THE UNIVERSITY OF MASSACHUSETTS MEMORIAL CANCER CENTER OF EXCELLENCE (UMMCCOE)
CLINICAL RESEARCH OFFICE (CRO)

Letter of Intent Template

Before a UMMCCoE or University of Massachusetts investigator writes an institutional protocol for any interventional study that does not receive scientific review from an NCI-approved review agency, he or she must submit a Letter of Intent (LOI) to the Protocol Review Committee (PRC) for approval. Before the LOI is presented to the PRC for approval, the Scientific Review Coordinator (SRC) will obtain approval from the Disease Section Leader via e-mail. An LOI is not required for a chart review or lab-based study. Pharmaceutical sponsored studies are also exempt from LOI submission and review. This letter should *briefly* address all of the following points. Use additional pages if necessary. If a category does not apply, write "N/A". Submit a completed LOI electronically to the current SRC, Annette Larsen, RN, BSN, Annette.Larsen@umassmemorial.org**.** Please note that this LOI does not constitute a complete CRO submission of your protocol. (If your LOI is approved, the complete submission will come later).

Proposed Title of Study:

_____

Principal Investigator:

_____

Phase of Study: ☐I ☐I/II ☐II ☐III ☐IV ☐Pilot ☐Not Applicable

Agent(s), Device(s) or Tool(s) to be used:

_____

Source of agent(s): *(NCI, drug company sponsor, commercially available, etc.)*

_____

Tumor Type and Stage:

_____

Performance Status Permitted *(ECOG scale)*: ☐0 ☐≤1 ☐≤ 2 ☐≤ 3 ☐≤ 4 ☐N/A

Abnormal Organ Function Permitted:

_____

Prior Therapy Permitted *(Surgery, Chemotherapy, Hormones, Biologics, Radiation):*

_____

Rationale/Hypothesis:

_____

Treatment Plan:

_____

Laboratory Correlatives:

_____

Primary/Secondary Endpoints:

_____

Statistical Considerations:

_____

Proposed Sample Size *(provide rationale):*

_____

Projected Dates of Accrual *(MM/YY to MM/YY):*

_____

Estimated **Annual** Accrual:_____

List any other institutions that will participate:

_____

_____

_____

_____

Funding Source *(if applicable):*

_____

List Competing Studies Currently Open:

With respect to any competing studies, what will be the priority of this study?

List References:

For PRC Administrative Use Only

Date SRC received:

Disease Section Leader Approval:

Date of PRC Approval:

Date Letter Sent to PI: