Policy #:	39.03.066
Issued:	October 2001
Reviewed:	
Revised:	February 12, 2015
Section:	39

Research Contract and Subcontracts

Purpose:
To provide guidance to Principal Investigators (PIs) and Research Administrators (RAs) on processing incoming contracts or subcontracts (subawards) where BMC is the contractor and the counterparty institution is a governmental agency, foundation, industry, non-profit or for profit private or public entity.

Policy Statement:
All incoming research contracts must be reviewed by the BMC office of Grants and Contracts or the BMC Clinical Trial Office prior to acceptance of an award. After the subaward /contract has been fully executed, signed by BMC and the sponsoring governmental agency and/or private or public entity counterparty, BMC can invoice based on the conditions stated in the contract.

Application:
All incoming research-related contracts and subcontracts awarded to BMC

Exceptions:
None

Definitions –

Contract means a legal instrument by which a non-Federal entity purchases property or services needed to carry out the project or program under a Federal award. The term as used in this part does not include a legal instrument, even if the non-Federal entity considers it a contract, when the substance of the transaction meets the definition of a Federal award or subaward.

Contractor means an entity that receives a contract.

Pass-through entity means a non-Federal entity that provides a subaward to a subrecipient to carry out part of a Federal program.

Subaward means an award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a Federal award received by the pass-through entity. It does not include payments to a contractor or payments to an individual that is a beneficiary of a Federal program. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract.

Subrecipient means a non-Federal entity that receives a subaward from a pass-through entity to carry out part of a Federal program; but does not include an individual that is a beneficiary of such program. A subrecipient may also be a recipient of other Federal awards directly from a Federal awarding agency.

Procedure: *Please note that sponsor requirements vary and may not always fit with the standard processes outlined below. Although Research Operations endeavors to follow these processes as laid out below, we will follow sponsor requirements as necessary.*

To determine if a contract/subaward is handled by the Clinical Trial Office or Grants and Contracts, please refer to Research Operations Decision Matrix for BMC Awarded Projects, Attachment A.

Grants and Contracts Office

New Contract/Subawards

The Pre-Award review of State, Federal and foundation contract/subaward proposals is similar to that performed for governmental, public or non-profit foundation grant applications.

The following materials are generally required when BMC is expected to be a subcontractor under a new or competing funding application being submitted by another institution:

- A Letter of Intent (LOI) (Attachment B) to enter into a consortium agreement, signed by the authorized signatory at both institutions;
- Detailed budget pages along with a budget justification;
- Biographical sketches for key personnel (if required);
- A Scope of Work (not required if included in the applicant institute's technical report);
- A National Institutes of Health (NIH) Public Health Service (PHS) 398 application checklist page (paper applications only); and
- Regular proposal submission materials (e.g., Proposal Summary Form, Attachment C), and Animal or Human Subject approvals as necessary).

Additional documentation pertaining to the contractual agreement may be required by the sponsoring agency or applicant institute; therefore, *Grants and Contracts strongly recommends that the contract instructions are carefully reviewed prior to submission of the application.*

Once the PI/ RA are notified that a contract/subaward is awarded to the "Prime" institution, they should contact the "Prime" to obtain a subaward/contract agreement. This document should be either mailed or e-mailed to the Grants and Contracts office for review and negotiation. The Pre-Award Proposal Development staff are responsible for updating the internal paperwork, and confirming that the InfoEd entry has been completed. Once received, agreements are reviewed by 1) the Research Contract Attorney, who will negotiate any language changes with the "Prime"; and 2) the BMC PI, and/or the RA, who will approve the budget and scope of work/protocol. When the parties agree upon an acceptable final version of the contract, the Research Contract Attorney will forward the agreement to the Contract Specialist who will ensure that a copy or copies of the contract are given to the Director, Grants and Contracts, or Associate Director, Research Finance, for signature.

If the contract is partially-executed, the Contract Specialist will either mail two copies of the originally signed contract to the "Prime" institute (as applicable and if the prime requires hard copies); or e-mail one copy to the Prime. The Contract Specialist will also make a copy of the contract for the pending file, which they will keep at their desk until the final contract is obtained. The Contract Specialist will also create a record in the Contract Tracking Database.

If the contract is "fully-executed (signed by both parties), the Contract Specialist will either mail one copy of the signed contract to the "Prime" or e-mail a copy to the Prime. The other signed original copy of the contract and the corresponding pending folder is given to the Associate Director, Grants and Contracts. A scanned PDF copy of the fully executed agreement should also be sent electronically to the PI/RA. A paper copy of the contract and supporting documentation are then given to the Business Analyst (BA) for activity setup in SAM and Lawson. The BA setup process closely tracks that of other new awards (e.g., an administrative folder is created and forwarded to the appropriate Research Finance Manager.)

Continuation Contract/Subawards

The process for obtaining contract **"continuations"** from the applicant institution or contracting agencies is the following:

- Prior to the start of the new budget period for the subaward/contract, the Research Financial Analyst (RFA) discovers whether or not the "Prime" institution (higher tier contractor) or contracting agency is going to send BMC an amended or new contract for the next year of the award;
- The RFA notifies the Business Analyst (BA), who in turn informs the Contract Specialist by adding "yes" a contract is needed to the final activity continuation list;
- The Contract Specialist works with the PI/RA and/or the RFA to prompt the "Prime" contractor for the new contract or amendment document. If necessary, the Contract Specialist will contact the "prime" institution to determine contract status;
- If the continuing contract is from a governmental entity (City/State), the RFA will work with the PI and/or RA to obtain the contract. Once a continuation contract is received from the

government entity, the Proposal Development staff put together the appropriate paperwork. The partially signed contract will go to the Contract Specialist for mailing and tracking.

- If an amended contract has not been received after 2 months, and at least three prompts have been sent to the originating organization, the Contract Specialist will consult with the RFA and/or PI/ RA to determine whether the activity should be put into Closeout.

Once the Grants and Contracts Office receives a copy(ies) of the amended agreement, the subaward/contract information should be reviewed and approved by the Contract Specialist in conjunction with the PI/RA. The RFA, the Director, Grants and Contracts, and Associate Director, Research Finance should also be informed that a new amendment has been received.

Once approved by the PI and/or their designee, the Director, Grants and Contracts, or the Associate Director, Research Finance, sign two copies of the amended agreement if a paper submission, or one copy if an electronic submission, and the Contract Specialist mails or e-mails the original documents back to the "Prime" institution or contracting agency with copies to the PI/RA.

A copy is given to the appropriate Research Finance Manager, who will determine if there will be a new activity setup or activity roll. Once this determination is made, the RFA will submit a SAM edit sheet to the BA if necessary. A photocopy of the fully-executed amended contract is also sent to the PI/RA, and the Proposal Development staff who will make sure all the appropriate internal paperwork has been collected.

Clinical Trial Office

New Contracts/Subawards and Contract/Subaward Amendments

Upon receipt of a Clinical Trial Agreement (CTA) or amendment to the CTA, the PI/Study team should complete the CTO Intake Form (Attachment D) and submit it along with the required documents (e.g., the Protocol, FDA-related documentation for drugs/devices, and draft versions of the Budget, Consent Form and CTA) to the Clinical Trial Office for review via email at CTO@bmc.org. Upon receipt in the CTO inbox, the project will be assigned to a Clinical Trial Financial Analyst (CTFA) and the Clinical Research Attorney. The Clinical Research Attorney will review the CTA or amendment, and any other legal documents that are required by the sponsor while the CTFA will review the budget and draft the appropriate financial documents. Once negotiations are complete, the finalized CTA or amendment and financial documents will be forwarded to the PI/Study Team for review and approval.

Once approved, the Clinical Research Attorney will forward the CTA and other documents to the Director, Grants and Contracts, or Associate Director, Research Finance, for signature. Once signed, the Clinical Research Attorney will return the signed CTA to the sponsor to be fully executed. Upon receipt of the fully executed CTA from the sponsor, a copy will be sent electronically to the Principal Investigator/Study team and to the CFTA. The CFTA will then

forward the appropriate documents to the BA for account set up, except in the case of an amendment where the existing account will remain in use.

Responsibility:

Principal Investigator
Research Administrator
Grants and Contracts
Clinical Trial Office
Research Finance

Forms:

39.03.066a Research Operations Decision Matrix for BMC Awarded Projects, Attachment A
39.03.066b Letter of Intent, Attachment B
39.03.066c Proposal Summary Form, Attachment C
39.03.066d Clinical Trial Office Intake Form, Attachment D

Other Related Policies:

N/A

References:

Boston Medical Center adheres to the following regulations regarding subcontracts:
OMB CIRCULAR A-110 (REVISED 11/19/93, As Further Amended 9/30/99); 2CFR §200.331, §200.332 Uniform Administrative Requirements, and Audit Requirements for Federal Awards; 45 CFR 74 subpart C §§ 74.47 and 74.48. All of BMC's federal procurement contracts (e.g., N01 awards) are governed by the Federal Acquisitions Regulations; Code of Massachusetts Regulations concerning *Procurement of Commodities or Services, Including Human and Social Services* 801CMR2.

Section: 39

Policy No.: 39.03.066

Title: Research Contract and Subcontracts

Initiated by: Grants and Contracts

Contributing Departments:

N/A

39.03.066a Research Operations Decision Matrix for BMC Awarded Projects
Attachment A

Research Operations Decision Matrix for BMC Awarded Projects:
Clinical Trial Office, Grants and Contracts, and Research Finance

Sponsored Project Type	Pre-Award Activities		Post-Award Activities	
			Department Responsible for Account Management	Department Responsible for Patient Care Charges
Clinical Research sponsored by Industry, Foundations, or Investigator-Initiated that has patient care charges associated with the project	**CLINICAL TRIAL OFFICE** • Medicare Coverage Analysis • Budget Development • Terms and Conditions		**CLINICAL TRIAL OFFICE** • Financial & Billing Management • Reporting & Auditing • Account Reconciliation & Closeout	**CLINICAL TRIAL OFFICE** • Reconciliation with SDK, as applicable • PI Attestation
Federally-Sponsored Clinical Research in which: • Patient care charges are associated with the project **and** • BMC is a subcontractor on the sponsored project **and** • Payment type is **fee-for-service** (not cost-billable). Cooperative group trials (ECOG, SWOG, NRG, AMC, etc.) that will be handled case-by-case	**CLINICAL TRIAL OFFICE** • Medicare Coverage Analysis • Budget Development • Terms and Conditions		**CLINICAL TRIAL OFFICE** • Financial & Billing Management • Reporting & Auditing • Account Reconciliation & Closeout	**CLINICAL TRIAL OFFICE** • Reconciliation with SDK, as applicable • PI Attestation
All Basic Research, regardless of Sponsor	**GRANTS AND CONTRACTS** • Budget Development • Terms and Conditions		**RESEARCH FINANCE** • Financial & Billing Management • Reporting & Auditing • Account Reconciliation & Closeout	N/A
Clinical Research sponsored by Industry, Foundations, or Investigator-Initiated that do not have patient care charges associated with the project	**GRANTS AND CONTRACTS** • Budget Development • Terms and Conditions		**RESEARCH FINANCE** • Financial & Billing Management • Reporting & Auditing • Account Reconciliation & Closeout	N/A
All Federally-Sponsored Clinical Research in which: • Patient care charges may be associated with the project • BMC is the **prime entity** (directly receives award) **or subcontractor and** • Payment type is **cost-billable** (not fee-for-service) Cooperative group trials (ECOG, SWOG, NRG, AMC, etc.) will be handled case-by-case	**GRANTS AND CONTRACTS** • Budget Development • Terms and Conditions	**CLINICAL TRIAL OFFICE** • Medicare Coverage Analysis • Provision of hospital service costs (pro and tech)	**RESEARCH FINANCE** • Financial & Billing Management • Reporting & Auditing • Account Reconciliation & Closeout	**CLINICAL TRIAL OFFICE** • Reconciliation with SDK, as applicable • PI Attestation

Definitions

Clinical Trial: 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. (Source: NIH definition as of October 23, 2014)

Fee for Service: Payment types in which an invoice needs confirmation from the Study Team to verify that the milestone, unit rate, or event to be invoiced has been achieved.

Cost Billable: Payment types that incur expenses and are invoiced for reimbursement. These invoices (with the exception of the final invoice) do not require confirmation by the Study Team.

39.03.066b Letter of Intent, Attachment B

Research Operations
Office of Grants and Contracts
660 Harrison Avenue, 2nd Floor
Boston, MA 02118-2908

Letter of Intent

Project Information				
Project Title:				
Prime Sponsor:				
Prime Investigator:	Phone:		e-mail	
Prime Business Contact:	Phone		e-mail	
Subrecipient Institute:				
Subrecipient Investigator:	Phone:		e-mail	
Subrecipient Address (street, city, state, ZIP):				
Subrecipient Contact:	Phone:		e-mail	

Project Budget Information	**Initial Year**	**Total Project**
Project Dates		
Total Direct Costs		
Total Indireet Costs		
Total Costs		

Subrecipient Informtion	
EIN:	DUNS Number:
Congressional District:	Cognizant Audit Agency:
F&A Rate Agreement Date:	F&A Rate:

Is the Subrecipient Institution subject to OMB Circular A-133? ☐ Yes ☐ No
Subrecipient Institution is: ◉ Non-Profit ○ For-Profit ○ Foreign ○ Government
Other _____

Animal Research? ☐ Yes ☐ No Assurance Number:
If Yes, Date Approved:

Human Subject Research? ☐ Yes ☐ No FWA Number:
If Yes, Date Approved:

Conflict of Interest (check one)

☐ Subrecipient Organization/Institute has in effect an up-to-date, written, and enforced conflicts of interest policy and administrative process ("COI Policy") to identify and manage financial conflicts of interest ("FCOIs"), which is consistent with the provisions of 42 CFR Part 50, Subpart F and 45 CFR Subtitle A, Part 94.

☐ Subcipient Organization/Institution does not have an active and/or enforced conflict of interest policy, but is in the process of creating a conflict of interest policy compliant with federal regulations 42 CFR Part 50, Subpart F and 45 CFR Subtitle A, Part 94 (a Model Policy will be provided upon request) prior to funding.

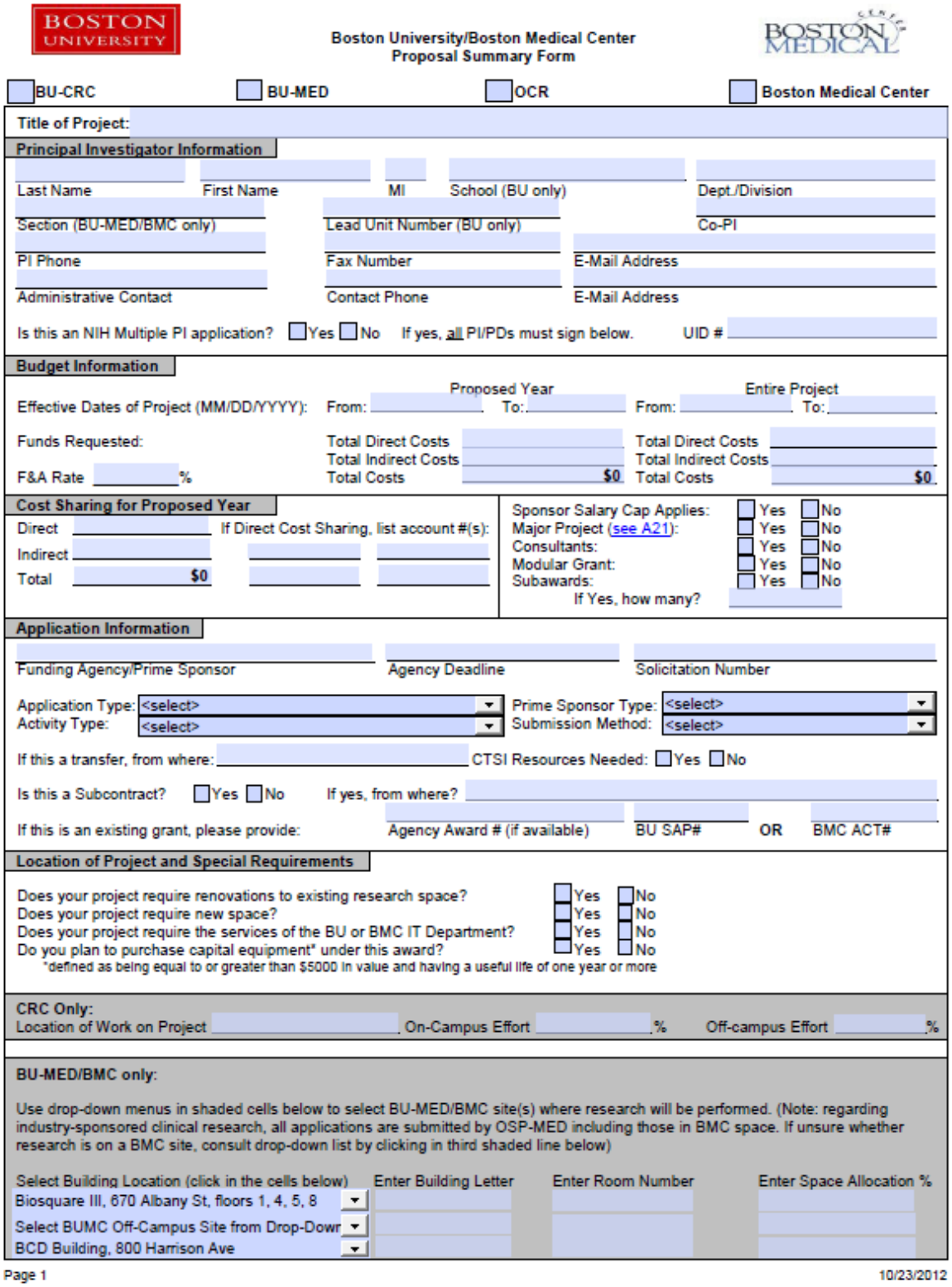
☐ Subrecipient Organization/Institution does not have an active and/or enforced conflict of interest policy and will adopt Boston Medical Center/Boston University (Prime Recipient) COI Policy. All subrecipient "Investigators," or, any person, *regardless of title or position*, who is responsible for the design, conduct, or reporting of research, as defined by Boston University and Boston Medical Center policy, prior to **submission of the research proposal application**, will complete disclosure and training via Boston University's electronic Financial Interest Disclosure module, eFind, by going to BU's Conflict of Interest webpage at bu.edu/orc/coi/forms/.

Other Certifications: By signing below, the above-named Subrecipient/Cooperating Institution certifies that:

Neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from any covered transaction by any federal agency (45 CFR Part 76 and Executive Order 12549); (2) It is in compliance with the requirements of 45 CFR Part 76, Subpart F (Drug Free Workplace); (3) It is in compliance with the requirements of 31 USC § 1352 (Lobbying); (4) It is in compliance with the requirements of 42 CFR Part 93 (Misconduct in Science); (5) It is in compliance with Title VI of the Civil Rights Acts of 1964, the Age Discrimination Act of 1975, Executive Order 11246 and Section 504 of the Rehabilitation Act of 1973 as amended, and certifies that it has valid Assurances of Compliance on file with DHHS; (6) It is in compliance with 45 CFR, Part 46, subpart A, "Protection of Human Subjects"; (7) If human subjects research is to be performed at Cooperating Institution, it will ensure Institutional Review Board review in compliance with 42 U.S.C. s. 289 (Health Research Extension Act of 1985) and 45 C.F.R. s. 46.103.

Prime Institution	Subrecipient Institution
Name	Name
Authorized Official Signature	Authorized Official Signature
Printed Name	Printed Name
Title	Title
e-mail	e-mail
Date	Date

39.03.066c Proposal Summary Form, Attachment C



BOSTON UNIVERSITY

Boston University/Boston Medical Center
Proposal Summary Form

BOSTON MEDICAL CENTER

☐ BU-CRC ☐ BU-MED ☐ OCR ☐ Boston Medical Center

Title of Project:

Principal Investigator Information

Last Name | First Name | MI | School (BU only) | Dept./Division

Section (BU-MED/BMC only) | Lead Unit Number (BU only) | Co-PI

PI Phone | Fax Number | E-Mail Address

Administrative Contact | Contact Phone | E-Mail Address

Is this an NIH Multiple PI application? ☐ Yes ☐ No If yes, all PI/PDs must sign below. UID #

Budget Information

	Proposed Year	Entire Project
Effective Dates of Project (MM/DD/YYYY):	From: To:	From: To:
Funds Requested:	Total Direct Costs	Total Direct Costs
	Total Indirect Costs	Total Indirect Costs
F&A Rate %	Total Costs $0	Total Costs $0

Cost Sharing for Proposed Year

Direct | If Direct Cost Sharing, list account #(s):

Indirect

Total $0

Sponsor Salary Cap Applies: ☐ Yes ☐ No
Major Project (see A21): ☐ Yes ☐ No
Consultants: ☐ Yes ☐ No
Modular Grant: ☐ Yes ☐ No
Subawards: ☐ Yes ☐ No
If Yes, how many?

Application Information

Funding Agency/Prime Sponsor | Agency Deadline | Solicitation Number

Application Type: <select> Prime Sponsor Type: <select>
Activity Type: <select> Submission Method: <select>

If this a transfer, from where: CTSI Resources Needed: ☐ Yes ☐ No

Is this a Subcontract? ☐ Yes ☐ No If yes, from where?

If this is an existing grant, please provide: Agency Award # (if available) | BU SAP# | OR | BMC ACT#

Location of Project and Special Requirements

Does your project require renovations to existing research space? ☐ Yes ☐ No
Does your project require new space? ☐ Yes ☐ No
Does your project require the services of the BU or BMC IT Department? ☐ Yes ☐ No
Do you plan to purchase capital equipment* under this award? ☐ Yes ☐ No
*defined as being equal to or greater than $5000 in value and having a useful life of one year or more

CRC Only:
Location of Work on Project | On-Campus Effort % | Off-campus Effort %

BU-MED/BMC only:

Use drop-down menus in shaded cells below to select BU-MED/BMC site(s) where research will be performed. (Note: regarding industry-sponsored clinical research, all applications are submitted by OSP-MED including those in BMC space. If unsure whether research is on a BMC site, consult drop-down list by clicking in third shaded line below)

Select Building Location (click in the cells below)	Enter Building Letter	Enter Room Number	Enter Space Allocation %
Biosquare III, 670 Albany St, floors 1, 4, 5, 8			
Select BUMC Off-Campus Site from Drop-Down			
BCD Building, 800 Harrison Ave			

Page 1 10/23/2012

Mentor (if applicable)

Last Name	First Name	MI	School (BU Only)	Department/Division

Phone	Fax Number	E-Mail Address

International Research

Does this project have any of the following international components (check all that apply)

- ☐ Yes ☐ No A collaborator outside of US
- ☐ Yes ☐ No Travel outside of US by any BU participant (e.g. faculty, staff, students) in this project (paid or unpaid)
- ☐ Yes ☐ No Travel to the US by any collaborator involved with this study (paid or unpaid)
- ☐ Yes ☐ No Transport of any samples (e.g. tissue, blood, chemical) to or from US

Please provide contact information for the individual who is familiar with this project and who should be contacted by the Export Control Director for further information.

Name: _____ Phone: _____ e-mail: _____

Compliance Information

Special Reviews:			Project Approval** (Date or "Pending")	Protocol/Approval No. for Each Project
IRB	☐ Yes	☐ No		
IACUC	☐ Yes	☐ No		
IBC: Biohazards	☐ Yes	☐ No		
IBC: rDNA	☐ Yes	☐ No		
IBC: Select Agents	☐ Yes	☐ No		
Laser	☐ Yes	☐ No		
Radioisotopes	☐ Yes	☐ No		
Human Embryonic Stem Cells	☐ Yes	☐ No		
SCUBA/Snorkeling/Boats	☐ Yes	☐ No		

Financial Interest Disclosure ☐ Yes (required)

The PI must ensure that all those responsible for the design, conduct, or reporting of the proposed program have completed the financial interest disclosure forms and training as dictated at http://www.bu.edu/orc/coi/forms/.

Final disclosure for this project was submitted: _____ Date

PI/PD Assurance

I certify that: (1) in conducting the proposed program, I am familiar with and will adhere to applicable Boston University/Boston Medical Center policies including, but not limited to, human and animal research, conflict of interest, misconduct in research, and patents and technology transfer (http://www.bu.edu/research/compliance/) as well as sponsor requirements and applicable Federal regulations; (2) the information submitted within the application is true, complete, and accurate to the best of my (the PI's) knowledge; (3) any false, fictitious, or fraudulent statements or claims may subject me (as the PI) to criminal, civil, or administrative penalties; (4) I (as the PI) agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application; and (5) I will abide, as applicable, by the Federal clinical trials (ClinicalTrials.gov: http://clinicaltrials.gov/) and NIH Public Access (http://publicaccess.nih.gov) regulations.

PI/PD	Date	PI/PD	Date
PI/PD	Date	PI/PD	Date

Approvals

Chief of Service (BMC only)	Date	Dean	Date
Department Chair	Date	OSP Director (BU-CRC only)	Date
Department Chair	Date	Institutional Official	Date
Dean	Date	Department/Staff Review	Date

Comments

39.03.066d Clinical Trial Office Intake Form, Attachment D

Clinical Trial Office (CTO) Intake Form

1. Where will the services for the study participants be performed? Please provide the address or building name:

2. Full Protocol Title:

3. Principal Investigator:

4. Study Team/Contact: Phone:

5. Sponsor/CRO:

6. Sponsor/CRO Contact Name: Email:
   Phone:

7. Is this study: ☐ NEW PROTOCOL SUBMISSION
   ☐ AMENDMENT SUBMISSION Choose an item

If Amendment please skip to question 18 unless changes are made per amendment for questions 9-17. If Amendment does not fit into one of the categories on drop down, it does not need to be reviewed by CTO.

8. Study Begin Date: 10/23/2014 Study Duration: Choose an item

9. Anticipated number of study participants to be enrolled:

10. Will there be any patient reimbursement/stipend on this study? Yes ☐ No ☐
    a) If yes, please explain what kind of reimbursement will be offered and how much.
    b) Please refer to Research Participant Compensation Policy for all study participant payments.

11. What type of study is this clinical trial? Device ☐ Drug/Biologic ☐
    If Device, select: Select an option If Drug/Biologic, select: Select an option
    a) If this is a Device trial, please attach /email IDE letter, the Medicare contractor approval letter and any other FDA related documents you have received.
       i. Please confirm if sponsor will be providing the device or if we will have to purchase.

Clinical Trial Office (CTO) Intake Form

12. Radiological assessment at BMC? Yes ☐ No ☐

If no, select department providing service:

13. Sponsor provided EKG machine? Yes ☐ No ☐

a) If the sponsor will not provide the machine, where will the EKG be performed?

b) If the sponsor is providing the machine, who will perform the EKG and where will it be performed?

14. Will Pathology Department services be used (histology, slide creation, etc)? Yes ☐ No ☐

15. Will there be sub-sites on the study? Yes ☐ No ☐

a) If yes, how many?

b) Please list names of Institutions below:

Name of Institution	Anticipated Enrollment

16. Please provide a list of the procedures that will be performed in hospital (clinic) space along with who will be performing them. Examples: Physical Exam (Principal Investigator), Weight/Vital Signs (Nurse/Research Nurse) or CT/MRI (Radiology)

Type of Procedure and CPT code	Performed By

If unsure of CPT codes or internal charge codes, please contact the PI and/or Revenue Integrity for guidance

17. Will the blood tests (e.g., serum chemistries) be done in a central or local (BMC) lab?

Version date: 10/23/2014

Clinical Trial Office (CTO) Intake Form

Amendment Only Questions:

18.	**Based on the amendment category chosen in question 7, what specifically is being changed that will affect the Medicare Coverage Analysis/Billing Grid?**
19.	**Anticipated IRB submission date:** 10/23/2014
20.	**Is the study enrollment suspended until amendment is IRB approved? Yes** ☐ **No** ☐

	02/05/2015
Print Name & Title	Date

** Please include all of the following items with your submission to the Clinical Trial Office (CTO).

New Protocol Submission Materials:

- ☐ Clinical Trial Office Intake Form
- ☐ Consent Form template
- ☐ Budget template from Sponsor
- ☐ Clinical Trial Agreement
- ☐ Study Protocol
- ☐ FDA-related Documents
- ☐ Other: _____

Amendment Submission Materials:

- ☐ Clinical Trial Office Intake Form
- ☐ Revised Consent Form template
- ☐ Revised Budget template from Sponsor
- ☐ Revised Clinical Trial Agreement
- ☐ Summary of Protocol Revisions
- ☐ Amended Protocol
- ☐ FDA-related Documents
- ☐ Other: _____