |
| [ClinicalTrials.gov](http://clinicaltrials.gov/), a service of the National Institutes of Health, was developed by the National Library of Medicine (NLM) in collaboration with the Food and Drug Administration (FDA).   * The FDA Amendments Act of 2007 (FDAAA or [U.S. Public Law 110-85](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf)) requires registration of “[applicable clinical trials](http://grants.nih.gov/ClinicalTrials_fdaaa/ACTs_under_FDAAA.htm)” involving drugs, biologics, or devices that are subject to FDA regulations. Note: For more information on FDAAA registration and result reporting requirements visit the Office of Compliance and Business Conduct Research Compliance portal page for [ClinicalTrials.gov](https://portal.bidmc.org/Intranets/Administrative/Office-of-Business-Conduct/Research/ClinicalTrials.aspx)    1. The Responsible Party (RP) is required to register the trial on ClinicalTrials.gov at study initiation and to update the record within 30 days of a change to Recruitment Status and Overall Recruitment Status data elements or the Completion Date. The RP is the IND/IDE holder or, in the absence of an IND/IDE, the responsible party is the industry sponsor, cooperative group, consortium, or other external non-federal sponsor that initiated the study. **At BIDMC, the responsible party for all investigator-initiated studies, regardless of funding, will be the principal investigator.**   2. The FDA defines an applicable clinical trial: * For trials of drugs and biologics: controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation. * For trials of biomedical devices: controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance. * NIH Policy requires ClinicalTrials.gov registration and result reporting for all clinical trials funded in whole or in part by NIH, regardless of study phase, type of intervention, or whether they are subject to the Final Rule.   1. The NIH Policy applies to clinical trials which are defined as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” * In addition to the FDAAA requirements and NIH policy, investigators or sponsors must register clinical trials in the Protocol Registration System (PRS) of ClinicalTrials.gov to comply with the [International Committee of Medical Journal Editors (ICMJE) Initiative](http://prsinfo.clinicaltrials.gov/icmje.html), which requires prior entry of clinical trials in a public registry as a condition for publication. ICMJE defines a clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. |
| Does this study require registration on ClinicalTrials.gov?  No, the study does not require registration on ClinicalTrials.gov.  Yes, the study meets the definition of ““applicable clinical trial” involving drugs, biologics, or devices that are subject to FDA regulations.  Yes, the study is funded in whole or in part by the NIH and meets the NIH definition of a clinical trial.  If yes registration is required, is this study registered on ClinicalTrials.gov?  Yes  Registration pending  If yes, provide NCT#: |
| If registration on ClinicalTrials.gov is required, is the PI the Responsible Party (RP)?  Yes  No  The RP is the IND/IDE holder or, in the absence of an IND/IDE, the responsible party is the industry sponsor, cooperative group, consortium, or other external non-federal sponsor that initiated the study. **At BIDMC, the responsible party for all investigator-initiated studies, regardless of funding, will be the principal investigator.**  **\*\* Clinical trials are registered at**[**ClinicalTrials.gov**](http://clinicaltrials.gov/)**via a web-based data entry system called the Protocol Registration System (PRS). If the Principal Investigator is the RP, please contact** [**Diana Cepeda**](mailto:dcepeda@bidmc.harvard.edu)**, the BIDMC PRS Administrator, for additional information on registration.** |
| The revised Common Rule requires that all clinical trials that are conducted by or supported by a federal department or agency to post the consent form on ClinicalTrials.gov.  Does this study meet the requirement to post the consent form to ClinicalTrials.gov?  Yes  No  If yes, the consent form must be posted AFTER the clinical trial has been **closed to recruitment** and **no later than 60 days after the last study visit by any subject** as required by the protocol.   * The consent form must be posted by the Responsible Party * Upload the most recent approved version to ClinicalTrials.gov; this must be an unsigned version, not a copy signed by a participant.   When is the anticipated end date for thestudy? |

A16. PRINCIPAL INVESTIGATOR CERTIFICATION AND SIGNATURE

The Committee on Clinical Investigations will ask the PI to submit periodic reports regarding the status of the research. Research subjects may be contacted by the CCI as part of its ongoing efforts to monitor the experience of research subjects in clinical investigations at the Beth Israel Deaconess Medical Center.

As principle investigator, I certify the following:

* the protocol and safeguards described in this application accurately and completely represent all aspects and phases of the proposed research activities and are in compliance with all applicable federal and state laws, including regulations issued by the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA);
* the protocol and safeguards described in this application are adequate to meet the standards of Beth Israel Deaconess Medical Center and of the U.S. Public Health Service with regard to the protection of human subjects involved in research activities in which the subjects may be at risk;
* the proposed research activities involving human subjects will be conducted in accordance with the policies and procedures governing research with human subjects at the Beth Israel Deaconess Medical Center as described in the CCI Policy and Procedure Manual;
* the potential benefits outweigh any risks involved, in accordance with the regulations governing human subject research;
* the rights and welfare of individuals will be respected and the subjects or their legally authorized representatives will have given their informed consent prior to any participation in the research;
* the privacy and confidentiality of all patients will be protected in accordance with the policies and procedures of Beth Israel Deaconess Medical Center, and applicable state and federal laws;
* all contemplated changes in the protocol, in the informed consent form, or in the method of obtaining informed consent will be presented to the CCI for review and approval prior to implementation;
* adverse events will be reported to the CCI in accordance with CCI policy (Section XII, G of the CCI Policy and Procedure manual) on reporting such events;
* protocol deviations/violations will be reported to the CCI in accordance with CCI policy Section XII, E of the CCI Policy and Procedure Manual) on reporting such deviations/violations;
* unanticipated problem which involve risks to subjects will be reported to the CCI in accordance with CCI policy (Section XII, E of the CCI Policy and Procedure Manual) on reporting such problems:
* for research activities involving access to and use of medical record information, all medical data relating to, and identifying an individual patient will be kept confidential and will not be disclosed to any other person or organization without prior written consent of the CCI, including reports or publications about the research study. Furthermore, neither subjects nor their families will be contacted without first obtaining approval from the CCI unless the PI is also the attending physician for the subject;
* for research activities involving the use of discarded human materials, logistical aspects of obtaining the discarded material will be arranged with the collaborating pathologist.

The principal investigator understands that by signing this research application the principal investigator is responsible for the conduct of the research and for compliance with all of the requirements referenced above, including the oversight of all study personnel and their activities as they relate to the conduct of this project. The principal investigator also understands that once final approval is granted for the project, the approval is granted for a period of no longer than one year, and must be renewed at least annually, **unless a shorter time period is specified by the CCI**.

I have read and understand the above statement.



9-16-20

Principal Investigator Signature Date

John Torous

Print Name