

Guide to Penn IRB Statuses

Temporary Statuses

Temporary statuses refer to statuses that are expected to change through the submission and review process.

Temporary Overall Statuses

The following temporary statuses are set automatically by the system.

Overall Statuses	Represents:	Applies to
Draft Submission Pending	The application is pending submission.	All submissions
PI Certification Pending	The submission is pending PI approval.	Initials, amendments, continuing reviews
Pre-submission Requirements	The submission is pending department chair approval.	Initial submissions
IRB Review Pending / Pending	A general status that indicates the submission was received by the IRB and is somewhere in the IRB review process.	Initials, amendments, continuing reviews
Preapproval Requirements	The submission is somewhere in the IRB review process. There are additional requirements that need to be completed prior to IRB approval (e.g., completion of COI disclosure, CITI training, etc.)	Initials, amendments, continuing reviews
Expired	A study required continuing review, but it expired before the continuing review was submitted or approved. This is automatic for all studies except reliance agreements. Action is required by the study team. The study team must request to reopen and then submit a continuing review. This is generated when the study team pushes the request to reopen button.	Protocol as a whole
Request to Reopen	After doing this, the study team must take an action (submit an amendment or continuing review, depending on what is appropriate). If no action is taken, the following day the study reverts back to expired or completed status, as applicable.	Protocol as a whole

Review Decisions

Review Decisions are temporary *submission* statuses set by the IRB staff when the submission is not ready for full approval. Review Decisions refer to situations where the submission still requires some action or response from the research team. When these review decisions are selected – the submission is returned to the research team to respond.

- These statuses can be viewed in the **Requirements table for stage submissions (initial, amendment, continuing review)**. The overall status of the stage submission remains IRB Review Pending or Pre-Approval Requirements.
- These statuses can be viewed in the **respective panels and modal form for protocol update submissions (personnel additions, deviations, exception requests, adverse events, annual check-ins, and closures)**.

Review Decision	Represents	Applies to
Modifications Required	An IRB staff person, Chair, or member determined changes are required. The submission has been sent back to the study team for response.	All submission types
Reliance Accepted	For reliance agreements it indicates that Penn IRB has agreed to rely but the paperwork is incomplete . In the case of a reliance agreement, this status would be changed to Approved Relying IRB once all the paperwork is received. IRB review is complete, but the IRB cannot release consent forms / issue full approval yet because of one of the following:	Initials
Administratively Finalized	• The injury language in the ICF must be reviewed. • Something requires formal submission and recognition by the IRB. For example, but not limited to, international studies that require local context review, a letter of support from an external site, or review of conflict of interest.	Initials, amendments
Withheld Approval	Study meets criteria for approval but and is approved contingent on pending response to minor issues raised by a Board. The response can be reviewed expedited (unless there are additional changes not requested by the IRB that require full board review).	Initials, amendments
Tabled	The full board review of the study noted issues that reflect that the study does not meet criteria for approval. Response to stipulations needed and the response requires full board review.	Initials, amendments
Approved Concept in Principle	A “just in time” grant has been reviewed by the IRB and the project has been determined to be approvable. Research cannot be done; this is for funding only.	Initials

Submission Determinations

Submission determinations reflect that the IRB review is complete. It may be a protocol level status or a submission level status. For stage submissions this is the “current status” noted in the system. These are similar to the legacy HSERA approval statuses. They represent final decisions on a submission such as an approval or acknowledgement.

The below table details the protocol statuses, what they represent, and what submissions they may apply to:

Overall Statuses	Represents:	Applies to
Approved	Study / submission is Approved Penn is the IRB of Record.	Initials, Amendments, CRs

	Reliance Agreement is Approved	
Approved-Relying	Penn has agreed to rely on another IRB and the central IRB approval and (if applicable) stamped ICF has been provided.	Initial Reliance Agreements
	Any amendment that is informational and does not require approval.	
Acknowledged	Deviations and reportable events are acknowledged when they have not received full convened review.	Amendments, Deviations, REs
Accepted	Deviation or RE reviewed by convened board	Deviations and REs
Conditional Reapproval	The most recent continuing review noted issues that require responses. <i>A response via amendment is required.</i> Study is approved but enrollment is held.	Continuing Reviews
Not Human Research	Project does not involve human participants; Represents further IRB Review is not required	Initials
Quality Improvement	Project is QI and does not meet the definition of human research; Represents further IRB Review is not required	Initials
Not Engaged	Penn team is not engaged in research	Initials
Prescreening Complete	Approval of legacy PRIME grant submissions	Continuing Reviews
Withdrawn / Amendment Withdrawn	Study team decided they are not moving forward with a protocol or a submission.	Any
Completed	Study is closed with the IRB – either the team submitted a closure, or the study was administratively closed by the IRB, or the study was automatically closed by the system due to failure to submit an annual check-in.	Closures
Suspended	IRB Approval has lapsed but there is a pending continuing review in process.	Continuing Reviews
Disapproved	The board determined the study did not meet criteria for approval and doesn't believe it can be revised in a way to meet the criteria.	Initials, Amendments
	Archiving happens automatically 6 years after closure or study expiration. It can also happen manually.	
Archived	Archiving deletes study documents and detailed protocol history. Only a shell record with minimal information is retained.	Protocol as a whole