

**UNIVERSITY OF CALIFORNIA, DAVIS
AUDIT AND MANAGEMENT ADVISORY SERVICES**

**UC Davis
Institutional Review Board
Audit & Management Advisory Services Project #21-07**

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**Institutional Review Board
AMAS Project #21-07
MANAGEMENT SUMMARY**

Background

As part of the fiscal year (FY) 2021 audit plan, AMAS evaluated the UC Davis Institutional Review Board's (IRB) review and approval processes and oversight.

An IRB is an appropriately composed group that has been formally assigned the duties of reviewing and monitoring research involving human subjects. An IRB has authority to approve, require modifications to, and disapprove this research. The main purpose of the IRB review is to assure the protections of rights and welfare of human participants in research.

An IRB is established at UC Davis to review and monitor research studies involving human subjects. New studies must be reviewed by the IRB before research involving human subjects is conducted. The IRB determines which method of review is appropriate for the research, taking into consideration the protocols involved, the level of risk posed to participants, and the types of participants that will be engaged. It will either perform a full committee review, an expedited review, or an exempt¹ project review.² An analyst in the IRB's administrative unit performs the initial intake of applications submitted to the IRB's system, and assigns the proposal to the appropriate category of review based upon criteria established in the IRB's standard operating procedures (SOPs). These SOPs are based upon federal regulations which detail requirements for making determinations over human subjects research review.

Research that has been determined to require full committee review is assigned to the agenda for one of three committees within the UC Davis IRB. These committees review any human subject research that has been considered to pose greater than minimal risk³, to subjects. There are two biomedical/clinical committees, and one social and behavioral committee. Full committee deliberations and determinations are guided by SOPs, including HRP-314 (Criteria for Approval and Additional Considerations). The biomedical/clinical committees meet twice monthly, and the social and behavioral committee meets once per month.

A study must fall under at least one of nine research categories which present no more than minimal risk to subjects to qualify for the expedited review process. The Code of Federal Regulations (CFR. §46.110) refers to a published notice in the Federal Register⁴ which contains a list of categories that may be reviewed by the IRB under expedited review procedure. Examples of categories of research allowing expedited review include studies involving hair or saliva samples, blood samples from healthy participants, and continuing review of research that is determined to involve no greater than minimal risk.

² The IRB might also determine that a study does not involve human subjects and therefore is not subject to oversight.

³ Per 45.CFR.46.102(j) (Common Rule), minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

⁴ [OHRP Expedited Review Categories](#)

Protocol submissions may also fall under the category of emergency use. Per the Code of Federal Regulations⁵, emergency use is defined as the use of an investigational drug or biological product with a human subject in a life-threatening situation where no standard acceptable treatment is available and where there is not sufficient time to obtain IRB approval. The emergency use provision under Food and Drug Administration regulations⁶ is an exemption from review and approval from the IRB prior to administration of the drug or product, and must be reported to the IRB within five days of the emergency use.

The IRB also reviews status reports for continuing research and modifications or amendments to existing research protocols. A similar intake process is used for post-approval submissions (that is, amendments or modifications, reports of new information, and continuing review or study closure information).

Purpose and Scope

The purpose of this audit was to evaluate the UC Davis IRB's processes for reviewing and approving human subjects research, and oversight and monitoring activities. Specifically, our purpose was to assess the alignment of IRB standard operating procedures (SOPs) with federal regulations; to determine whether the IRB adhered to SOPs in their convened committee and expedited review processes; to evaluate the composition of the IRB against federal requirements; to review third party evaluations of the IRB; and to assess the appropriateness of documentation submitted for protocols under the emergency use category.

In order to accomplish these objectives, we analyzed documentation retained in the IRB system of record, including consent forms, protocols, letters of determination, and meeting minutes; interviewed relevant management, staff, and researchers; reviewed federal regulations and standard operating procedures; and reviewed third party evaluations of the IRB and Investigator Quality Improvement Assessments. We also obtained IRB rosters and user listings for the system of record (IRBNet) for purposes of testing IRB membership and access controls.

The timeframe under review was March 2020 through March 2021.

Conclusion

We found that the standard operating procedures (SOPs) in use by the UC Davis IRB adhered to federal regulations, and that both the full committee review and expedited review processes followed SOPs.

We also found that a change in management within the IRB resulted in a change in reporting lines. The individual performing the Investigator Quality Improvement Assessments and the IRB Director will be reporting to the same manager. While this is not definitively a conflict of interest under existing standards, it does result in fewer layers of accountability and less transparency.

We also conclude the following:

- Degrees and certifications were not listed for all IRB members of the membership roster;

⁵ 21 CFR 56.102(d)

⁶ 21 CFR 56.104(c)

- There was no formal process for account administration in the system of record for research studies reviewed and monitored by the IRB.

Observations, Recommendations, and Management Corrective Actions**A. IRB Member Qualifications****Degrees, certifications, and designations were missing in the IRB member roster.**

The UC Davis IRB membership roster includes a listing of certifications, licenses, and degrees for each member. Our review found four members without any such designations listed. Per Code of Federal Regulations §46.108, IRBs must maintain a current list of IRB members including their earned degrees and indications of experience such as board certifications of licenses sufficient to describe each member's chief contributions to IRB deliberations. Failing to maintain an accurate membership roster increases risk of noncompliance with federal regulations.

Recommendation

UC Davis should update its roster to accurately reflect IRB member designations.

Management Corrective Action

1. By July 31, 2021, IRB will update its membership roster to include certifications, licenses, and degree information for all members.

B. User Account Management**There is no formalized process for account management in the IRB's system of record.**

UC Davis IRB uses IRBNet for processing and storing data relating to human subjects research. This system is utilized by IRB staff for processing and reviewing studies, and by researchers to submit and monitor their study proposals or post-approval documentation. Access to the system does not fall under the university's single sign-on system. Users login via the vendor's web-based interface.

At the time of our review, there was no documented process for IRBNet access management. Further, IRB management approvals are not required or documented when access is requested. In reviewing a list of current users, we also determined that individuals no longer employed by UC Davis had administrative or reviewer role accounts, and there exist two non-user privileged accounts. We also found individuals not affiliated with the university who possessed accounts.

BFB-IS-3 requires that institutional information classified at Protection Level 2 or higher has controls to prevent unauthorized access. A lack of defined processes for provisioning and decommissioning of accounts may lead to unauthorized access from individuals who should no longer require it.

Recommendation

IRB should formalize a process for user account management for its system of record.

Management Corrective Actions

- 1) By November 30, 2021, IRB will review current user access to the IRBNet system and perform revocations and recertifications of access as needed.
- 2) By November 30, 2021, IRB will formalize a process for user access management. This should include at least the requirement for obtaining and retaining management approval records for new account creation, the process for provisioning and decommissioning user accounts, and a process to regularly review access within the system of record. Management should also maintain records of individuals with access to non-user privileged accounts and regularly verify the appropriateness of the access.
