# Report on Operations Quarterly Report

## Harvard University Area IRB Advisory Committee

## Quarterly Meeting: July to September 2025 (Quarter 1)

## 11 September 2025

# Mission

The Harvard University Area (HUA) IRB aims to promote a culture of compliance and to establish across the University the highest expectations for performance and oversight of research involving human subjects. The IRB is committed to the education of the Harvard research community and outreach to collaborating institutions.

The mission of the IRB is to ensure that all participants are protected from any unnecessary risk when enrolled in a research study, that they can make an informed decision to participate, and, when possible, that participants and/or society at large benefit from the knowledge gained from the research study. The goal of the IRB is to assist investigators in developing appropriate research protocols in accordance with federal and University policies, and within accepted ethical guidelines.

***The IRB is guided by the ethical principles of respect for persons, beneficence, and justice.***

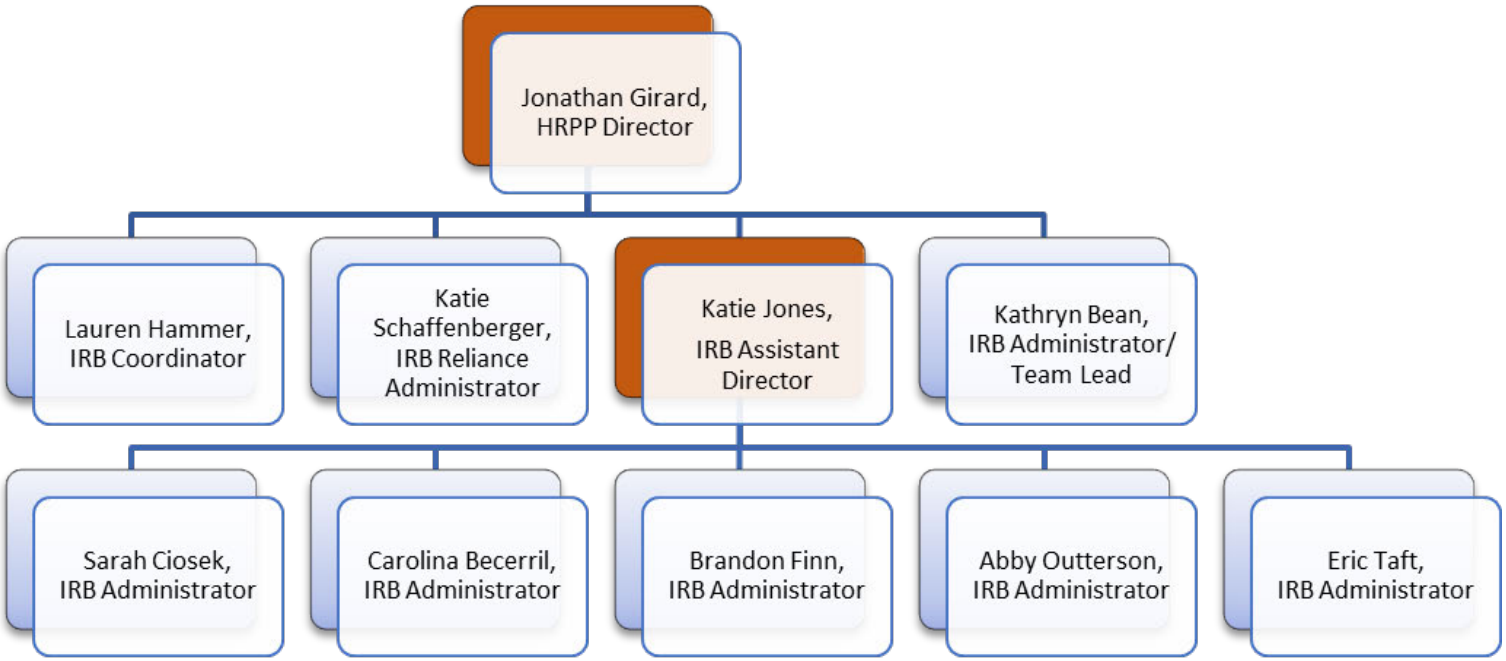
# Ethical Principles

All Human Subjects Research conducted by Harvard University investigators, regardless of source of funding or location of the research, is guided by the ethical principles set forth in the April 18, 1979, report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, also known as "The Belmont Report"—**respect for persons, beneficence, and justice.**

# Who We Are

## *The IRB*

The Harvard University Area includes the Faculty of Arts and Sciences, Harvard Graduate School of Education, Harvard Kennedy School, Harvard Divinity School, Harvard Business School, Harvard Law School, Harvard Graduate School of Design, the Harvard School of Engineering and Applied Sciences, Harvard University Health Services, and the Radcliffe Institute for Advanced Study. The IRB of record for the Harvard University Area is referred to as the Committee on the Use of Human Subjects (CUHS).




## *The IRB Office*

The HUA IRB administrative office is responsible for managing the day-to-day operations and support of the IRB. The HUA IRB office staff perform a variety of functions in addition to supporting the IRB such as providing IRB determinations, reviewing studies on behalf of the IRB, assisting researchers with IRB related questions, and providing training and outreach.

# Measure of Efficiency

## *Metrics Summary*

Table 1 and Graph 1 represent staff review time (in calendar days) for those submissions (according to review type) completed by the IRB staff in the last 12 months, as compared to the overall review time (i.e., total time including the days with investigators). Table 2 and Graph 2 may be used to make a comparison with the preceding 12 months.

Please note that, while the IRB provides many types of reviews and determinations, only the most common are included here.

The review time for a submission is calculated as the time that a submission enters our e-submission system, ESTR (Electronic Submission, Tracking, and Reporting), until the time that a determination is made. Any study's time-to-completion may be affected by the time taken by the IRB, or the time taken by the study staff, by the type of review (e.g., convened IRB review takes longer as there is only one meeting per month), or by the difficulty of the submission (e.g., a modification that involves substantial changes to an IRB submission versus a modification to add a study team member).

**Please see next page →**

**Table 1**

| IRB Staff Review Time versus Total Review Time Current 12 Month Period | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Sep-24 | | Oct-24 | | Nov-24 | | Dec-24 | | Jan-25 | | Feb-25 | | Mar-25 | | Apr-25 | | May-25 | | Jun-25 | | Jul-25 | | Aug-25 | |
| | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total |
| Expedited | 22 | 51 | 21 | 54 | 21 | 62 | 25 | 72 | 19 | 47 | 24 | 55 | 15 | 48 | 13 | 40 | 12 | 40 | 14 | 39 | 11 | 28 | 3 | 3 |
| Exempt | 11 | 23 | 12 | 38 | 14 | 50 | 14 | 31 | 12 | 33 | 12 | 30 | 9 | 28 | 11 | 35 | 11 | 32 | 11 | 28 | 5 | 12 | 2 | 4 |
| NHSR | 13 | 30 | 8 | 13 | 4 | 35 | 4 | 14 | 6 | 22 | 7 | 20 | 8 | 20 | 4 | 14 | 9 | 23 | 6 | 15 | 4 | 9 | 3 | 5 |
| Expedited Modification | 4 | 8 | 4 | 13 | 3 | 10 | 3 | 7 | 4 | 8 | 3 | 6 | 5 | 16 | 4 | 13 | 4 | 9 | 2 | 4 | 2 | 6 | 1 | 4 |

**Graph 1**

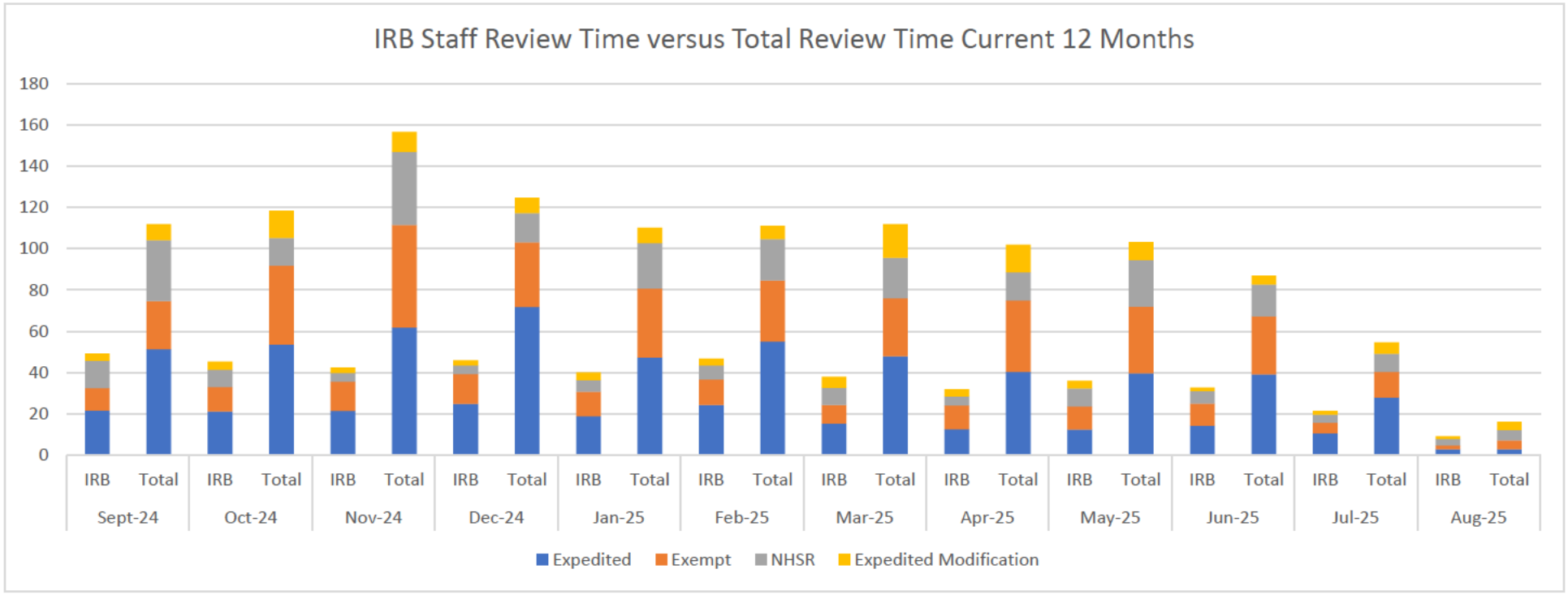


**Table 2**

| IRB Staff Review Time versus Total Review Previous 12 Months | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Sep-23 | | Oct-23 | | Nov-23 | | Dec-23 | | Jan-24 | | Feb-24 | | Mar-24 | | Apr-24 | | May-24 | | Jun-24 | | Jul-24 | | Aug-24 | |
| | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total | IRB | Total |
| Expedited | 13 | 50 | 15 | 60 | 26 | 69 | 31 | 73 | 24 | 49 | 23 | 63 | 20 | 75 | 33 | 59 | 23 | 41 | 11 | 33 | 27 | 59 | 26 | 64 |
| Exempt | 7 | 25 | 7 | 33 | 9 | 26 | 12 | 34 | 10 | 25 | 13 | 28 | 13 | 39 | 13 | 34 | 15 | 27 | 20 | 40 | 17 | 30 | 15 | 33 |
| NHSR | 4 | 8 | 6 | 13 | 6 | 19 | 8 | 19 | 7 | 18 | 8 | 14 | 8 | 18 | 10 | 22 | 9 | 18 | 6 | 12 | 11 | 24 | 4 | 10 |
| Expedited Modification | 3 | 7 | 4 | 11 | 3 | 7 | 6 | 15 | 3 | 7 | 5 | 10 | 6 | 11 | 5 | 9 | 5 | 9 | 5 | 9 | 5 | 11 | 3 | 10 |

**Graph 2**

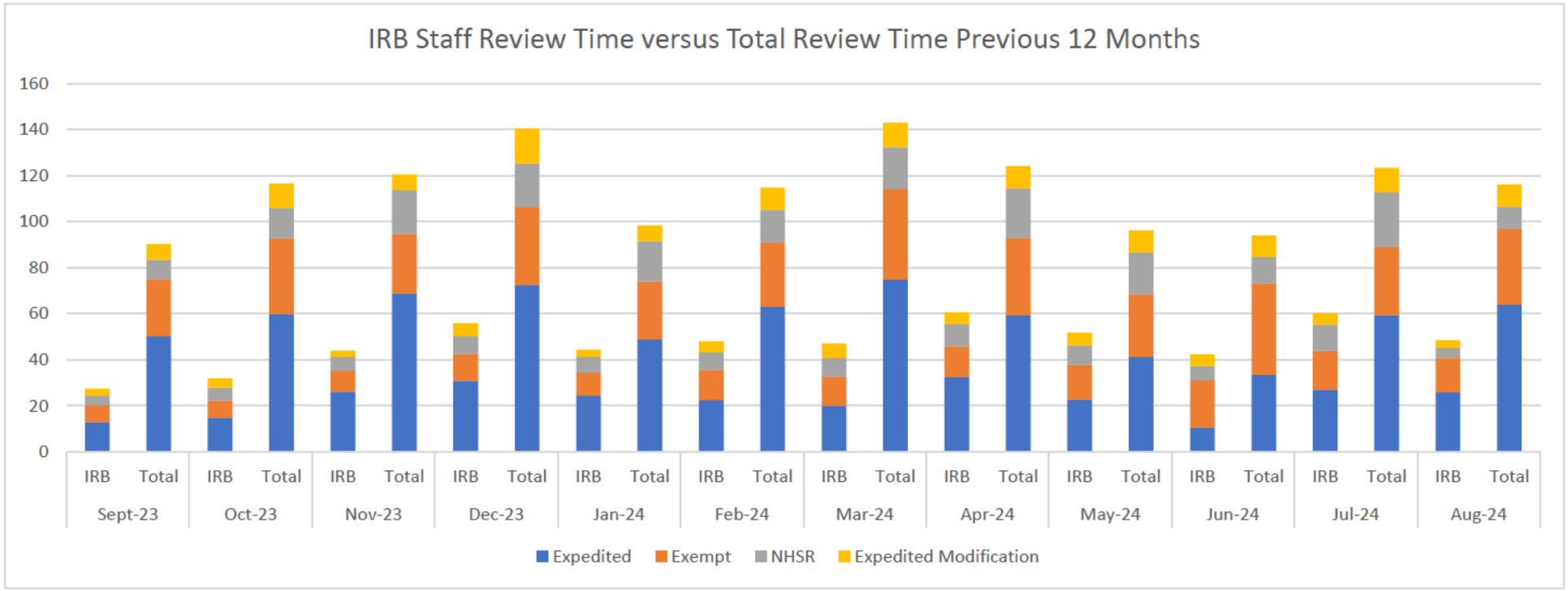


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for Calendar Years 2022 through 2025. These submissions include initial submissions and follow-on submissions. Initial submissions are all new studies that receive an approval or determination (e.g., Convened IRB, Expedited, Exempt, Not Research, etc.). Follow-on submissions "follow" the initial submission and include modifications, continuing reviews, and reports of new information (RNIs).

**Table 3**

| Total Incoming Submission Volume | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sep** | **Oct** | **Nov** | **Dec** |
| **2022** | 144 | 181 | 198 | 195 | 212 | 249 | 199 | 185 | 204 | 167 | 152 | 97 |
| **2023** | 165 | 168 | 147 | 148 | 212 | 243 | 183 | 218 | 214 | 177 | 192 | 141 |
| **2024** | 179 | 178 | 189 | 204 | 227 | 235 | 213 | 173 | 192 | 167 | 190 | 126 |
| **2025** | 146 | 167 | 153 | 153 | 177 | 231 | 171 | 172 | | | | |

**Graph 3**

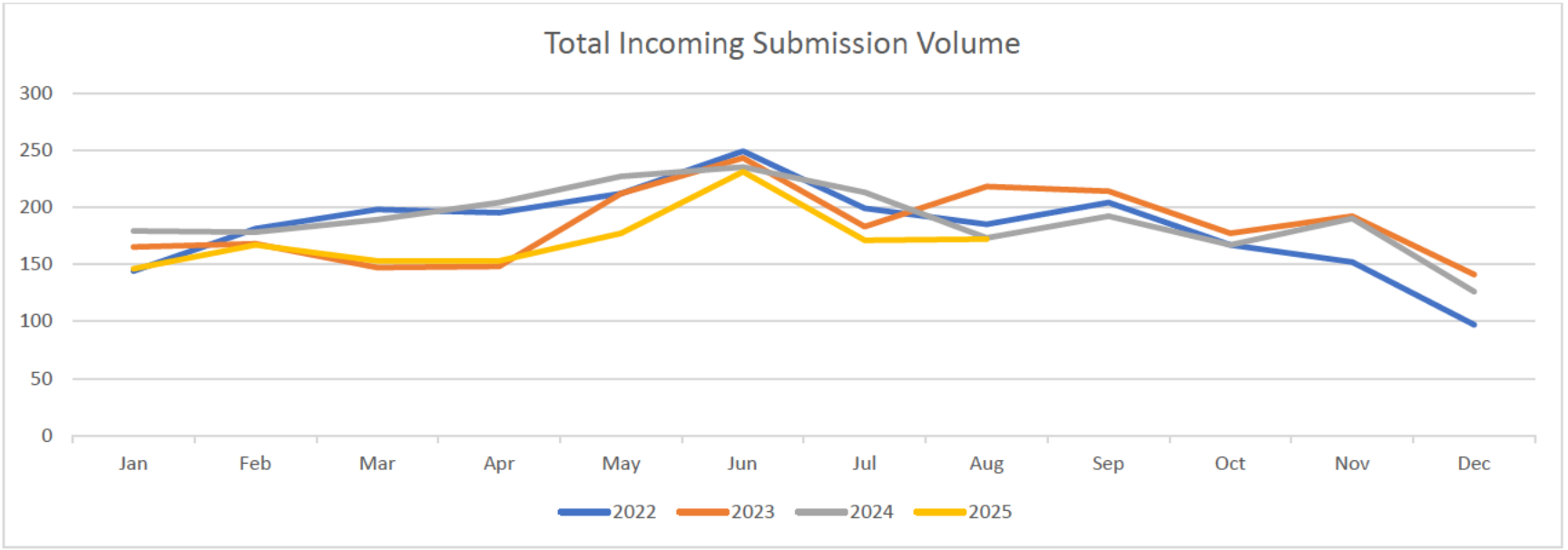


Table 4 represents the IRB's completion rate for the last 12 months. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in January 2025, the IRB office received a total of 73 initial submissions. Of those 73 submissions, 27 received a determination or approval by the month's end while 46 submissions were at some point in the review process[1].

**Please see next page →**

[1] *Clarifications requested (the submission has received review and has been sent to the research team); Pre-review (the submission has either not started review or is back from the research team and is now under review by IRB staff); or Modifications required (the submission has been sent to the research team and is in a state where there are outstanding items that are needed such as a reliance agreement or data security review)*

| Complete vs. in-Review (for initial submissions only) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *Sep-24* | *Oct-24* | *Nov-24* | *Dec-24* | *Jan-25* | *Feb-25* | *Mar-25* | *Apr-25* | *May-25* | *Jun-25* | *Jul-25* | *Aug-25* |
| **Initial Study Total Received** | **71** | **94** | **98** | **66** | **73** | **90** | **81** | **93** | **86** | **91** | **75** | **69** |
| Approved Full | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Approved Expedited | 2 | 3 | 1 | 4 | 5 | 4 | 1 | 5 | 3 | 3 | 1 | 1 |
| Approved Exempt | 13 | 15 | 6 | 8 | 14 | 13 | 17 | 16 | 10 | 7 | 15 | 18 |
| Not Human Research | 7 | 9 | 11 | 10 | 7 | 12 | 5 | 12 | 12 | 13 | 11 | 6 |
| Human Research, Not Engaged | 0 | 2 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 |
| Disapproved | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **Review Complete** | **22** | **29** | **19** | **23** | **27** | **29** | **23** | **33** | **26** | **23** | **27** | **25** |
| Clarification Requested (Pre-Review & Designated Review) | 35 | 44 | 47 | 30 | 30 | 38 | 31 | 47 | 42 | 40 | 38 | 25 |
| Modifications Required | 0 | 1 | 0 | 0 | 0 | 1 | 2 | 2 | 2 | 2 | 3 | 1 |
| Pre-Review | 14 | 20 | 32 | 13 | 16 | 22 | 25 | 11 | 16 | 26 | 7 | 18 |
| **In-Review** | **49** | **65** | **79** | **43** | **46** | **61** | **58** | **60** | **60** | **68** | **48** | **44** |
| **Percent Complete per Month** | **31%** | **31%** | **19%** | **35%** | **37%** | **32%** | **28%** | **35%** | **30%** | **25%** | **36%** | **36%** |

# Measures of Quality and Compliance – Quarter 1

As outlined in HRP – 060 – HUA – Evaluations of the HRPP, we use the following processes monthly to measure compliance of the HRPP. These outcomes are reported to the Advisory Committee at our quarterly meetings, and an overall assessment including these and other required assessments takes place at the end of each calendar year.

## Investigator QI Assessment

- *A randomly selected Investigator is sent a checklist to complete and return to the HUA IRB within a specified timeframe.*
- *The checklist that was sent out the previous month has the results tracked and examined for significant trends.*

| Month | PI Name | ESTR # | Study Title | Department/School | CY Quarterly Check-In Date |
|---|---|---|---|---|---|
| ***June 2025*** | [redacted] | [redacted] | [redacted] | *HGSE* | *7/15/2025* |
| ***July 2025*** | [redacted] | [redacted] | [redacted] | *HGSE* | *10/7/2025* |
| ***August 2025*** | [redacted] | [redacted] | [redacted] | *HKS* | *10/7/2025* |

## Conduct assessment of minutes with regulatory compliance

- *The minutes from the previous month are analyzed to ensure regulatory compliance as well as the days required to complete the minutes.*
- *Significant trends in adherence to the regulations and days to complete the minutes are tracked and examined.*

| Meeting Date | Minutes to Chair & Director within 7 calendar days? | General Minutes Requirements Notes | CY Quarterly Check-In Date |
|---|---|---|---|
| ***June 2025*** | *Yes* | *Items at the June 2025 meeting were Tabled, which prompted questions about documentation tools, including the Minutes Assessment; the Assessment was revised in several items to clarify that Tabled is an option, ensuring that selection can be properly documented in the Assessment; selecting Tabled in ESTR* | *7/15/2025* |

| | | | |
|---|---|---|---|
| | | *is not an option (not part of the Huron package) and workarounds must be used (either using Deferred or returning the submission to Non-Committee review) depending on the circumstances* | |
| ***July 2025*** | *Yes* | *No issues identified* | *10/7/2025* |
| ***August 2025*** | *Yes* | *Names of absent members not listed in the Vote section for submission under review as established in institutional practice; absent members did not prompt any substitutions or impact quorum, and the Vote section noted the number of absences as required* | *10/7/2025* |

# Training, Outreach, and Other Initiatives - Quarter 1

### HUA IRB Website

Our website continues to be a good resource for the research community. For the period from **6/1/2025** through **8/31/2025**, our website had about **6,400** visitors with **14,500** page views. The most visited pages include:

- Required Ethics Training Overview
- Do You Need IRB Review and Why? (IRB Lifecycle)
- So, How Do You Submit An IRB Proposal? (IRB Lifecycle)

### IRB Outreach & Training

For the period from **6/1/2025** through **8/31/2025**, the HUA IRB office held the following outreach and training sessions:

- 67 IRB office hour sessions (general meetings)

The above reflects investigator meetings scheduled through the Bookings system. IRB staff often meet with researchers outside these office hours as well depending on urgency and researcher availability.

## IRB Newsletter

The July edition of our newsletter included:

- Data Use Agreements
    - Local Context
    - IRB Review
    - Exempt Human Research
    - Human Subjects Research Training Guide for International Enumerators
    - Provostial Review
    - Planning Ahead
- Biological Material Import/Transport

The August edition of our newsletter included:

- Data Use Agreements
- OVPR Bulk Data Guidance
- Library Support for Qualitative Research

The September edition of our newsletter included:

- Welcome Back!
- IRB Lifecycle Guide – Your Lifeline for All Things IRB
- Funding and ESTR
- Do you speak IRB? PI Eligibility and Assurance

Previous newsletters may be found in the IRB Newsletter Archive.

## IRB Member Continuing Education

To keep IRB members apprised of regulatory changes, institutional practice, and common regulatory concerns, a portion of each IRB meeting is devoted to a continuing education topic. During the last quarter, the IRB received training on key topics related to items under review:

- Reports of New Information--Key Definitions: The IRB discussed our institution's definitions for serious noncompliance, continuing noncompliance, and unanticipated problems involving risks to subjects or others (UPIRTSOs) before reviewing a few Reports of New Information describing potential noncompliance.
- Expedited Categories: The IRB received an overview of the Expedited review process as outlined in the Common Rule, how our institution approaches Expedited review at the Committee and Non-Committee level, what procedures are captured in each Expedited category, and

how to approach minimal risk research with procedures that do not fall into our commonly applied Expedited categories (directly relevant to a review at the August 2025 meeting).

### IRB Staff Continuing Education

As regulations change over time, it is important to not only cover regulatory items on a regular basis but also to check in to ensure that everyone is on the same page in their approach. As part of our weekly staff meeting, a regulatory/continuing education topic is covered, often through the discussion of studies currently in review. Recent topics included discussing two webinars (AI case studies and reviewing Exempt level research) presented by our colleagues in PRIM&R, reviewing repository protocols, reviewing umbrella protocols, local ethics review in international research, public vs. private setting observations, and writing IRB meeting minutes/Convened IRB requests to researchers.

### Research Participant Community Outreach

***HUA IRB Website***

The HUA IRB offers materials for the research participant community, including a Participants Bill of Rights. For the period from **6/1/2025** through **8/31/2025**, our "For Participants" website had about **154** visitors with **203** page views.

***Other Initiatives***

See Updates section below.

# Updates – Quarter 1

### Human Research Protection Program Goal Setting

To start each academic year, the HUA IRB staff and the Advisory Committee set broad goals for the coming year.

*Reflecting on goals from 2024-2025:*

- **Community outreach to share information about the HUA IRB, educate those that wish to take part in research about their rights as research subjects and to empower those that wish to take part.**
  *Those that take part in research are often only aware of their rights as a research subject during the consent process and, as such, those that take part are only marginally aware of their rights as well as the role of an Institutional Review Board. The goal of this effort is to take a*

*proactive approach in educating our local community as well as those communities where Harvard research takes place about research subject rights, afforded protections, and the role of the IRB.*

The HUA IRB maintains a For Participants page on its website that offers resources like a participant's Bill of Rights as well as links to OHRP resources. We maintain a relationship with Harvard Catalyst, which includes access to their Community Engagement Program and Community Coalition for Equity in Research. This summer the HUA IRB identified a new community representative for the IRB who is a fellow with the Community Coalition for Equity in Research and a former Chair of the Human Rights Commission for the city of Medford—an advocate for the community.

The IRB maintains consent form templates for investigators to draw from in the Library of documents in ESTR. Two such templates, the Adult Consent Form and Parent/Guardian Permission Form, include contact information for the IRB in accordance with regulation, which requires contact information for a party other than the research team. In addition to the IRB's contact information, these templates were revised to directly link to the "For Participants" webpage to provide potential subjects with helpful information before agreeing to take part in a study, and preliminary answers to questions for current participants before they reach out to the IRB for help.

IRB staff contacted study staff from participant pools/registries/repositories under IRB oversight to evaluate the possibility of including information about the IRB and participant rights in their pool's participant onboarding process. The purpose of this project was to enhance the IRB's outreach to research participants by ensuring they have direct access to important resources even in advance of seeing or signing a consent form. By incorporating a link to our "For Participants" webpage into the onboarding materials, websites, and/or other participant-facing materials of large repositories and study pools, we aim to reach more participants and potential participants in a more direct way. In June 2025, a list of current repositories was compiled. This list was then reviewed to determine which repositories would be a good fit for the project. Out of the 13 repositories that are currently active in ESTR, 8 were determined to be eligible (i.e., based on the purpose and procedures of the repository). The QA/QI Administrator emailed the study teams for each of these projects, asking if they would be willing to include a link to the "For Participants" page on their website, in their consent form, or in any other onboarding materials. The outcome thus far is as follows:

- 3 study teams have added the "For Participants" link to their websites:
  - https://andl.wjh.harvard.edu/
  - https://learnlab.hsites.harvard.edu/sign-up
  - https://www.harvardlds.org/
- 1 study team has agreed to participate, but has not made any updates to their materials yet
- 1 study team indicated they would forward the request to the new head of their study pool once they were appointed
- 1 study team indicated that their study pool did not seem to be a good fit for the project; we clarified our request and provided some options that may make sense for them, however, no response was received

- 1 study team indicated that they were in the process of combining their participant database with another created by a different PI that was on our original list – this other study team was one of the 2 that added the link to their website
- 1 study team has not responded to the request

Participant outreach is core to our human research protection program and any new developments will continue to be reported quarterly in this report.

- **Expand our Quality Assurance/Quality Improvement Program to develop and monitor measures of effectiveness and compliance for both researchers and internal practices.**
  *The HUA HRPP has several processes in place for measuring the effectiveness and compliance of our program, outlined in our SOPs for Annual Evaluation and QA/QI Program. These include assessments of investigators and IRB meeting minutes, as well as annual activities undertaken by the Advisory Committee each December. While these measures fulfill our basic obligations for AAHRPP accreditation, there is room for more proactive monitoring and richer engagement with the research community and our own processes.*

  During the last year, the IRB has made progress on the following QA/QI activities:

  1. Annual Department Website and Handbook Review: This project was developed this year, initiated this summer, and is ongoing. The purpose of this annual project is to establish a process for ensuring that Harvard department and school websites and handbooks that include information about the IRB and human research provide current content, correct contact information, and active links. IRB staff are creating a log of all Harvard University Area websites that include information about human research. Two test cases have been contacted by IRB staff to advise revisions, and IRB staff provided suggested wording/content that was gladly accepted. IRB staff will contact other departments with websites requiring revision once the log of all sites is complete.
  2. Annual PI Eligibility Policy Update: This project was developed this year and will be implemented for the first time this month. The purpose of this annual project is to establish a process for ensuring that the HUA IRB maintains the most up-to-date, school-specific PI Eligibility policies on file. Having accurate policies on file will allow IRB staff to provide better guidance to investigators and make appropriate determinations regarding PI and Faculty Sponsor Eligibility.
  3. Participant Outreach via Repositories: This project was developed this year, initiated this summer, and is ongoing (see section above). The purpose of this project is to enhance the IRB's outreach to research participants by ensuring they have direct access to important resources. By incorporating a link to our "For Participants" webpage into the onboarding materials, websites, and/or other participant-facing materials of large repositories and study pools, we aim to reach more participants and potential participants in a more direct way.
  4. Semiannual Review of Submissions in Pre-Submission Status: This project was developed this year and will be implemented for the first time later this semester. The purpose of this twice annual project is to identify and review submissions (including Initial submissions, Modifications, Continuing Reviews, and RNIs) that have been in pre-submission status in ESTR for six months or longer. The HUA IRB

Coordinator and QA/QI Administrator will work together to contact study teams and/or IRB Administrators to determine the status of these submissions, and submissions that are either confirmed as inactive or receive no response will be discarded. This semiannual review will reduce the number of abandoned draft submissions in ESTR, leading to a more accurate representation of current research activity.

5. Annual Review of Active (Approved) Submissions: Project development began this year and is ongoing. The purpose of this annual project is to identify and review active studies (marked as Approved in ESTR) that were initially reviewed at the Expedited or Convened IRB level (i.e., nonexempt human research) and for which a Continuing Review is not required. Since the implementation of the Revised Common Rule in 2019, minimal risk research has not required annual Continuing Review unless stipulated by the IRB. Investigators receive annual reminders of their responsibilities, including Study Closure. This project will proactively identify studies eligible for Closure and for which the investigator has not initiated Closure, including studies in which the investigator is no longer affiliated with Harvard (e.g., students).
6. IRB Member Evaluation: Project development began this year and is ongoing. The contribution of IRB members is evaluated each year. Presently, evaluations are brief and note members' meeting attendance (i.e., percentage of meetings attended through the calendar year) as well as the percentage of submissions reviewed by the Convened IRB that they were responsible for presenting. This project intends to improve the IRB member evaluation process, ensuring it is more useful to members and supports the success of the IRB as a whole. A draft evaluation has been created and reflects this; it includes both a self-evaluation and evaluation of the IRB onboarding and meeting process. Members have received the draft evaluation and have begun providing feedback. IRB staff will meet with interested members this semester to learn more about their thoughts on the evaluation. A revised version will be implemented at the end of the next academic year.

*Setting Goals for 2025-2026:*

- **Expand our Quality Assurance/Quality Improvement Program to develop and monitor measures of efficiency and compliance for Exempt-level human research.**
  *The HUA HRPP has several processes in place for measuring the effectiveness and compliance of our program, outlined in our SOPs for Annual Evaluation and QA/QI Program. These include assessments of investigators and IRB meeting minutes, as well as annual activities undertaken by the Advisory Committee each December. Assessments of IRB reviews have occurred in limited ways (e.g., review of IRB meeting minutes, a subset of the IRB portfolio) or ad hoc ways (e.g., senior IRB staff evaluating reviews completed by IRB Administrators following investigator inquiry or Administrator question).*

  IRB staff will utilize existing SOPs to implement more consistent and structured internal monitoring of projects that will occur on a regular basis (e.g., regular assessment of particular regulatory determinations, consistency in documentation and reporting to researchers, etc.).

This will begin with a focus on Exempt-level IRB reviews. In support of this, an evaluation tool has been drafted, and a formal project plan is in development.

In addition to the retrospective evaluation of completed reviews, additional resources will be developed to support IRB Administrators in decision making, which may be of particular use in Exempt research. The HUA IRB staff currently maintain an Administrative Manual, a supplement to formal SOPs that describe some of the more informal "tips and tricks" of IRB review. Included is a section on Review Methods, which sets the general flow of how to approach reviewing an application. This resource is currently brief but will be augmented to identify mission critical decisions that require the most attention and have the greatest possibility of creating a compliance concern (e.g., properly identifying what projects are human research vs. what are not, addressing informed consent in some manner in all studies, the additional agency requirements in federally funded research). Identifying the most critical areas to address in reviews is not intended to diminish overall review quality or quality in other areas of the review; rather, it is intended to more squarely focus reviewer and researcher attention and time to what most demands it.

The focus on Exempt-level research is in part a response to feedback from researchers about the efficiency of these reviews, including the prescriptiveness of requests they receive from the IRB and timeliness of responses to PI revisions. In general, IRB Administrators should ensure their determinations are grounded in relevant regulations or policies, clearly understanding and articulating the reasons behind their requests or requirements to researchers. Administrators are empowered to make decisions independently so long as they are justifiable. Understanding these principles, and that Exempt-level research is generally of lower risk and thus subject to less regulatory and policy scrutiny, should result in a more streamlined review experience.

- **Develop additional training and outreach resources to support the research community, especially those determining if their work requires IRB oversight and preparing submissions to the IRB for the first time.**
  *The HUA HRPP has many training resources in place. These include the Lifecycle Guide on the CUHS website (which walks researchers through different stages of the IRB review process), monthly newsletters describing core IRB concepts and recent regulatory/policy changes (which are retained in a library available to the community), a comprehensive Undergraduate Research Training Program, and in-person training sessions at the request of faculty. While these offerings remain useful and will be retained, there is room for more proactive engagement with the research community through training sessions, and a need to provide support to first-time submitters.*

  IRB staff will evaluate existing training resources through quantitative (e.g., website analytics for current training pages) and qualitative means (e.g., staff meeting discussion of what webpages or documents in the ESTR Library IRB reviewers regularly use/share with investigators). This will help inform future resources by identifying the type of documents/tools that have proven usefulness, where there

may be gaps in existing resources, and where there is opportunity to expand website resources by creating standalone guidance in a new library of materials. The IRB currently maintains an Investigator Manual in the ESTR Library; this serves as the definitive resource for PIs on regulatory requirements, Harvard policy requirements, and institutional approach to IRB review. IRB staff will assess what information in this guide should be extracted into more digestible, topic-based tools available outside ESTR on the CUHS website.

Additional areas of growth for the training program include a training request function on our website and regularly scheduled drop-in trainings on introductory IRB topics or other specific topics. At present, training sessions typically occur at the invitation of faculty members who have a research ethics component of their course. Many faculty who request training sessions for their students have done so for years and are familiar with the IRB. A formal training request form prominently on the CUHS website would potentially encourage new faculty to make requests, administrators in other areas of research compliance to make a request, or even a group of students who self-organize within their discipline to reach out. The IRB will be proactive by developing a recurring training session as well. At present, the IRB schedules such sessions for undergraduate students only; however, we can leverage that existing process to establish a standing training in IRB basics for the broader community, like what work requires IRB oversight and how to prepare an IRB application. This may be of particular interest to student researchers and those new to Harvard.