Purpose: To serve as a guideline for study selection to ensure that sufficient resources exists in the GIHCRO to support Division priorities.

Prior to a study’s initiation, there are multiple processes that must be completed including budget/contract negotiations and regulatory submissions (1572, financial disclosure forms, IRB, etc.). Due to the high rate of studies in which the Division participates, starting November 2015, the Division will be implementing a formal process to determine which studies will be selected for an opportunity to have UW be a site.

ANY new study that a PI wishes to use the GIHCRO resources for will need to be presented to the Research Committee (RC), which ever members are present, for consideration. These will be informal presentations and only thereafter will a study be considered. Guidelines for how these studies will be evaluated for feasibility are outlined below.

Fellow projects will not be a part of this process.

Industry/Foundation Sponsored Trials

- Present to Research Committee
- Evaluate: 1. How many providers are interested/willing to recruit to the study?
  - Research Program Manager (RPM) will send out a poll to gauge interest.
  - We expect at least an 85% consensus for GIHCRO to take on the study.

  2. Do we have any other competing protocols?
  - If yes, we expect an 85% consensus AND will consider closing the competing study in a reasonable timeframe, especially if it is not recruiting well.

  3. Budget, effort, and timeline
  - Is there regulatory and/or study coordinator support?
  - How involved is the study once it is open?
  - What is the projected timeline?

Investigator Initiated Trials (IIT)

- RPM will send protocol and review form to Research Committee for pre-review
- Committee members will complete form prior to meeting
- PI presents to Research Committee
- Make changes according to feedback, changes will be sent to Research Committee for final scoring
- Protocol must score an average score of 4 at the final review to be selected
Review Form

Please score the protocol on a score of 1-5 for each section below, (1 high, 5 low)

1. Overall Impact (likelihood for project to lead to an independent grant, peer reviewed publication(s))
2. Significance (does project address important problem/critical barrier to progress field, how will knowledge improve problem/barrier?)
3. Innovation
4. Practicality (do we have the essential elements to complete the study? overall strategy/methodology/analysis appropriate and well-reasoned?)
5. Comments