
Yale University Human Research Protection Program Guidance

Guidance: 100 GD 10 Documentation of IRB Submission, Review and Approval

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Overview and Access.....	1
Submission of Documents to the IRB for Review:.....	1
Documentation of IRB Review, Approval and Acknowledgement:.....	1
References	2

Overview and Access

Yale University uses the Coeus™ IRB module as its system for tracking the creation, review, approval and acknowledgement of submissions and actions related to human research protocols. The system tracks and monitors submissions to the IRB from Yale’s research faculty and affiliated research investigators as well as the review and approval determinations made by IRBs designated by Yale.

The system includes role based security whereby individuals are assigned access based on their unique role in the conduct or oversight of human research. Unique system identification codes and passwords are assigned by Yale Information Technology Client Accounts to each user once their access has been approved by the Human Research Protection Program (HRPP) Director or designee.

Investigators are assigned Aggregator roles which permit the creation of IRB protocols and related submissions, such as responses to the IRB for requests for revisions, requests for continuing review (renewal of IRB approval), amendments and other submissions informing the IRB of events related to the protocol, e.g., deviations or unanticipated problems and data and safety monitoring reports.

Business managers or others may be assigned “view only” user access which would allow the user to review protocol activities within his/her department, section or specific performing organization, such as, but not limited to Yale New Haven Hospital, the Yale Cancer Center, the Magnetic Resonance Center at TAC or the PET Imaging Center.

Complex routing maps are created by the HRPP Director and/or designee in conjunction with appropriate University authorities, who share the obligation to protect Yale’s research volunteers. These maps identify the specific approvals that must be obtained prior to the protocol submission being received by the IRB. These routing maps are determined by specific business rules within the University’s schools and colleges and/or HRPP policies. Therefore, individuals authorized to approve these submissions in routing are also assigned specific roles permitting them to fulfill their obligation.

Finally, IRB Chairs, staff and designated members are assigned unique administrator roles. These roles are the only roles capable of approving a protocol, renewal or amendment, requiring revisions of the investigator, deferring an action or acknowledging other submissions.

Submission of Documents to the IRB for Review:

All principal investigators (PI) and members of research teams can submit an initial protocol or related submission to the IRB. Submissions can be performed either electronically if user access has been granted or via paper. PIs are required to approve the electronic submission in routing or sign a paper copy to indicate that they are knowledgeable of the submission and have the skills, experience and resources required to conduct the research.

Documentation of IRB Review, Approval and Acknowledgement:

Submissions to the IRB are automatically assigned a date stamp upon data entry. The identity of the user creating and submitting the document is also recorded.

The submission is reviewed by an IRB staff member assigned to triage the submission to ensure completeness of the submission. The identification of the triager and the date the submission received this review is automatically captured within the system.

Upon review, submissions found to be lacking or providing insufficient or inaccurate information will be rejected. The reason for and date of the rejection will be identified and communicated back to the research team. Submissions must be corrected and resubmitted by the researcher prior to the IRB scheduling the review of the submission. The date and person performing the resubmission is captured within the system.

Initial protocol submissions also receive an additional review process performed by an experienced IRB Regulatory Analyst. This review is intended to identify and correct submission deficiencies early on so that the submission can be revised and resubmitted by the researcher and then approved by the IRB without requesting further revision. Dates of review and the user performing the review as well as any resubmission dates are captured within the system.

All complete submissions are scheduled, reviewed and approved (unless deemed exempt) within the system in accordance with IRB Review Procedures 100.1 (Full Committee), 100.2 (Expedited Review) and 100 PR 3 (Exemption Determination).

System design and user functionality preclude anyone other than authorized IRB Chairs, staff and members from generating letters from the IRB that indicate approval, a request for revisions, deferral or acknowledgement.

References

Yale University IRB Review Policy 100; IRB Review of Research Protocols

http://www.yale.edu/hrpp/resources/docs/IRBPolicy100IRBReview5_5_10.pdf

Yale University IRB Review Procedure 100 PR1 Review by a Fully Convened IRB

http://www.yale.edu/hrpp/resources/docs/100PR1fullboard5_04_10.pdf

Yale University IRB Review Procedure 100 PR2 Expedited Review

http://www.yale.edu/hrpp/resources/docs/100PR2expeditedreview_000.pdf

Yale University IRB Review Procedure 100 PR3 Exemption Determinations

<http://www.yale.edu/hrpp/resources/docs/100PR3exemption.pdf>

Yale University Coeus eIRB Information

<http://www.yale.edu/coeus/>

The official version of this information will only be maintained in an on-line web format. Any and all printed copies of this material are dated as of the print date. Please make certain to review the material on-line prior to placing reliance on a dated printed version.