Clinical Research Institute (CRI) Research Application

Westchester Medical Center
Westchester Medical Center Health Network
7 Skyline Drive, Suite 385; Hawthorne, NY 10532
Office: 914-326-1516; Fax: 914-493-2149

Prior to completing the application, make sure you are working with the most current version, which can be found at: *http://icare/Departments/patient-care/clinical-trials/Pages/default.aspx* or *http://www.westchestermedicalcenter.com/clinical-trials*

E-mail complete application to Research@WMCHealth.org. It should be submitted at the same time you submit your application to the IRB for its review/approval. Please note that the CRI review encompasses both the study documents (e.g. protocol) and Clinical Trial Agreements (CTA); Hospital approval cannot be given until the study documents AND legal documents have been approved/executed.

In order for a CRI Application to be complete, all documents indicated as 'required' in the checklist at the end of the Application must be available to CRI. Once a complete submission is on file, the study can be added to the Review List.

Enter Study Title & NCT NUMBER _____

Directions: Please provide complete each question below. If you need clarification, contact the CRI Office.

	Principal Investigator (PI)	Study Coordinator
Name:		
Phone Number:		
Preferred E-mail Address:		

Cannot use personal E-mail addresses; Please provide preferred business E-mail address

Private Practice Name: _____

Practice Mailing Address: _____

_____

1. Is this research proposal approved by your WMC Department Director or his/her designee? ◯ Yes ◯ No

2. Where will recruitment take place (check all that apply) ◯ WMC ◯ MHRH ◯ Private Practice ◯ Good Sam ◯ HAHV

3. Does the study require a subject to be admitted to the hospital for a procedure or overnight (inpatient) stay in order to be a research participant? **If YES, complete 3a** ◯ Yes ◯ No

3a. What Department will oversee the procedure &/or in-patient stay? _____

4. Is this a Multi-Site Study? **If YES,** complete 4a and 4b, below. ◯ Yes ◯ No

4a. Will your site be acting as recruitment site? ◯ Yes ◯ No

4b. Will your site be acting as Data Coordinating Center (DCC)/Lead Site? ◯ Yes ◯ No

If YES: DCC Standard Operating Procedures required to oversee a multi-site project must be submitted with your application.

5. Does study design require collection of images or voice recordings of subjects? ◯ Yes ◯ No

If YES: the study protocol must include a description of procedures detailing (but not limited to) equipment to be used, personnel designated to use/handle equipment, 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 Hospital Patient Photography, Videotaping and Imaging Policy

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

If YES: the study protocol must include a description of methods used to control subject anonymity and privacy protection.

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

If YES: the study protocol must include a detailed description of how samples should be collected, processed, stored, shipped, etc. In the absence of such a description, a stand-alone Lab Manual may be provided. Depending on protocol requirements, IATA certifications should also be provided to the CRI at the time of submission.

8. Does study (e.g. observational study, chart review) involve data extraction from Hospital medical records? ☐ Yes ☐ No

If YES: provide a Word .doc that lists each variable that will be extracted & what data source will be queried/variable

9. What Hospital system(s) will you need to access to get the data necessary to complete your review (e.g. paper charts, A2k, pACS, etc.)

_____

10. What specific diagnosis will be used to identify the medical records you need? Include ICD-10 codes if known.

_____

11. What is the beginning date and end date that will be used to identify your subject population?

Start date for search : _____ End date for search: _____

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

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

13. List all research staff that will be requesting medical records from Health Information Management (HIM).

_____

NOTE: WMC's Medical Records went electronic in 4/2013. A $30/chart fee may be assessed for each paper chart retrieved by HIM has to retrieve to satisfy your medical records request.

14. Indicate the location(s) that will be used to conduct research activities during the study. Check all that apply.

	Inpatient Services	Hospital Outpatient Clinics	Physician Private Practice
Location	_____	_____	_____
Location	_____	_____	_____
Location	_____	_____	_____
	Include Hospital, Floor, Unit	*Include clinic name and location*	*Include practice name & location*

15. Indicate what Ancillary Services will be used to conduct research-only labs and procedures for this study.

_____

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Documentation Checklist (Each item should have a response.)
The following items, when applicable, are a required element of the CRI Research Submission. If a required item is not made available to the CRI/submitted with this application, your submission will be incomplete and your study cannot be added to the queue for review.

1. Study Protocol
2. Study Informed Consent/Assent or Request for Waiver
3. Study HIPAA Form or Request for Waiver
4. Verbal Consent (in person or over the phone) script and documentation plan
5. Copies of surveys, questionnaires, data collection forms
6. Word document listing variables to be extracted from medical records
7. CITI Certifications for Investigators & Consenting Professionals
8. Multi-site SOPs **(REQUIRED** if you answered YES to Q4b**)**
9. FDA 1571/1572 (**REQUIRED** if study involves an investigational medication**)**
10. FDA IND Letter (**REQUIRED** if study involves an investigational medication**)**
11. Investigator Brochure (**REQUIRED** if study involves an investigational medication**)**
12. Investigator Device Form (**REQUIRED** if study involves investigational device)

A copy of this form is **available** on the CRI iCARE page. If you do not have access to iCARe, please contact the CRI Office

13. Clinical Trial Agreement (**REQUIRED** if Sponsored/Supported)

If applicable, a copy of the CTA (or Work Order, Sub Award Agreement, **Purchasing** Agreement, etc.) must also be included.

14. Sponsor Budget Template (**REQUIRED** if funded)

The budget template provided by the sponsor must be submitted with application. This includes Funding Sheets for Cooperative Group Studies.

15. Line Item Budget (**REQUIRED** if funded)

The Line Item (or itemized) budget is the budget that you draft internally based on the Events Table of the protocol. It is the tool used to ensure the Sponsor's template covers all activities (including labs, procedures, time and effort, supplies, shipping, etc) required to conduct the study.

Principal Investigator (PI) Attestation and Signature

To the best of my knowledge the information contained in this application is correct. As the PI, I agree to abide by the requirements of Westchester Medical Center and the IRB of record 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 and Date

Hospital Department Director/Section Chief Signature

Hospital Department (PLEASE PRINT)	**Department Director/Section Chief** (PLEASE PRINT, SIGN & DATE)	