Yale *Human Research Protection Program*

HRPP News Forum

April 14, 2026

Yale *Human Research Protection Program*

Purpose

- Quarterly updates and overview of operations of the HRPP and Yale IRB;
- Opportunity to ask questions or offer feedback and suggestions;

Topics

Agenda		
1.	Approval numbers – 1st Quarter	Slide# 4
2.	Career Opportunities within the HRPP	Slide # 7
3.	New Documents: Continuing Review Guide and Progress Report	Slide #9
4.	Human Subjects Protection and GCP Training Updates	Slide #12
5.	IRES IRB Upgrade - Update	Slide# 13
6.	Frequently Asked Information: RNIs and Deviations	Slide# 14
7.	Question from Audience: Sharing Data/Specimens for Research Purposes	Slide #17

Yale IRB Approvals: 1st Quarter in 2026

Type of Submission	Expedited	Full Board	Exempt	Not Human Subjects
Initial Study *(447)*	81	34	262	70
Site Review* *(16)*	16	0	N/A	N/A
Continuing Review *(271)*	199	72	N/A	N/A
Modification *(914)*	854	60	N/A	N/A
Personnel Change *(667)*	667	0	N/A	N/A
Modification to Site* *(31)*	31	0	N/A	N/A
Continuing Review and Modification *(49)*	25	24	N/A	N/A
Grand Total *(2093)*				

Yale *Human Research Protection Program*

* *Yale IRB serves as the IRB of Record for another site*

External IRBs: 1st Quarter of 2026

Topic	Information
Number of Studies Authorized for Reliance	104
Number of Unique IRBs	19
Types of IRBs	Commercial – 6 Academic/Non-Profit – 13
IRBs with Highest Numbers	Advarra – 47% WCG – 29% NCI CIRB – 5%

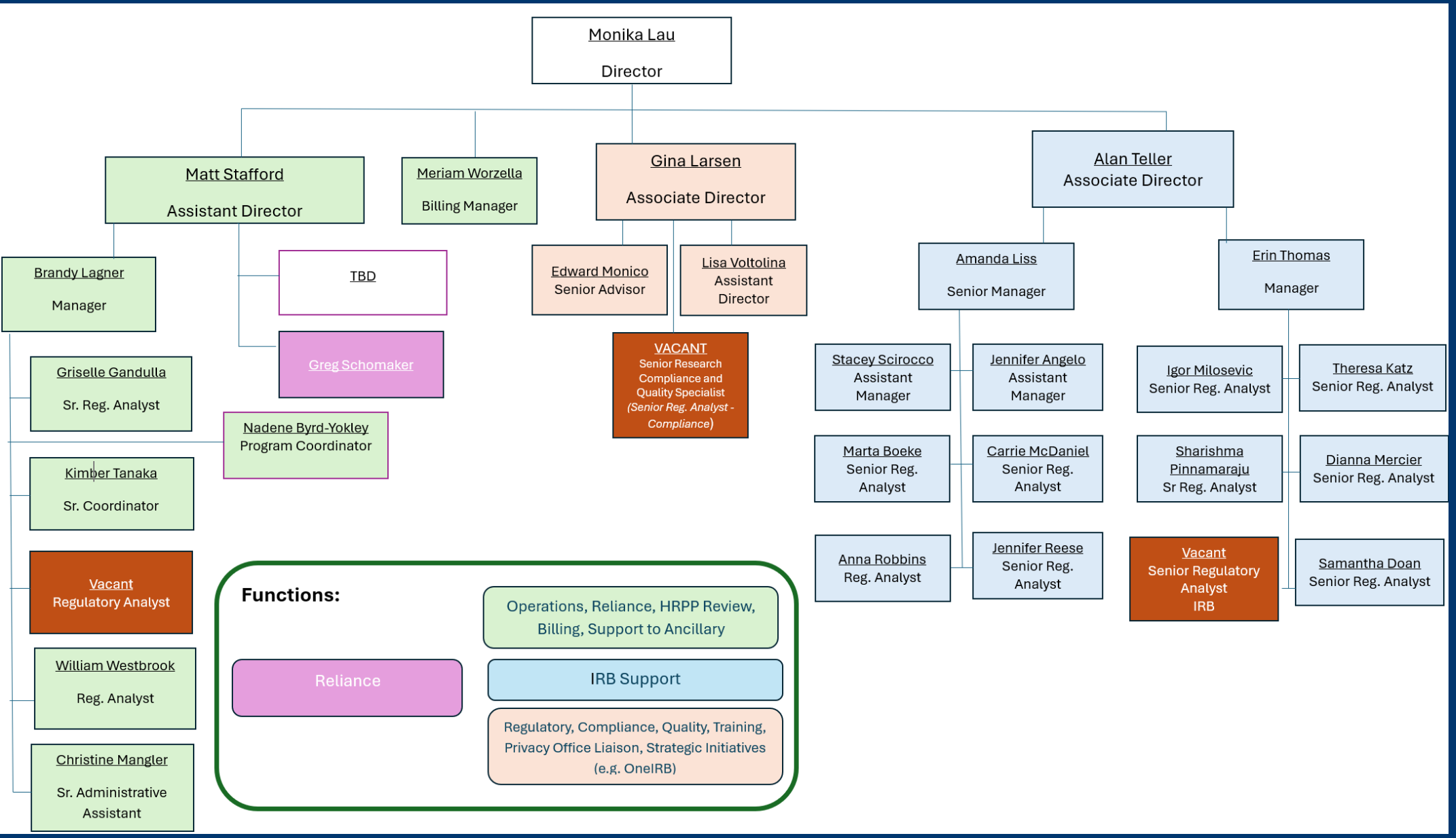
** For comparison, in 2025 HRPP authorized 333*

Approval Turn-Around Times: Average in Calendar Days, Initial – 1st Quarter of 2026

	Enter to Approve (Total Approval Time)	Submission to Acceptance (Pre-Review State)	Time on PI Side in Pre-Review	Acceptance of Submission to Approve (IRB Review State)	PI Side During IRB Review	Total PI Side	% of PI Time	Total HRPP/IRB Side
Full Board	107 (*Median: 78*)	20	18	87	47*	65	61%	42
Expedited	58 (*Median: 44*)	16	14	42	23	37	64%	21
Exemption	24 (*Median: 13*)	12	10	12	7	17	71%	7
NHSR	12 (*Median: 1*)	9	7	3	2	9	75%	3

** Includes 4 studies in deferral state of average of 48 days*

Career Opportunities at the HRPP



Post-Retirements Organizational Chart

New Positions: Focus

Regulatory Analyst Human Research Protection Program (Requisition #134063WD)	Senior Research Compliance and Quality Specialist – HRPP Compliance (#134059WD)	Senior Regulatory Analyst – Yale IRB (134064WD)
Functional Team: Operations and HRPP Review	Functional Team: Regulatory, Compliance, Quality, & Education	Functional Team: IRB
Main focus: Reviewing incoming submissions for compliance with institutional requirements; assigning the appropriate level of review; coordinating reviews with applicable ancillary committees	Main focus: Conducting audits of studies under HRPP purview; investigating compliance matters; performing quality assurance activities; advising on CAPAs	Main focus: Facilitating IRB review of submissions requiring convened board review; attending committee meetings, participating in discussion, and preparing meeting minutes and other correspondence that reflect the committee's determinations; conducting IRB review of studies via expedited review procedures
Expectations for all positions: apply applicable ethical principles, standards, regulations, guidelines, and policies to the review of research studies; advise and assist research teams with questions related to regulations, policies and guidance; participate in educational initiatives; participate in departmental projects,		

New Documents

- Data shows that IRB frequently asks for clarifications and modifications on submissions of continuing reviews related to information that could have been provided at the time of submission

- Result: Continuing Review Progress Report form and Quick Guide on Submitting Continuing Reviews

- Effective Date: Submissions of continuing reviews on or after May 1, 2026

Progress Report

Elements of progress report:

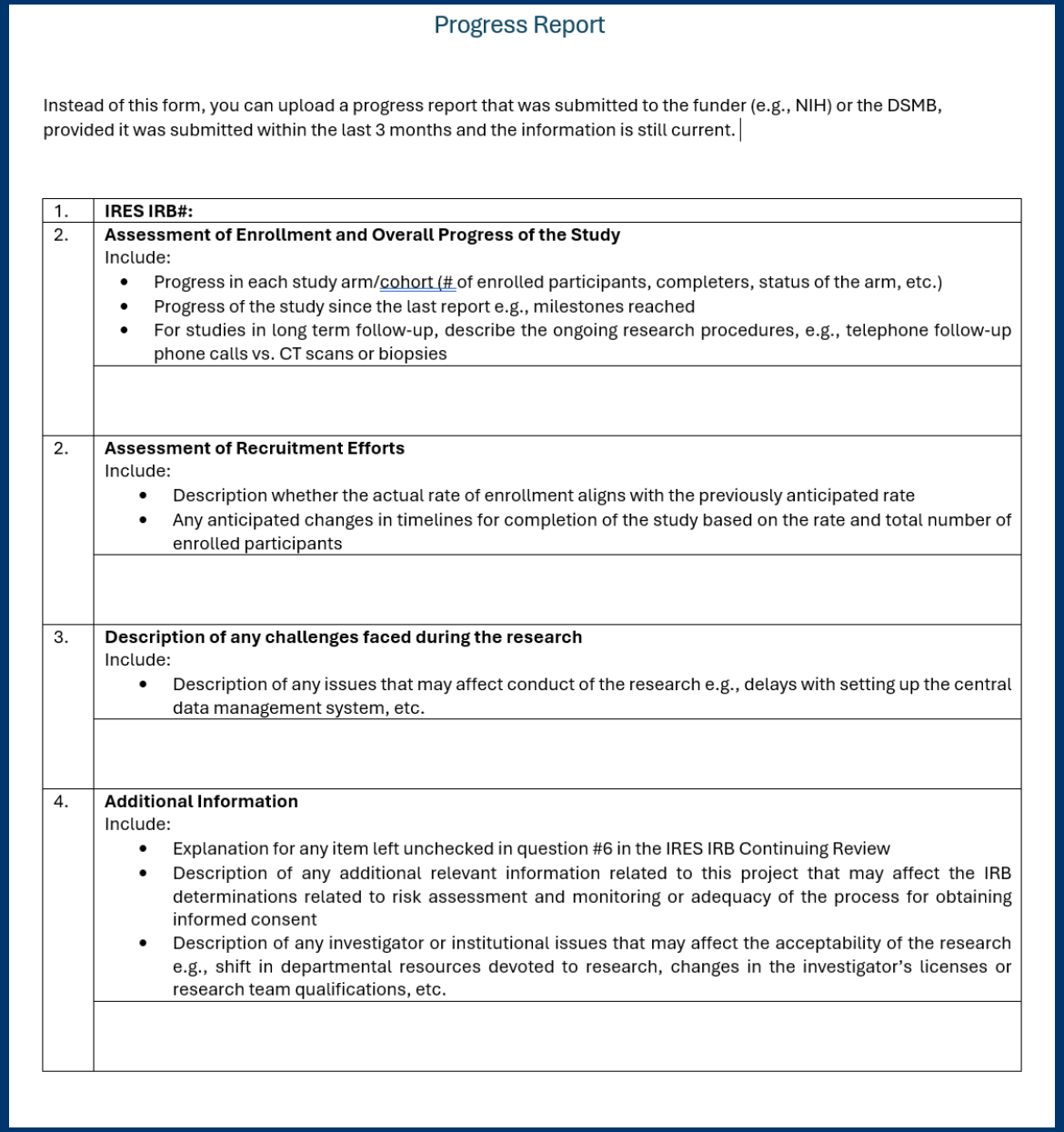
- The assessment of the recruitment efforts and whether enrollment is progressing as planned;
- Description of the progress in each study arm (including number of subjects enrolled);
- Any anticipated changes in timeline for completing data collection and analysis;
- Confirmation that informed consent procedures are being followed appropriately;
- Description of any challenges faced during the conduct of the study.

Progress Report Format

- Progress Report template is available in **IRES IRB Library/ Other Forms**

- If you have a progress report that had to be submitted for other purposes within the last 3 months (e.g., federal funder or DSMB), you can use it in lieu of the Yale template

- Effective date: CRs submitted on or after May 1, 2026



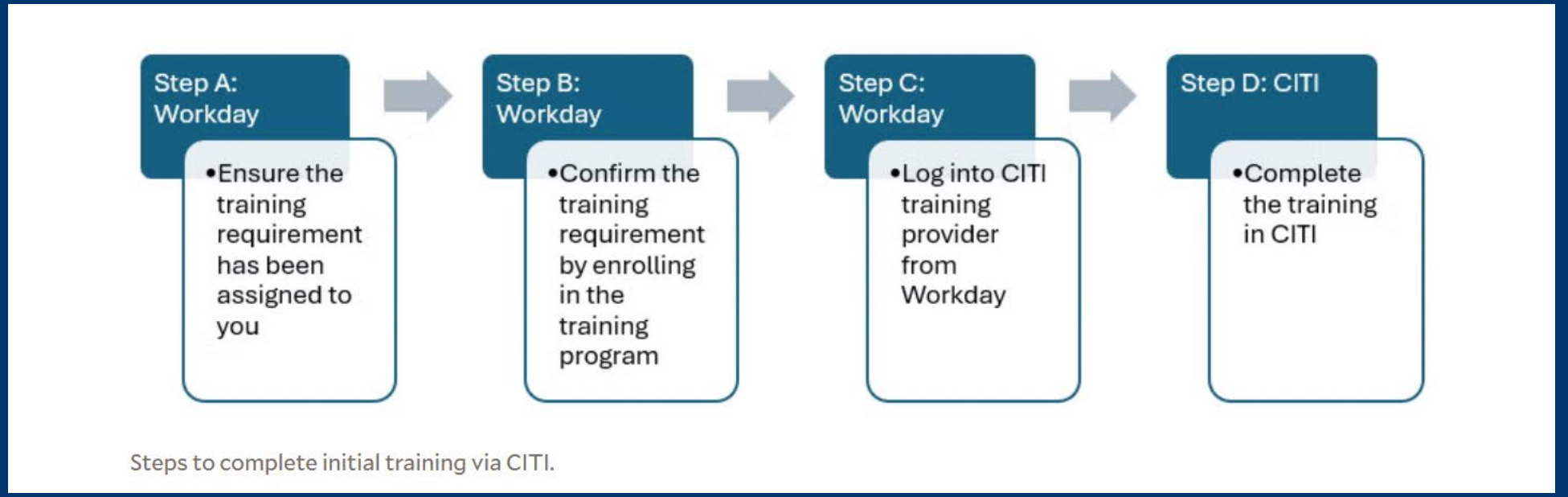
Progress Report

Instead of this form, you can upload a progress report that was submitted to the funder (e.g., NIH) or the DSMB, provided it was submitted within the last 3 months and the information is still current.

1.	**IRES IRB#:**
2.	**Assessment of Enrollment and Overall Progress of the Study** Include: • Progress in each study arm/cohort (# of enrolled participants, completers, status of the arm, etc.) • Progress of the study since the last report e.g., milestones reached • For studies in long term follow-up, describe the ongoing research procedures, e.g., telephone follow-up phone calls vs. CT scans or biopsies
2.	**Assessment of Recruitment Efforts** Include: • Description whether the actual rate of enrollment aligns with the previously anticipated rate • Any anticipated changes in timelines for completion of the study based on the rate and total number of enrolled participants
3.	**Description of any challenges faced during the research** Include: • Description of any issues that may affect conduct of the research e.g., delays with setting up the central data management system, etc.
4.	**Additional Information** Include: • Explanation for any item left unchecked in question #6 in the IRES IRB Continuing Review • Description of any additional relevant information related to this project that may affect the IRB determinations related to risk assessment and monitoring or adequacy of the process for obtaining informed consent • Description of any investigator or institutional issues that may affect the acceptability of the research e.g., shift in departmental resources devoted to research, changes in the investigator's licenses or research team qualifications, etc.

Training and Workday and IRES IRB Integration

- Issues with CITI-Workday-IRES IRB integration continue



Steps to complete initial training via CITI.

- Direct links to CITI training are now available for initial and refresher Human Subjects Protection courses, and Good Clinical Practice training: check HRPP website (*listed in description for Step D*)

IRES IRB Testing

- Testing of upgrade to IRES IRB is in progress
- No major impact for users
- Change: Once upgrade is in place, submitters of RNIs will be able to assign multiple additional users who can edit the RNI submission and respond to the IRB clarifications (*currently, the only the person who can respond to clarifications on RNI is the person who created and submitted it*)

Frequent Information Requests: RNIs and Planned Deviations

- Report of New Information (RNI) is a mechanism to report events that meet REPORTABLE CRITERIA to the IRB:

  - Unanticipated problems that resulted in harm or that indicate an increase in risk to participants or others e.g., serious and unanticipated adverse events that are or could be related to the participation in the study e.g., a new unexpected risk of the drug that resulted in prolonged hospitalization;
  - Incidents of noncompliance or deviations that resulted in negative impact on participants or their rights and welfare or imposed harm; e.g., administering a wrong dose of a study drug, not stopping the study when stopping criteria were met, enrolling a participant did not meet safety related eligibility criteria;
  - Decision of the DSMB to suspend the study;
  - Breach of confidentiality that has a likelihood of compromising security of data e.g., stolen laptop with identifiable research data;

Planned vs. Unplanned Deviations*

	Unplanned/unintentional violation/deviation	Planned Deviation/Protocol exception *If you know it in advance and have time to plan it, it's not a deviation yet—it's a protocol change or exception, and the IRB should review it first.*
Description	An unintentional change from the approved protocol for a specific participant	A prospective/planned change from an approved protocol for a specific participant
Example	Out-of-window visit because participant misses the visit and shows up late or participant illness prevents timely attendance; missed collection of lab data	Eligibility exception – enrolling participant who does not meet all of the inclusion criteria, planning to reduce or increase a study drug dose outside the protocol for a participant, allowing a participant to come 15 days late due to travel or allow for flexibility due to scheduling constraints
Requirements for IRB reporting	Significant protocol deviations that affect subject safety, or their rights and welfare, or data integrity must be reported to the IRB via a Report of New Information (RNI). Deviations that do not meet these criteria, do not need to be reported.	Requires sponsor and IRB approval prior to implementation, Yale IRB has a specific form for single subject exception request. The request must be submitted for approval via a modification.
Additional info	If the IRB makes a determination that the deviation is considered a serious or continuing noncompliance or an unanticipated problem, the determination may need to be reported to the applicable regulatory agency e.g., OHRP or FDA.	The IRB can require a modification to the protocol if the request affects multiple participants.

**This discussion does not apply to changes necessary to eliminate apparent immediate hazards to human subjects.*

Information Requests: Sharing Specimens and Data From Individual Studies

Specimens and data obtained from human subjects can be shared with others for research purposes if:

- Sharing of identifiable specimens/data is allowed in the consent form*; *OR*
- Sharing is not prohibited by the consent form AND data/specimens are deidentified OR the IRB issued a waiver of consent/HIPAA, and Data Use Agreement is in place;

**Addressing sharing is a required element of consent form for studies subject to current Common Rule – regulations for federally funded research*

Sharing Specimens and Data Resources

Yale Privacy Office Resource: https://privacy.yale.edu/resources/sharing-data *(addresses contractual requirements)*

Guide: Sharing Data for Research Purposes (*also addresses sharing data obtained from medical records*)

Consent Glossary: section *Secondary Research with Data and Biospecimens (currently #39)*

Resources

Human Research Protection Program

- https://your.yale.edu/research-support/human-research-protection-program/yale-new-haven-health-system-ynhhs-research

Email Subscription

- https://subscribe.yale.edu/

**HRPP Newsletter is available in Research Administration category*

Questions for next HRPP News Forum (July, 2026)

- https://yalesurvey.ca1.qualtrics.com/jfe/form/SV_8eozZatbGncF3sG

Questions?

Questions? Contact HRPP@yale.edu or monika.lau@yale.edu
Yale HRPP Website

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