

<b>Abstract Title</b>	<u>MEETING THE CHALLENGE: Development of an Ad-Hoc IRB to address fast-track protocols</u>
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Research institutions face new challenges in ensuring that laboratory discoveries arrive at the bedside as safely and efficiently as possible. We developed an ad-hoc IRB to meet an institutional mandate to activate early phase oncology studies within a six-week timeline (42 days) from the execution of the Confidential Disclosure Agreement to the activation of enrollment.

The Rapid Activation Process, spearheaded by Research Administration and Samuel Oschin Comprehensive Cancer Institute, defined the key milestones in the life of a protocol, and identified players critical in achieving these milestones. A leadership group including the Samuel Oschin Comprehensive Cancer Institute, the Office of Sponsored Research and Funds Administration, Office of Research Compliance, study personnel, and ancillary committees (Radiation Safety, etc.), developed a Study Calendar which assigned deadlines to each processing milestone and initiated weekly check-in meetings to track progress and identify “rate-limiting” steps.

Acknowledging that it may not always be possible to meet activation target dates with current meeting schedules, an Ad-hoc IRB was developed. This additional board meets regulatory requirements and considers and approves proposals qualifying for Rapid Activation. Meetings may be convened very quickly and utilize existing and experienced IRB members. Membership is limited to five seats: three clinician researchers, one bioethicist, and one nonscientist/non-CSMC affiliated public member (dual role). Members of other CSMC IRBs supplement the available expertise of the Ad-hoc IRB as consultants. Meetings are only held when members concur that they have sufficient time to review the materials available on-line and may be conducted in person or via teleconference.

Analysis of Rapid Activation activities has demonstrated that IRB processing exceeded processing targets. The biggest success of this endeavor has been the ability to meet the challenge with existing resources.

Others can easily implement similar approaches and strategies in order to implement an Ad-hoc IRB at their own institution.