



## IRB Glossary

<b>STUDY STATES</b>	
<b>Acknowledged</b>	Reportable New Information (RNI) has been acknowledged
<b>Active</b>	The study is active
<b>Approved</b>	The submission has been approved by the IRB
<b>Approved with Modifications</b>	Study approval will be given as long as the requested revisions are made
<b>Awaiting Site Materials</b>	Participating site has not submitted materials for IRB review
<b>Clarification Requested</b>	IRB has requested clarifications from the PI
<b>Closed</b>	The study team closed study
<b>Deferred</b>	Tabled; IRB determines that it is unable to approve the study and suggests modifications that might make the study approvable
<b>Discarded</b>	The study team discarded the submission
<b>External IRB</b>	The study was approved by another IRB
<b>Invitation Pending</b>	Invitation to participate in the MSS has not been sent to pSite
<b>IRB Review</b>	Study is in review by a designated reviewer or Committee
<b>Lapsed</b>	IRB approval for the study has expired
<b>Modifications Required</b>	Explicit conditions; Designated Reviewer/Committee Review determined that changes were needed for submission to be approved
<b>Non-Committee Review</b>	The submission is being reviewed by a Designated Reviewer
<b>Post-Review</b>	Study is awaiting finalization by IRB coordinator
<b>Pre-Review</b>	IRB staff is currently reviewing
<b>Pre-Submission</b>	PI still needs to review & click Submit
<b>Withdrawn</b>	PI has removed the study from IRB review
<b>Discarded</b>	PI has
<b>STUDY DATES</b>	
<b>Approval end</b>	Study expiration date
<b>Effective date</b>	On the main study, the effective date will update whenever a modification/continuing review is approved. Effective dates on Mods and CRs will essentially be the same as the initial effective date
<b>Entered IRB</b>	The date and time the submission reached the IRB inbox via submit by PI/Proxy
<b>Initial approval</b>	Date a determination was made on the submission either through Designated/Full Board. This includes the determination of “mods required to secure approval
<b>Initial effective</b>	Original effective date. This can be either when the full approval was obtained at the time of determination or when the mods

	were reviewed and determined to be acceptable for approval by the IRB. This date is editable by the staff
<b>Last updated</b>	Date when the last update was made to the submission. Most activities will change this date
<b>TERMS</b>	
<b>Archived Studies</b>	Studies with the state: discarded, terminated, closed, lapsed, disapproved
<b>Clarification Requested</b>	Initiated by IRB, replaces former email conversations regarding revision/additional submission of study documents
<b>Comment</b>	Allows you to send a study-specific comment within the system. The comment will remain with the study record and is viewable by all users associated with the study. Additionally, can send a notification to PI/PI Proxy/Primary Contact, Study Team or IRB Coordinator when creating the comment
<b>Comment (Private)</b>	Only for IRB office. Comments on the associated study are only viewable by IRB staff and Committee Members
<b>Committee Review</b>	Full Board Review
<b>Follow-on Submission</b>	The following submissions are considered a Follow-on: Modification, Continuing Review, RNI
<b>Guest List</b>	Study staff may add guests to a study to permit read-only access
<b>IRB Coordinator</b>	IRB Analyst
<b>Modification</b>	Study amendment
<b>My Inbox</b>	Items that require you to take action
<b>Non-Committee Review</b>	Exempt/Expedited review
<b>PI Proxy</b>	A PI proxy can perform PI activities on the PI's behalf, such as submitting the study to the IRB, modifying the study and submitting continuing review. PI proxies must be listed on the study submission as study team members. Only PIs can assign PI proxies. The PI Proxy designation only applies to activities in the IRB module.
<b>Primary Contact</b>	A primary contact acts as the study team's main point of contact for communications with the IRB. The primary contact receives notifications, in addition to the PI (and any designated PI Proxies), when the IRB communicates a decision or requires the study team to take action. Unless modified, the primary contact is defaulted to whomever creates the initial study submission. This role does not have permission to submit to IRB
<b>Relying Sites</b>	Research sites that rely on UT as the IRB of record in multi-site studies
<b>Reportable New Information (RNI)</b>	Unanticipated problem, non-compliance, complaints, etc. In the new system anyone may submit RNI. RNI can be linked to multiple studies
<b>Study Team Change (submitted via Modification)</b>	Personnel change