RAPID ACTIVATION SUMMARY

I. Objectives

II. Committee Composition

III. Guiding Principles

IV. Process and Procedures

V. Tracking and Documentation

I. Objective

Rapid Activation (RA) was developed as a mechanism by which the start-up process for select clinical trials could be fast-tracked without compromise to subject protections, regulatory compliance and scientific integrity, accelerating patient access to new therapies.

II. Rapid Activation Committee

The Rapid Activation Committee members are responsible for ensuring that high priority clinical trials, as identified by leadership, are activated within 42 days. The Rapid Activation Committee represents two distinct bodies: leadership and the RA working group; members of these bodies do not overlap. All members participate in regular RA meetings.

III. Leadership

The Rapid Activation Committee is composed of senior leaders drawn from departments and institutes as well as research administration and operations, institutional review board, compliance and representatives of scientific and safety committees. Leadership is responsible for oversight of the working group, invoking infrastructure or procedure changes as needed to allow the committee to fulfill its objective and when applicable and approving institutional policy exceptions associated with processing RA protocols. This body defines the project parameters, engages ad hoc members on a per protocol basis and provides necessary support and resources to carry out objectives. Below is a sample membership list for cancer research.

SAMPLE: Rapid Activation Committee Member Structure
Cancer Institute Director
Associate Director, Translational Research
Medical Director, Clinical Trials Office
Director/Manager, Clinical Trials Office
Director, Institutional Review Board
Vice President/Director of Research Administration
Vice President/Director of Service Line Operations
Chair of Institutional Biosafety Committee
Chair of Protocol Review and Monitoring Committee
Chair of Medical Radiation Safety Committee

IV. Working Group

The RA Working Group consists of an independent project manager and at least one senior manager and/or director from the following areas:

- Clinical Trials Office or equivalent
- Research Informatics or equivalent
- Institutional Review Board (IRB) operations
- Office of Research Compliance

- Sponsored Research Administration
- Applicable Scientific and Safety Review Committees

The RA working group is responsible for collectively managing the protocol activation workflow within the timeline. This group assigns staff, provides protocol specific oversight, and monitors resources and progress for each selected protocol to ensure the 42 day timeline is met. The working group provides routine status updates to the RA Committee. The working group may also make recommendations for research infrastructure improvements. The RA team engages leadership as necessary to mitigate institutional risks and prevent challenges from obstructing the 42 day deadline.

V. Guiding Principles

The RA process is utilized within a set of guiding principles as shown in the following example.

- *Protocol Selection:* Rapid activation is limited to clinical trials that meet the rapid activation criteria as established by the Institution. In general only protocols that meet the highest institutional priority and demonstrate strong sponsor commitment will be considered.
- *Scope:* Policy to be established based upon available staffing
- *Capacity:* No limitations
- *Deadline:* Due to holiday closures and the number of sponsor dependent processes for successful activation, all RA protocols should be initiated prior to November 15th or after January 1st of every calendar year.
- *Disqualification:* The 42 day deadline relies heavily on sponsor commitment. The sponsor should review and commit to the protocol specific timetable prior to activation. It is recommended that the sponsor be made aware that if any two key milestones are missed by ≥ 7 days, the committee may elect to remove the protocol from RA and continue to activate it via standard processing.

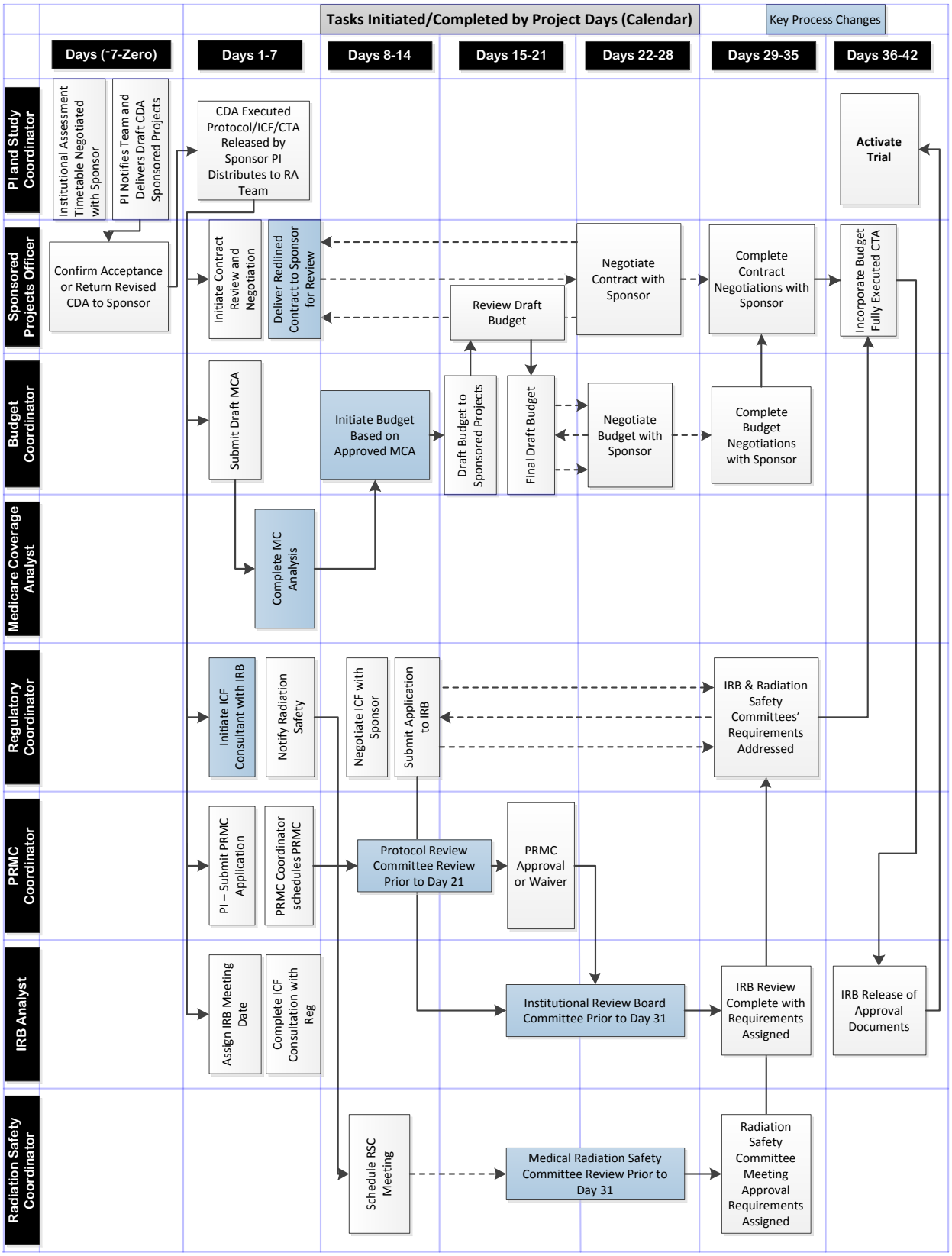
VI. Process and Procedures

All rapid activation protocols will be processed as outlined in RA flow/calendar as shown in the Appendix.

VII. Tracking and Documentation

The Protocol Rapid Activation Tracking (PRAT) online system is used to track the progress of each step described in the Appendix for all RA protocols. The working group members are responsible for ensuring the accuracy and timeliness of the data. The RA committee (leadership) members may access PRAT to view current progress of each study and identify delays or delinquencies. The working group will track time and effort associated with RA protocols and document all associated process changes.

Appendix: *RA Process flow/calendar for Cancer Center Studies*



Note: Protocol Review and Monitoring Committee (PRMC) for cancer studies, represents departmental review