# Clinical Research Institute *General Research* Application

**Directions:** Submit this application to the Clinical Research Institute (CRI) at the same time you provide the New York Medical College (NYMC) IRB with your 'Initial Submission' for review.

Completed CRI Applications can be emailed to Research@wcmc.com or delivered to 19 Bradhurst Avenue, Suite 2000N, Hawthorne, NY 10532 between 8:30am and 5pm. For questions, please contact 914-493-2014.

**To be considered 'complete' a CRI Application must include:**

1. CRI Application
2. NYMC IRB Application
   - a.Study protocol
   - b.Informed consent (or waiver)
   - c.HIPAA form (or waiver)
   - d.Data collection forms (CRFs)
   - e.CITI Basic & Conflict of Interest Certifications (if not previously submitted to CRI).

**Study Title:**

## SECTION 1: Information about the Investigator(s)

Please complete the following information. If any of your responses require more space than allotted on this application, please attach a separate sheet of paper.

### Section A - Principal Investigator

Investigator Role: Select from the following ▼ Name (First, Last): _____

Title: _____ Department: _____

Phone #: _____ Email Address: _____

Address — Building Name: _____ Office #: _____

Street Address: _____

| **Please answer the following questions** | **YES** | **NO** |
|---|---|---|
| **1.** Does study have Co-Principal Investigator(s)? ***If Yes***, *Complete Section B* | ☐ Yes | ☐ No |
| **2.** Does study have sub-investigator(s)? ***If Yes,*** *Complete Section C* | ☐ Yes | ☐ No |
| **3.** Does study have a Coordinator? ***If Yes***, *Complete Section D* | ☐ Yes | ☐ No |

Proposed Project Start Date: _____ **mm / dd / yyyy** Proposed Project End Date: _____ **mm / dd / yyyy**

### Section B - Co-Principal Investigator

Investigator Role: Select from the following ▼ Name (First, Last): _____

Title: _____ Department: _____

Phone #: _____ Email Address: _____

Address — Building Name: _____ Office #: _____

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## Section C - Sub-Investigator

Investigator Role: Select from the following ▼ Name (First, Last): _____

Title: _____ Department: _____

Phone #: _____ Email Address: _____

Address Building Name: _____ Office #: _____

Street Address: _____

## Section D - Study Coordinator (Primary contact person for study)

Name (First, Last): _____

Title: _____ Department: _____

Phone #: _____ Email Address: _____

Address Building Name: _____ Office #: _____

Street Address: _____

## SECTION 2: Information about the Study

**1.** Is this research proposal approved by your Departmental Chair or by his/her designee? ☐ Yes ☐ No

**2.** Is there funding for this study? **If Yes,** complete 2a and 2b, below. ☐ Yes ☐ No

2a. Funding Agency: _____

2b. Proposed Award Start Date: _____ Proposed Award End Date: _____

**mm / dd / yyyy** **mm / dd / yyyy**

**3.** Is this a Multi-Site Study? **If YES,** complete 3a and 3b, below. ☐ Yes ☐ No

**3a.** Will your site be acting as recruitment site? ☐ Yes ☐ No

**3b.** Will your site be acting as Coordinating Center/Lead Site? ☐ Yes ☐ No

**If YES**, Standard Operating Procedures (SOPs) required to oversee project must be included.

**4.** Does study design require collection of images or voice recordings of subjects? ☐ Yes ☐ No

**If Yes,** protocol must include a description of procedures detailing (but not limited to) the following: equipment to be used, personnel designated to use/handle equipment, if any training/standards required for use, # of tapes/photos to be taken, what will be content of tapes/photos, how will tapes/photos be labeled/identified, where recordings will be stored, for how long & who will have access to them, etc. Must comply with WMC Policy HP-14 PATIENT PHOTOGRAPHY, VIDEOTAPING AND IMAGING

**5.** Does study involve administration of questionnaires, personality tests, quality of life assessments or other surveys or inventories? ☐ Yes ☐ No

**IF YES,** provide name & 1 copy of each instrument to be used.

**6.** Does study include online surveys or other forms of electronic communication or data collection? ☐ Yes ☐ No

**If Yes,** protocol must include a description of methods used to control subject anonymity and privacy protection

**7.** Does study include sample (fresh or archived) collection, processing/shipping, etc.? ☐ Yes ☐ No

**If Yes,** protocol must include a description of applicable procedures and may require IATA certification.

**8.** Does the study require a subject to be admitted to the hospital for an overnight (inpatient) stay in order to be a research participant? **If YES, complete 8a & 8b.** ☐ Yes ☐ No

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8a. What are the # of required inpatient stays? _____

8b. What is the average length of stay for each inpatient visit? _____

**9.** Indicate the location(s) that will be utilized during the conduct of this study. Check all that apply.

☐ **WMC Inpatient Clinic 1 (Include clinic name, address and room number)**

Address Building Name: _____ Office #: _____

Street Address: _____

☐ **WMC Inpatient Clinic 2 (Include clinic name, address and room number)**

Address Building Name: _____ Office #: _____

Street Address: _____

☐ **WMC Outpatient Clinic 1 (Include clinic name, address and room number)**

Address Building Name: _____ Office #: _____

Street Address: _____

☐ **WMC Outpatient Clinic 2 (Include clinic name, address and room number)**

Address Building Name: _____ Office #: _____

Street Address: _____

☐ **Physician Private Practice 1 (Include name of private practice, address and room number)**

Address Building Name _____ Office #: _____

Street Address _____

☐ **Physician Private Practice 2 (Include name of private practice, address and room number)**

Address Building Name _____ Office #: _____

Street Address _____

**10.** Does study involve any special procedures? ☐ Yes ☐ No

**If YES**, list procedures & name of the WMC credentialed staff member(s) who will perform the procedure(s).

10.a. Procedure (include ICD-9 Code): _____

Credentialed Staff Member(s): _____

10.b. Procedure (include ICD-9 Code): _____

Credentialed Staff Member(s): _____

**11.** Does study require the use of the WMC Ancillary Services listed below? ☐ Yes ☐ No

**If yes,** select the service(s) that will be used and indicate which procedures will be requested. Check all that apply.

☐ **GI Lab**

☐ Colonoscopy ☐ Enteroscopy ☐ Endoscopic retrograde Cholangiopancreatography (ERCP)

☐ Esophagogastroduodenoscopy (EGD) ☐ Other (Please describe) _____

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☐ **Imaging Services *(including Bradhurst Radiology)***

☐ Bone Scan ☐ MRI ☐ PET Scan ☐ Kidney (Renal) Scan ☐ CT Scan

☐ Thyroid Scan ☐ X-RAY ☐ Other (Please describe) _____

☐ **Lab Tests**

☐ Phlebotomy Only (Include # draws/subject; over what time period)

_____

☐ Specific tests (list each test, including CPT code, if provided by Sponsor)

_____

☐ **Non Invasive Cardiology**

☐ ECHO ☐ EKG ☐ MPI or MUGA

☐ Other (Please describe) _____

☐ **Pathology**

Please Describe: _____

☐ **Pharmacy**

Please Describe: _____

☐ **Other**

Please Describe: _____

12. Will Medical Records be required for this study? ☐ Yes ☐ No

**If YES**, answer questions 12a through 12g below.

12a. What specific diagnosis will be used to identify the medical records you need? Include ICD-9 codes if known. _____

12b. Start date for search : _____ End date for search: _____

**mm / dd / yyyy** **mm / dd / yyyy**

12c. What is the total number of records you are requesting? _____

12d. What is the minimum number of charts (meeting all protocol inclusion/exclusion criteria during the time frame listed above) needed to conduct this study? _____

12e. Medical records went electronic in April 2013. How many records included in your request are prior to April 2013? _____

12f. There is a $30/chart fee for each paper chart retrieved by Health Information Management (HIM). Are funds available to cover the applicable charges? ☐ Yes ☐ No

12g. List all research staff that will be requesting medical records from HIM. _____

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13. Does the study involve an investigational new drug (IND)?
**IF YES,** include FDA 1571/1572 and a copy of the Investigator Brochure (IB) ☐ Yes ☐ No

14. Does the study involve an investigational device (IDE)? **IF YES,** include IDE Form ☐ Yes ☐ No

## Section 3 - Study Conduct

List the name(s) of the staff that will be responsible for the following activities.

| | Activity | Name(s) | Where are documents/data stored? |
|---|---|---|---|
| 1. | Draft Study Implementation Standard Operating Procedures | | |
| 2. | Convene Implementation Meeting | | |
| 3. | Maintain Staff Training Logs | | |
| 4. | Maintain Signature & Delegation Log | | |
| 5. | Maintain Enrollment Logs | | |
| 6. | Maintain Consent Binders | | |
| 7. | Data Acquisition | | |
| 8. | Data Entry/QA | | |
| 9. | Maintain Research Files | | |
| 10. | What electronic application(s) will be used to store/analyze data? | | |

## Section 4 - Clinical Trial Billing and Finance

All funded studies (investigator initiated, grant funded, industry sponsored,) must include:

1. The clinical trial agreement (CTA), as applicable
2. The grant, as applicable
3. The budget template provided by the funding sponsor
4. Line item budget outlining the costs associated with each activity included in the Events Table of the protocol

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**Section 5 - Documentation Checklist**
Are the following items attached to this Application? Each item should have a response.

1. NYMC Application **(REQUIRED)** -
2. Protocol **(REQUIRED)** --
3. Consent Form or Consent Waiver -
4. Verbal Consent (in person or over the phone) script and documentation plan --
5. Assent Form or Assent Waiver --
6. HIPAA or HIPAA Waiver --
7. CITI Certifications for Investigators & Consenting Professionals **(unless previously submitted to CRI)** -
8. Multi-site SOPs **(REQUIRED IF YOU ANSWERED YES TO QUESTION 3B, SECTION 2)** -
9. Data Collection Instrument(s) **(REQUIRED IF YOU ANSWERED YES TO QUESTION 5, SECTION 2)** -
10. FDA 1571/1572 **(REQUIRED IF YOU ANSWERED YES TO QUESTION 13, SECTION 2)** -
11. Investigator Brochure **(REQUIRED IF YOU ANSWERED YES TO QUESTION 13, SECTION 2)** -
12. Investigator Devices (IDE) **(REQUIRED IF YOU ANSWERED YES TO QUESTION 14, SECTION 2)** -
13. Medicare Coverage Analysis Form -
14. Clinical Trial Agreement **(REQUIRED IF SPONSORED)** -
15. Sponsor Budget Template **(REQUIRED IF SPONSORED)** -
16. Line Item Budget **(REQUIRED IF SPONSORED)** -

**Principal Investigator (PI) Attestation and Signature**

To the best of my knowledge the information contained in this application is correct. As the Principal Investigator, I agree to abide by the requirements of Westchester Medical Center and New York Medical College specific to human subject research, and stipulated in the agreement with the sponsor(s) in the conduct of the protocol. I will comply with all federal, State and Institutional regulations governing human subject research, and all regulations related to research reimbursement.

PI SIGNATURE_____ DATE_____

**Departmental Attestation and Signature:** Provide the name(s) of all WMC Departments involved in the conduct of the proposed study and the name/signature of each Department Chair.

| **WMC Department** (PLEASE PRINT) | **Department Chairperson** (PLEASE PRINT) | **Chairperson Signature and Date** |
|---|---|---|
| | | |
| | | |
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