August 28, 2025

**Minutes of IRB meeting**
**Date:** August 28, 2025
**Location:** Zoom meeting
**Chair:** Sylvie Blondelle

**Attendees:** Committee members including Susan Webster (new member), Sylvie Blondelle, Cecilia Marcondes, Daniel Murin, Giselle Mejia.

**1. Welcome and opening**
The chair opened the meeting, welcomed the members, and extended a special welcome to Susan as a new committee member. A minor correction to an email address was noted and resolved at the outset.

**2. Approval of previous minutes**
The minutes from February 2025 were reviewed; no corrections were requested. A motion to approve was made and seconded, and the minutes were approved unanimously.

**3. Protocol review**
**3.1 IRB-24-005-JDD (Joanna Davies, continuing renewal): *Immune cell subset analysis before type 1 diabetes onset***
The committee reviewed a continuing renewal designated exempt category 4. Although the institute receives coded samples, identifiers reside only with the external collaborator; at the institute level the work involves analyzing previously collected pediatric samples from a collaborator-run study. Activities include flow cytometry and sequencing to evaluate whether frequencies of specified T-cell subsets (for example, TH2) and associated gene-expression levels correlate with time to disease onset. No changes were reported; all samples were collected between 2015 and 2022 and are now archived; there were no new findings, no added risks, and no clinical interventions. One additional investigator has been added; the committee requested that this be reflected in the appropriate section of the submission. With that administrative addition, the renewal was approved.

**3.2 IRB-24-001-GS (Gregory Seumois, continuing renewal): T*ranscriptomic analysis of asthma***
The continuing renewal reported no progress since the prior approval because funding was not secured, no samples were obtained, and no study activities were initiated. The committee discussed the general practice of obtaining IRB approval in advance of funding to facilitate preliminary data collection and to satisfy just-in-time requirements; this was deemed acceptable. The renewal was approved despite inactivity.

**3.3 IRB-23-001-MCM (Cecilia Marcondes; continuing renewal): Methamphetamine and HIV interactions in the regulation of glial activation**
The committee noted that this work uses postmortem brain tissue data only and therefore does not constitute human subjects research under applicable guidance. The protocol has remained listed as exempt to align with the original grant file, but the committee can provide a letter stating that the project is not human subjects research for future submissions. The renewal was approved as exempt.

Cecilia Marcondes was absent during the review of her protocol and did not participate in the discussion or vote.

**3.4 IRB-23-003-JDD (Joanna Davies; continuing renewal): Determining peripheral CD4+ precursor cell numbers and ratios in normal human blood**
The committee revisited whether an institute-level IRB is necessary when collection and donor confidentiality are governed under the Scripps IRB with a legal agreement prohibiting release of identifiers. Members agreed that when the institute receives only de-identified material under such an agreement, the activity at the institute does not constitute human subjects research. Differences were noted for other sources, such as UCSD, where a PI may or may not be named on a collaborating IRB; when the PI is not covered on that external IRB and the institute undertakes new human subjects activities, local IRB review can be required. For Joanna's Scripps-sourced work, future continuing renewals are not required, and a confirming letter of non-human-subjects status will be issued.

**3.5 IRB-23-004-JDD (Joanna Davies; continuing renewal): A biomarker for the breakdown of immune homeostasis**
**Repository PBMC protocol**
The committee affirmed that work using PBMCs obtained from repositories that do not release identifiers is not human subjects research at the institute. The submission does not require continuing renewal and a confirming letter of non-human-subjects status will be issued.

**4. Policies and SOPS**
**4.1 Policy on protection of human subjects**
The committee reviewed the institute policy based on 45 CFR 46, including Belmont principles and delineated responsibilities of the institute, the IRB, and investigators. No edits were requested.

**4.2 IRB review procedures**
The committee reviewed procedures covering application, administrative pre-review, expedited review, full committee review, continuing review, and records retention. Members requested that the document include explicit criteria indicating when a full committee review is required, for example, studies exceeding minimal risk, projects requiring institute-originated informed consent, complex multi-site collaborations, or other factors not appropriate for expedited review. A revision adding these criteria will be prepared and circulated.

**4.3 Adverse events and non-compliance**
The committee reviewed the policy describing definitions, reporting requirements, and IRB actions for adverse events, protocol deviations, lapses in continuing review, and non-compliance. No changes were requested.

**5. Other business**
No regulatory changes affecting the committee's work were identified. Members confirmed that, while few full-committee items are expected, the IRB must meet at least once per year. The next meeting is tentatively targeted for late January or early February 2026, with an earlier session scheduled if needed for time-sensitive reviews. Members complimented the efficiency of the session. A housekeeping note was recorded to ensure that the update date appears on policy documents when revisions are made.

August 28, 2025

**6. Closing**
With no further business, the chair thanked members for their participation and adjourned the meeting. Special thanks were extended to Susan for joining the committee.

End Meeting at 12:45 pm