Project Title:

Principal Investigator/Program Director:

Will the Applicant serve as a PI on a Multiple PI Project?

◯ Yes ◯ No

Please enter the submission deadline date.

Please enter requested award start date.

Please provide the name of the sponsor, if NIH, enter Name of Institution.

If Federal:
Please provide the Opportunity ID (PA or RFA #).

If Non-Federal:

Please select the type of proposal.

◯ Research Projects

◯ Community Initiative

◯ Clinical Translational Science Awards

◯ Non-Federal Individual Training

◯ Foundation Research Grant

◯ Internally Funded by Boston Children's Hospital

◯ Non-Federal Institutional Training

Please attach the RFA, RFP, or program guidelines (if available):

OR

Enter URL (if available):

Is this submission a transfer from another institution?

◯ Yes ◯ No

Is this project relevant to cancer research?

◯ Yes ◯ No

Is work being conducted in BCH space?

◯ Yes ◯ No

If YES,

Please indicate the BCH location where the proposed research will be conducted.

Please select the type of research factoring in the space where your project will be conducted. This information will used to calculate your department's, division's, or program's annual space/dollar density report.

- ○ 25% Basic, 75% Clinical
- ○ 50% Basic, 50% Clinical
- ○ 75% Basic, 25% Clinical
- ○ Basic Research
- ○ Basic Training
- ◉ Clinical Research
- ○ Clinical Training
- ○ Training
- ○ Community Initiative or Conference Grant

Please provide Major Goals of Project, if available.

Number of years being requested?

Is a subaward being received FROM another institution (BCH is not submitting directly to sponsor)?

○ Yes ○ No

If YES:

Please provide the name of the Prime Institution.

Please enter the name of PI at Prime Institution.

Will a subaward(s) be issued TO another institution (BCH is submitting directly to sponsor)?

○ Yes ○ No

Name of BCH Employee	Role	Key Personnel? Yes/No	% effort (1 -100%)	* Conflict of Interest Disclosure: This individual is responsible for the Design, Conduct or Reporting (DCR) of the research, *regardless of title or position*. Yes/ NO
	PI			

Name of Non-BCH key Personnel	Role	Key Personnel? Yes/No	% effort (1 - 100%)	Non-BCH Key Personnel Email	Name of Home Institution.
	PI				

Have any matching fund/cost sharing commitments been made?

◯ Yes ◯ No

NOTE: Cost Sharing occurs when an applicant contributes resources to a sponsored project beyond the amount funded by the Sponsor. Cost sharing may be "mandatory" or "voluntary."
Mandatory Cost Sharing: When cost sharing is "mandatory," the requirement for cost sharing will be described in the application guidelines. If the Sponsor is silent about cost sharing or states that cost sharing is "encouraged," cost sharing is not mandatory. For mandatory cost sharing the Sponsor may require a certain percentage/type of cost sharing or that applicants "match" the Sponsor's contribution according to a certain formula. Any quantifiable cost sharing described in the proposal then becomes a condition of the award that results and must be documented and reported to the Sponsor.
Voluntary Cost Sharing: Cost sharing is considered "voluntary" when an applicant describes a quantifiable amount of resources it will contribute to the project in the proposal even though the Sponsor does not state in the proposal guidelines that cost sharing is required.

Is the cost sharing required by sponsor?

◯ Yes ◯ No

Does this project include the use of services provided by ICCTR (Institutional Centers for Clinical and Translational Research)?

◯ Yes ◯ No

NOTE: The use of these services needs to be approved by each center. Please submit an online service request at @ Request ICCTR Services via RedCap

If YES:
Indicate the ICCTR service(s):

◯ ETIT – Services: Clinical trials support with drugs, devices or novel platforms, Study start- up/Study Implementation Support, Regulatory Assistance, Study Monitoring, Project/Study Management, Study Coordinator Support.
Cindy Williams, DNP and Andy Place, MD/PhD, Co-Directors ETIT

◯ CTSU – Services: Outpatient or Inpatient Study Visits, Nursing Support, Phlebotomy, Lab Processing, Exam and Consult Rooms, Nutrition.
Cindy Williams, DNP and Andy Place, MD/PhD, Co-Directors ETIT

◯ Biostatistical – Services: Statistical/Study Design, Statistical/Data Analysis, Database Development and Programming, Health Economics/Cost Effectiveness Design, Survey implementation/administration, Qualitative data collection, Qualitative Research Design/Methods, Survey Design/Methods, etc.
Edie Weller, PhD, Director of Biostatistics and Research Design

◯ PopSci – Services: Health services research (e.g. observational cohorts, bio-sample collection and evaluation of care delivery), Study Start-Up/ Study Implementation, Database Development, Project/Study Management, Study Coordinator Support, Data Collection etc.
Lise Nigrovic, MD MPH and Jennifer Mack, MD, MPH Co-Directors of Population Health Sciences.

Please attach a copy of the Statement of Work (SOW) that was submitted to and approved by the ICCTR. If an SOW has not yet been submitted, please contact Request ICCTR Services via RedCap to request services.

For assistance, please contact ICCTR at icctr@childrens.harvard.edu or 857-218-4732.

Is the Children's Hospital Trust aware of this submission?

◯ Yes ◯ No

If YES:
Please enter the name of the Trust staff member with whom you are working.

Are there income-generating activities proposed?

◯ Yes ◯ No

Does this project include the use of services provided by the Boston Children's Hospital Research Pharmacy?

Yes No

If Yes, please describe:

Does this project include the use of services provided by the Biobank Core Lab?

Yes No

If yes:
Submitted budget must reflect Biobank Core Lab pricing

☐ I attest that the submitted budget reflect Biobank Core Lab Pricing, as appropriate for either academic or industrially sponsored projects.

For up-to-date pricing information, please refer to the Biobank Service and Precision Link Service Fees.

Service Request Forms are available @ Request Samples.

The Biobank Core offers courtesy consultations to help with planning your research for grant submissions, including evaluating research protocols to recommend best practices for specimen collection; processing and management; identifying and estimating costs for budgets; supplying core description text for resources/environment sections; and providing letters of support.

For further information, please call 617-355-7243 (internal: x57243).

Does this project involve the use of vertebrate animals?

Yes No

If yes,

Fish
Fogs
Guinea
Pig
Mice
Swine
Rabbits
Rats
Sheep
Hamsters
Other

If other, please specify:

List all IACUC protocol numbers that apply to this research
or specify pending:

Does this project involve the use of human subjects, materials or medical chart/records review?

Yes No

If Yes:

Is IRB protocol number(s) at BCH?

Yes No

If Yes, **Please list all BCH IRB protocol numbers that apply to this research.**

Is IRB protocol at DFCI?

Yes No

If Yes**, Please list all DFCI IRB protocol number(s) that apply to this research.**

Does the project involve Genome Wide Associated Studies (GWAS)?

◯ Yes ◯ No

Is this a Clinical Trial?

◯ Yes ◯ No

If yes:

Is this a Phase III Clinical Trial?

◯ Yes ◯ No

Does the project involve a Single Institutional Review Board (IRB)?

◯ Yes ◯ No

If yes, (Please contact the IRB Office @ x57052 or irb@childrens.harvard.edu for guidance):

Will it be at BCH?

◯ Yes ◯ No

If No: **Please enter the name of the Institution where it will be located.**

Does the project utilize stem cells from human embryos or fetal tissue?

◯ YES ◯ No

If yes, **Is proposed work approved by the ESCRO (Embryonic Stem Cell Research Oversight) Committee?**

◯ Yes ◯ No

Does this project involve the use of Human Fetal Tissue from elective abortions?

◯ Yes ◯ No

If *yes* and you are submitting an application to the NIH, please refer to NOT-OD-19-128 and NOT-OD-19-137 for additional application requirements, including the use of the detailed budget form.

NIH Definition of Human Fetal Tissue (HFT) from elective abortions: *research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following:*

- *human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.*
- *animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.*
- *derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.*

any human extra-embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

Does this project involve hazardous materials?

◯ Yes ◯ No

If Yes:

◯ Radioisotopes
◯ Regulated Hazardous Carcinogens
◯ Recombinant DNA
◯ Biological agents regardless of pathogenicity to humans (See note below for more information)
◯ Human and non-human primate blood, unfixed tissues, or cell lines (established or primary) for laboratory study only

Please list all IBC protocol numbers that apply to this research:

NOTE: Biological agents include bacteria, viruses, parasites, rickettsia, fungi, microbial toxins and prions. (E.g. Staphylococcus aureus, Pseudomonas aeruginosa, Listeria monocytogenes, Diphtheria toxin, Staphyloccocal enterotoxin)

Does this project have an international component (sponsor, subaward, consultant or any collaborating personnel)?

Yes No

If Yes:
Please list the countries. Please limit the text to 55 characters, including spaces.

Please select the type of international component (more than one type may be selected):

Foreign Sponsor
Subaward from a Foreign Collaborator
Subaward to a Foreign Collaborator
Foreign Collaboration

Does this project involve the generation of large scale genomic data?

Yes No

If yes:

Please select the data type(s):

Genomic-wide Association Studies (GWAS)
Single Nucleotide Polymorphisms (SNP) arrays
Transcriptomic Expression Data
Metagenomic Expression Data
Epigenomic Expression data
Gene Expression Data
Other

If Other, please specify:

Please select the source of the large scale genomic data:

Human
Non-Human
Human and Non-Human

Answering the questions below will assist OSP in determining if a Certificate of Confidentiality applies to your NIH-sponsored research project, if awarded.

Does this project involve collecting or using data or bio specimens that are identifiable to an individual[research participant]?

Yes No

IF Yes:

Does this project involve a small risk that some combination of the bio specimen, a request for the bio specimen, and other available data sources could be used to deduce the identity of individual [research participant]?

Yes NO

Does this project involve the generation of individual level, human genomic data?

Yes No