

# Multidisciplinary Oncology Group (MOG) Clinical Trial Review Form

## Section 1

Completed by Regulatory Pre-Study Team

- 1) **MOG:** Pre-Study Number: \_\_\_\_\_
- 2) **Study Title:** . \_\_\_\_\_
- 3) **Principal Investigator:** \_\_\_\_\_
- 4) **Sponsor / Funding Source:** \_\_\_\_\_
- 5) **Is this trial investigator initiated?** Yes \_\_\_\_ No \_\_\_\_
- 6) **Is this a dose escalation study?** Yes \_\_\_\_ No \_\_\_\_

### **Additional information from Sponsor for prioritization:**

**How many sites are planned to open this study:**

**How many of these sites are already open?**

**Projected first subject first visit (MM/YYYY):**

**Number of subjects currently enrolled:**

**Number of subjects planned to be enrolled:**

**Projected last subject first visit (MM/YYYY):**

## Section 2

Completed by PI or MOG Leader

- 7) **Relevant members of the MOG consulted about the trial, and are they supportive of opening the study?**  
Yes \_\_\_\_ No \_\_\_\_ (if "No", please explain): \_\_\_\_\_
- 8) **Please list those MOG members included in the discussion.**  
HCCC:  
Mission:  
QC:
- 9) **Were participating ancillary services who help in patient's recruitment & treatment plan (e.g., inpatient attending physician, radiology, surgery, pathology, radiation oncology) consulted about the trial and are they supportive of opening the study?**  
Yes \_\_\_\_ No \_\_\_\_ (if "No", please explain): \_\_\_\_\_
- 10) **Projected accrual:**  
HCCC:  
Mission:  
QC:  
a) **How many patients do you expect to consent for screening purposes?**

HCCC:  
Mission:  
QC:

b) **What is the minimum projected accrual for this study?**

HCCC:  
Mission:  
QC:

c) **What is the minimum annual projected accrual for this study? If minimal overall projected accrual is < 5, please explain why this study should be opened. 3-5:**

HCCC:  
Mission:  
QC:

11) **Please identify line of therapy:**

- Neoadjuvant
- Adjuvant
- 1st line metastatic
- 2nd line metastatic
- 3rd line metastatic and/or beyond
- Maintenance
- Other: \_\_\_\_\_

12) **Please identify investigational interventions involved (check all that apply):**

- Immunotherapy
- Bi-specific / BiTE antibodies
- Intra-tumoral therapy
- Cellular therapy
- Antibody-drug conjugated chemotherapy
- Vaccine
- New device
- Targeted antibodies (e.g. Anti EGFR, VEGF)
- Targeted therapy (Oral TKI or small molecule inhibitor)

13) **How many months on average patients are expected to stay on active therapy/intervention?**

14) **Does this trial compete with open studies in your disease portfolio?**

HCCC:  
Mission:  
QC:

**If Yes, what the Protocol Title or IRB number of the competing study or studies?**

**If Yes, what will be the strategy to prioritize this vs other competing studies for patient enrollment?**

15) **Provide a statement of justification as to why this study is important to you as the PI, to your patients, and to the Institution.**

16) Please add any additional Sub-Is or APPs that are not listed below that will be included on this study (individual personnel must be named):

**PIs need to reach out to any sub-Is outside of their site to assess interest and site feasibility:**

HCCC Required:

Add:

Mission Required:

Add:

17) PI/Study Chair Signature and Date: \_\_\_\_\_

### **Section 3**

To be completed by the MOG Leader/Co-leader

This protocol was presented, discussed, and accepted at the Lymphoma Multidisciplinary Oncology Group meeting on \_\_\_\_\_ (date). Potential accrual, competing studies, and priority issues have been adequately discussed and addressed by the MOG leader.

Studies below have been approved by this MOG and will be processed for activation to enroll patients. These studies are either waiting for receipt of start-up documents from sponsor, TREC review, or clinical research services (CRS) resource availability. Please rank all the studies below according to the MOG's priority. This will help CRS process studies in the way that is aligned with MOG's needs and/or priority.

**Table:** Studies in this MOG pending for activation

Study Title	PI	Study status	Ranking (1 being highest priority)

Further comments/clarifications:

**MOG Leader/Co-leader Signature and Date:** \_\_\_\_\_