

CUH IRB IRB Guidance on Recommended Start and End Dates for IRB Protocols

Purpose of This Guidance

Selecting appropriate start and end dates for your IRB protocol is essential for compliance and for maintaining a realistic research timeline. Dates should account for IRB review processes, possible revisions, and study logistics.

IRB Review Capacity and Timing Considerations

When planning your proposed start date, please be aware that **IRB members serve in their review roles as part of institutional service and are not typically compensated for protocol review**. Federal regulations permit institutions to compensate IRB members, but compensation may not be tied to review outcomes, and many academic IRBs rely on members who review protocols **in addition to their regular professional responsibilities** (e.g., teaching, research, clinical, or administrative duties) (see 45 CFR 46.108 and OHRP/ FDA IRB guidance).

As a result:

- **Exempt reviews** are conducted by the IRB Chair or Vice-Chair as availability permits.
- **Expedited reviews** depend on the availability of the assigned IRB reviewer.
- **Full Board (Convened)** reviews depend on scheduled meeting dates, quorum being reached, and available agenda time (typically allowing discussion and voting on only a limited number of protocols per meeting).
- Review timelines may vary, particularly if submissions are incomplete or require multiple rounds of revision.



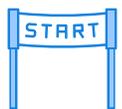
Students are encouraged to plan conservatively and allow adequate time for IRB review, revisions, and approvals when selecting proposed start dates.

Recommended Start Date

Your proposed **start date should always be set after IRB review and approval**. Students should not assume immediate approval when selecting a start date.

The IRB recommends:

- Selecting a start date approximately **4–6 weeks after initial IRB submission**
- Allowing additional time if your study:
 - Requires **Full Board (Convened IRB) review**
 - Involves external sites, data-sharing agreements, or institutional permissions
 - Is missing required documents at the time of submission



Important considerations when setting a start date:

- **Convened (Full Board) Studies**
 - The IRB meets on a scheduled basis.
 - Each convened meeting typically allows sufficient time for discussion and voting on approximately 1–2 protocols.
 - Quorum may not always be reached, which can delay review.
 - If revisions are required, the protocol may need to return to a future meeting.
- **Expedited Review**
 - Review timelines depend on the **availability of the assigned IRB reviewer**.
 - Additional revision cycles may be required before approval.
- **Exempt Review**
 - Review timelines depend on the **availability of the IRB Chair or Vice-Chair**.
 - Exempt status does not mean immediate approval.

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Recommended Start Date (Continued)

- **Revision Cycles**

- Many protocols require more than one round of revisions.
- Incomplete or less detailed submissions typically require additional revision cycles, which can extend the review timeline.

- **Additional Approvals and Permissions**

- Consider time needed for:
 - Site permissions or letters of support
 - Data governance approvals
 - Data use or data-sharing agreements with other institutions
 - Organizational or departmental approvals

Reminder:

- You may not begin recruitment, consent, data collection, or data access until IRB approval is granted, even if your proposed start date has passed.

Recommended End Date

Your **end date** should reflect the full duration of the project, including:

- Recruitment
- Data collection
- Follow-up activities (if applicable)
- Data analysis and study closure



When selecting an end date, consider:

- The time it may take to **recruit participants**, which often takes longer than anticipated
- Scheduling challenges, holidays, academic breaks, or site availability
- Multiple data collection points (e.g., pre/post surveys)
- Alignment with your academic milestones (e.g., dissertation timeline, degree completion)

If your study extends beyond the approved end date, you must submit a **continuing review** or **amendment** before the approval expires. Please contact the IRB Chair for guidance.

Additional Guidance

Common Issues to Avoid

- ✗ Selecting a start date that occurs before IRB approval
- ✗ Underestimating the time needed for IRB review and revisions
- ✗ Failing to account for recruitment delays or external approvals
- ✗ Using overly short study periods that are not realistic

If You Need to Adjust Dates

If timelines change or revisions are requested:

- Update start and/or end dates when revising your protocol
- Ensure revised dates allow adequate time for IRB review and approval

Questions?

If you are uncertain about appropriate start or end dates for your study, please contact the IRB before submitting or resubmitting your protocol. You may contact the IRB for additional information at irb@chaminade.edu.