



U-MIC TRANSCRIPT

Single Institutional Review Boards (sIRBs): IRBMED Process

A UM principal investigator in multi-site research for which IRBMED serves as single IRB—commonly referred to as the “overall principal investigator”—bears additional responsibilities. Overall PIs should expect significant additional responsibility beyond that of leading a UM study team alone.

IRBMED has developed a checklist of additional responsibilities that an overall PI should be prepared to accept. Working with IRBMED, overall PIs must:

- ensure adequate and qualified study team members
- determine and document specific roles and responsibilities for communicating and coordinating key information to relying institutions
- obtain documentation of each relying site’s approval to cede review
- promptly respond to questions from study teams and IRB personnel at each relying site
- prepare and submit AE/ORIOs, amendments, and continuing reviews on behalf of all relying sites, to report site activations, personnel updates, reportable events, and enrollment activity; this involves:
 - collect information from each relying site regarding local variations in study conduct, such as:
 - recruitment
 - informed consent
 - and subject identification
 - ensure that consent documents follow the IRBMED-approved templates and include required local-context language
 - assure that each relying site is informed of all IRBMED determinations and communications, including those for:
 - initial review
 - continuing review
 - amendments
 - and all reportable events
- when agreed upon in coordination with IRBMED, promptly inform the relying site of information or events that are related to or may affect subjects at the relying institution, including:
 - unanticipated problems involving risks to subjects or others
 - other research-related subject injuries

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- or significant subject complaints
- and, upon request, provide access to study records for audit by IRBMED and other regulatory or monitoring entities

Contact IRBMED for more information about additional responsibilities of overall principal investigators in multi-site research.

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