

Principal Investigator: \_\_\_\_\_ Sponsor: \_\_\_\_\_

Title: \_\_\_\_\_

## **Critical Steps: Clinical Study Initiation OVPR, Clinical Research – UMass Worcester**

### **IMPORTANT:**

**Three critical processes must occur *before* you  
recruit for a new study**

**IRB Approval\***

The IRB must have reviewed and approved the protocol; an IRB approved, stamped consent form must be received before recruitment  
(\*other committees if applicable, e.g., radiation, biosafety/IBC)

**Fully Executed Clinical Study/Trial Agreement (CSA/CTA)**

The CSA/CTA must be signed by all parties: University and the Sponsor and (usually) PI. The binding signature for all industry contracts is the University representative through the Office of the Vice Provost for Research (OVPR). All budgets for CSA/CTA must be signed and approved by both the PI **and** the OVPR.

**Account Numbers in Place**

The Grant Account Number is established by UMMS's Financial Services (Grant Accounting) after the contract is fully executed **and** the Transmittal Form has been received in the OVPR.

The Clinical Research Billing Number ("98"number) is established by the *clinical* system for research charges that need cross-system payment. To expedite this, UMMHC's "Special Accounts Authorization Form" should be sent to the Office of Research *with* the Transmittal Form. The grant account number will be added by Clinical Research – OVPR; once received, the form will be signed by OVPR, then sent by fax to UMMHC Patient Accounts (Anna Walne) for assignment of "G98" number. Identified study coordinator and research administrator will then receive this number back from Anna Walne in Patient Accounts.

**Recruitment can then be initiated!**

**Questions or concerns with this process should be addressed to:**

Sheila Noone, Asst Vice Provost for Clinical Research - x65015

or

Marsha Fox, Manager, Clinical Research Operations – x68981