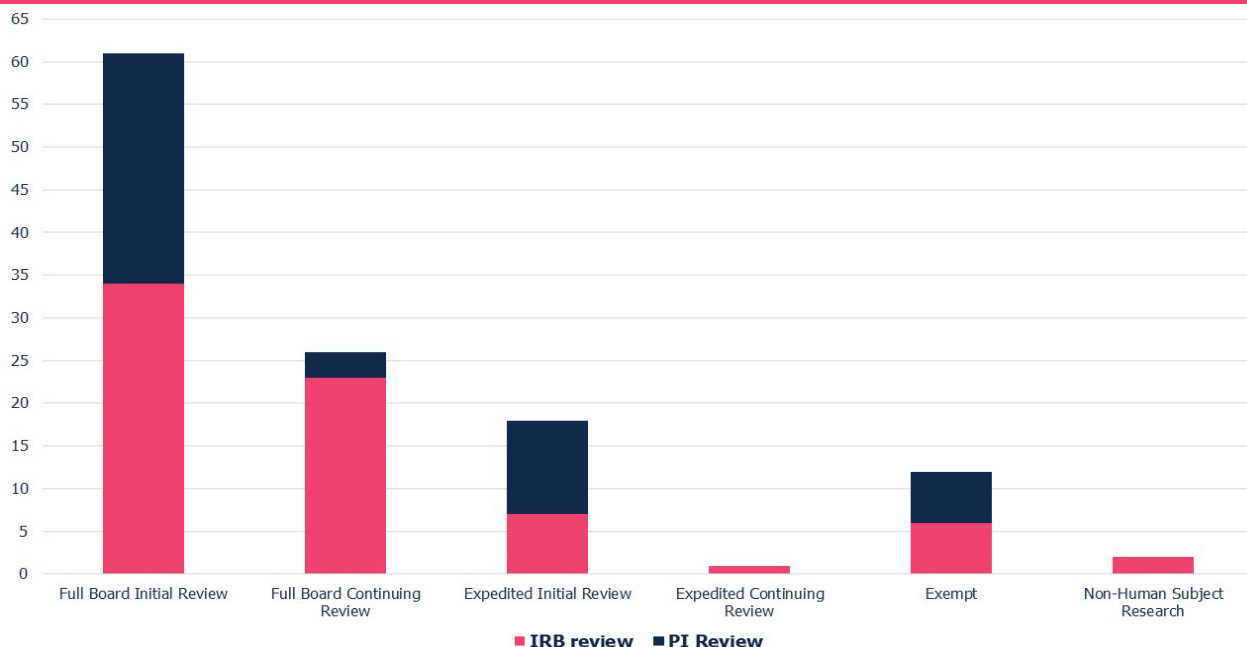


NEWS FROM THE OHRE AND IRB

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Average Turnaround Times for Study Reviews for 2024 (Year to Date)



Full Board Initial Review: 61 days

IRB Review: 34 days

PI Review: 27 days

Full Board Continuing Review: 26 days

IRB Review: 23 days

PI Review: 3 days

Expedited Initial Review: 18 days

IRB Review: 7 days
PI Review: 11 days

Expedited Continuing Review: 1 day

IRB Review: 1 day
PI Review: 0 days

Exempt: 12 days

IRB Review: 6 days
PI Review: 6 days

Non-Human Subject Research: 2 days

IRB Review: 2 days
PI Review: 0 days

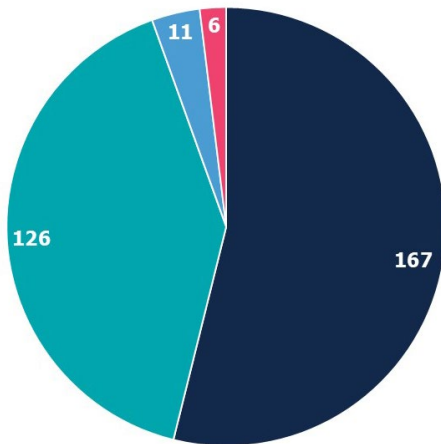
Average Turnaround Times for Rely On Study Reviews in 2024 (Year to Date)



Rely On Review: 73 days

IRB Review: 27 days
PI Review: 46 days

Full Board Determinations (Jan 2024 – July 2024)



Full Board Studies Reviewed: 310

Minor Stipulations: 167 (53.8%)
Approved: 126 (40.6%)
Deferred: 11 (3.5%)
Noted: 6 (1.9%)

■ Minor Stipulations ■ Approved ■ Deferred ■ Noted

Themes in Rational for Board Deferral

Unable to Assess Risk to Subjects	Pregnant Persons Considerations	Consent Process	Study Design/Procedures	Imaging
<p>Missing documents, DSMP</p> <p>Protocol references documents not provided with application Lack of study stopping rules</p> <p>Risk mitigation plan incomplete for vulnerable subjects</p>	<p>More information needed about reproductive risks</p> <p>Missing information about pregnancy testing procedures</p> <p>Study procedures for subjects who become pregnant</p>	<p>Conflicting/missing information about consent about how consent would be obtained</p> <p>Missing information about whom would be obtaining consent</p> <p>Insufficient disclosure of risks to subjects in consent form</p>	<p>Study design generally unclear</p> <p>Schedule of events unclear: imaging/scans</p> <p>Unclear what procedures are done for research vs. clinical care</p>	<p>Poor application completion</p> <p>Schedule of events</p> <p>General lack of information about imaging procedures</p>

Announcements

IRBIS Changes for Renewal Submissions with External Sites Relying on UNC

Renewal submissions for studies that have external sites relying on the UNC IRB now require an IRBIS progress report for UNC and each relying site. The information requested for each relying site is similar to what has been required previously for the overall study but asks for the information specifically for each site. Having this information helps strengthen UNC's regulatory oversight for the overall study and for external sites relying on UNC.

If you have questions or problems completing these new progress reports, please contact the Reliance Team at IRBReliance@unc.edu.

2025 IRB Meeting Dates Published

[Click here to see the dates online](#) or [download a PDF of the 2025 calendar](#).

Staffing Updates

OHRE is excited to welcome new IRB Analyst Cinya Brand and new Compliance Analyst Krystal Parks. Liz Joyce and Justin Feussner have both been promoted to Senior IRB Analyst.

Guidance

Criteria for Reliance Requests

As requests for reliance increase, we want to remind the research community of the criteria used in considering if UNC will serve as the IRB of record for external sites or when considering if we will rely on an outside IRB. [Click here to read the full criteria](#).

Three-year Exempt Check-in

Although Exempt determinations do not have an expiration date, it is imperative that the University maintains an accurate record of ongoing research. To fulfill that requirement, studies that have been determined to be exempt from the full regulatory requirements will have a "check in" every three years after the initial determination. The notification will be

sent at the 3-year anniversary with reminders sent at one week and two weeks after the notification. If a response is not received by 21 days after the initial notice, the study will be closed automatically.

To complete the check-in submission, you must use the link in the notification. There is not an option to draft one on the IRB Study Management page.

This automated reminder is being provided as a courtesy.

To: Luke Skywalker
Department of the Rebellion

From: UNC Chapel Hill Office of Human Research Ethics

Date: 06/05/2024

RE: Notice of Exempt 3-year review
Study Title: Diagnosis of Midi-Chlorian infection

Please submit an **Exempt Administrative 3-year Review** form by following the link below. **Failure to respond to this request is considered non-compliance with IRB requirements and University policies. If a response is not received within 14 days, the IRB record will be closed and all research must cease.**

<https://orisdev.research.unc.edu/irb/index.cfm?event=home.administrativeReviewExempt&masterId=384988> ←

No modifications to this study will be processed until the Exempt Administrative Review form is received.

If you do not intend to continue this study, please respond to the **Exempt Administrative 3-year Review** form in IRBIS accordingly.

The Check-in contains only a single question regarding whether you are still conducting the research. Once you provide a response and submit the form, you will receive a confirmation window.

If you are continuing the research, the study will continue for an additional three years at which time you will need to complete the Check-in to continue. Once you have completed the research, you can close at any time.

Meet the Chairs

Meet Kim Brownley, Chair of IRB C & F



Dr. Brownley is the Associate Director of Policy & Initiatives in the OHRE and an Adjunct Professor of Psychiatry. She's a founding member of the [UNC Scientific Review Committee](#), and previously was co-Director of the [NC TraCS Regulatory Services](#). She has 35 years of research experience, and for the past ten years, she's chaired IRB committees C and F.

[In this article](#), Dr. Brownley discusses the most interesting ethical issues she's wrestled with at the IRB, explains her most common reasons for deferring a study, and gives advice for researchers submitting to the IRB at UNC for the first time.

Education

Protection of Pupil Rights Amendment

How can a simple student survey turn into a Federal lawsuit? One way is to run afoul of the Protection of Pupil Rights Amendment (PPRA)

[In this video](#), Senior IRB Analyst Liz Joyce explains what the PPRA is, who it's designed to protect, and when the law applies. She discusses what the PPRA means for research studies and describes what compliance looks like.



THE CASE STUDY

CN. Versus Ridgewood Board of Education (2001), which was heard by the Court of Appeals for the third circuit.

Upcoming Events

NC TraCS Clinical Protocol Development Series 10/31 & 11/01



The goal of this two-day series is to provide researchers with the knowledge, tools, and resources to aid in the development of a scientific protocol for a clinical research study. Both sessions will begin at 9:00 a.m. ET and a question-and-answer session will follow each presentation.

Presenters:

- Kim Brownley, PhD, CIP – Associate Director - Policy & Initiative, UNC Office of Human Research Ethics
- Monica Coudurier, BA – Clinical Trials Project Manager, UNC Office of Clinical Trials
- Terry Hartman, MPH, MS, CCRC – Director of Regulatory Operations, NC TraCS Institute.

[Click here](#) to register for the event or learn more.

Pop Up Office Hours and Meet and Greet with the Office of Human Research Ethics - 10/22

Stop by the [Administrative Office Building](#) on October 22nd between 10:00am – 2:00pm for pop up office hours with the Office of Human Research Ethics/Institutional Review Board (IRB) staff.

This is an in-person event! Please bring your IRB questions or just come by the office to meet some of the staff members.

Register for Upcoming Office Hours with an IRB Analyst

Need OHRE offers 15 minute Zoom consultations with IRB analysts from 9am – 11am, twice per month on Wednesdays.

[Click here to see all upcoming office hours.](#)

Contact Us

We'd love to hear from you! Email us at irb_questions@unc.edu or call us at 919-966-3113 for general questions or [visit our contact page](#) for specific inquiries.



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