Checklist: Scientific value of proposals for multi-center clinical trials

In an effort to help in increasing the value and minimize the waste of valuable resources, the CRI will be assessing the scientific value of investigator-initiated clinical trial proposals by AUBMC faculty. This will be done through an internal peer review process, supplemented by external peer review as needed.

The peer review will consider the following factors:

Study Protocol

Assessed the need and usefulness of the trial, by considering:

- ☐ The published literature addressing the same or very similar questions, including published trials, and a systematic review of the evidence when available
- ☐ Ongoing trials addressing the same or very similar questions

☐ Adheres to standard and best practices of clinical research according to the type of study (e.g., randomization in type 3 trials), or justifies any non-adherence

☐ Provides well-written design and analytical plans

☐ Addresses potential challenges (high drop-outs, unpredicted results, and adverse events)

☐ Details how potential post-hoc decisions and deviations from the preconceived plans will be recorded and reported

☐ Provides a plan to register the protocol (when, which registry (ies))

☐ Follows standard reporting practices for trial protocols, e.g., SPIRIT statement (http://www.spirit-statement.org)

Sample size calculation

☐ Not applicable, pilot study

☐ Provides sample size calculations and expected power that are clear, realistic, and based on well-justified and described clinically relevant outcomes

Stakeholders' involvement

☐ Reports whether and how statisticians and methodologists are involved (if not, justify why)

☐ Reports a detailed plan of communication between the members of the trial team

Conflict of interest issues

☐ Conflict of interest declaration

Reproducibility and reward systems

☐Description of plan to make raw data and analyses publically available (e.g., publicly using open access clinical trials data platforms; or upon request)

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