

**Clinical Research Center
University of Massachusetts Worcester
Ambulatory Care Center – AC1-044**

Thank you for your interest in the research support services available through the Conquering Diseases Clinical Research Center (CRC) at UMass Worcester.

This memo and attached Service Agreement clarifies the scope and costs of the services available.

The *Clinical Research Center* is dedicated to efficient, reliable and high-quality study support for UMass clinical investigators. For a reasonable cost, researchers and their staff can utilize the following services as needed:

- ◆ **Experienced Clinical Research Nurses and support staff**
- ◆ **Accessible and comfortable space for participants, just off the main lobby of ACC**
- ◆ **Six (6) exams rooms for study conduct**
- ◆ **Three infusion bays with comfortable recliners for lengthy visits**
- ◆ **Touchdown space for visiting researchers, their support staff and external monitors**
- ◆ **Conference room for start-up meetings, sponsor visits and research staff use**
- ◆ **In-unit laboratory equipped with centrifuge, hematocrit machine, -20 and -80 freezer space;**
- ◆ **Prep area for packaging and shipping central lab specimens according to protocol requirements**
- ◆ **Regulatory support for IRB submissions; assistance with external regulatory communications; assistance with posting to *clinicaltrials.gov***

Normal hours of operation: *We are flexible to suit the needs of investigators and study participants.* Our standard hours are 8:00am - 5:00pm, although other arrangements for extended hours may be made through the CRC nurse manager as required for your protocol. Please note this is **NOT** an overnight unit, but we can accommodate a 10-12 hour day for PK studies or other clinical research needs.

Scope of services: Study space (exam room and/or infusion room) is available and should be booked through the main CRC number (x62800) after a “Service Agreement” is signed. *Room charges may vary based upon your funding source.* A conference room or workstation for your study-related meetings or monitor visits is also available at no charge by calling x62800.

Research Coordination services are available with our staff of nurse coordinators. Depending upon needs of your study, you can contract for “% effort”, billable hours @ negotiated rate, or adhere to a unit cost budget sheet which is agreed upon *before* study is initiated. *The latter will most often be used with short-term industry-initiated trials.* Please note: Should the research coordinator attend an off-site investigator or start-up meeting, your account will be charged a day rate as noted on the attached “Service Agreement.” Please note that **NO** clinical care visits are allowed in the CRC.

Emergency Response: The Clinical Research Center is located in the Ambulatory Care Building on the South Road of University campus. Because it is outside the hospital, both good practice standards and licensing require that we conduct only research visits. Study drug infusions can be performed, but for medications with a heightened concern regarding adverse reactions, the hospital may be the appropriate site. The decision regarding safety in the CRC will be made with the PI, investigational pharmacist, CRC staff, Director and Medical Director at the time of study initiation. Final decision about appropriateness of the trial for the CRC will be made by the Medical Director. On recommendation of the UMMMC resuscitation committee, the CRC is equipped with an AED and limited meds for anaphylaxis. In the event of an emergency, the unit will call emergency 911 as would be done in any area outside the hospital; the study subject will be transported to the appropriate clinical area for care and treatment.

Accountability and Time Tracking: Although the Principal Investigator is ultimately responsible for all aspects of study conduct, the CRC employs experienced nurse coordinators who can assist the PI with study initiation, recruitment and the vast array of study conduct activities. Their work, and any related room charge, is documented for each and every study. The principal investigator will receive a monthly accounting of charges in the Clinical Research Center. Any questions related to this should be directed to the CRC nurse manager.

Should your need for CRC services change once your study is initiated, please contact Celia Hartigan (x63676 or x62800) or Sheila Noone in OVPR (x65015) to renegotiate the terms of the CRC Service Agreement.

Account # _____ G98 # _____

SERVICE AGREEMENT: Clinical Research Center (CRC)

Principal Investigator: _____ **Dept:** _____

Study Name: _____

Study Sponsor: _____

IRB Docket # _____ **IRB Approval Date** _____

Start date of services: _____ **End date (if known)** _____

SCOPE OF SERVICES:

_____ **Room charges* (\$40./subject/hour)**

* Rate differs with funding source

_____ **Research nurse coordinator services:**

___ Billable hours at \$55/hr to maximum of _____

___ Agreement for ___ % effort for total of _____/month

___ Charges according to unit cost budget appended

_____ **Regulatory Assistance:** _____

Day rate for investigator meeting: _____

Other arrangements: _____

As **Principal Investigator** for the above-noted study:

- **I remain the responsible party for all aspects of study conduct, and will ensure the latest version of study protocol is always on file in the CRC**
- **I have read and understand the emergency response procedures for CRC**
- **I will receive a monthly report of study charges to my research account**
- **When possible, I will give a two week notice for cancellation of services**

_____ Date: _____
PI Signature

_____ Date: _____
Department Administrator Signature

_____ Date: _____
OVPR Director Signature

_____ Date: _____
CRC Nurse Manager Signature

Sheila B. Noone, Ph.D. – Asst Vice Provost, Clinical Research @ x65015
Celia Hartigan, RN, MPH - Nurse Manager @ x63676 or 62800