

UC DAVIS OFFICE OF RESEARCH

AAHRPP Preparation UC Davis Human Research Protection Program (HRPP) Plan Part 2

Miles McFann, CIP

Be ready for the AAHRPP Interviews!




HRP-101: Human Research Protection Program Plan



[research.ucdavis.edu/
irbadmin](http://research.ucdavis.edu/irbadmin)

What training does the IRB require of IRB members, IRB staff and others involved in the review of Human Research?



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1. CITI training every three years
 2. Training on SOPs
 3. Training on Checklists
 4. Training on Worksheets

What training must investigators and research staff obtain before participating in the conduct of Human Research?



For research involving **> than minimal risk**: CITI online training program.

For research involving **≤ minimal risk**: Online CITI or the NIH Protection of Human Research Participants Course

For **clinical trials**: GCP training through CITI (or they may provide a copy of ACRP or SoCRA certification)

*** Training must occur at least every 3 years.*

If someone has a concern, complaint, allegation of undue influence or noncompliance – where and how to they report their concern?





Concerns may be reported to the IRB Chair, IRB Administration, Organization Official, Legal Counsel, Deans or Department Chairs.

Reports can be anonymous and concerns may be reported orally or in writing.

Which of the following are responsibilities of the IRB?

- A. Approve, require modifications to secure approval or disapprove research;
- B. Suspend, terminate approval of research;
- C. Determine whether an activity is Human Research;
- D. Observe, or have a 3rd party observe the consent process or the conduct of research.






All of the choices are correct.



When may the IRB suspend or terminate approval of Human Research?



The IRB may suspend or terminate approval of the research when the research is not being conducted in accordance with the IRB's requirements or if has been associated with unexpected serious harm to subjects.

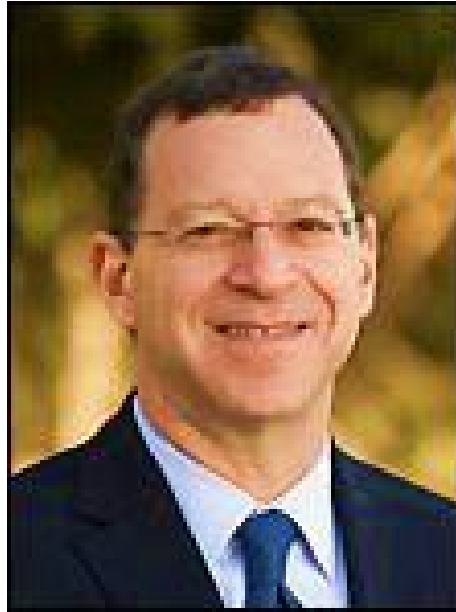
May the Organization
Official suspend or
terminate a study that has
been approved by the IRB?



Yes, the Organizational Official can ***suspend or terminate*** an IRB-approved study, ***but*** the Organization Official may not ***approve*** a study that has been disapproved by the IRB.




Who is the Organizational
Official for UC Davis?



The Vice Chancellor for Research, Harris Lewin

May an individual who is responsible for UC Davis business development serve on the IRB?





No. Such a role is prohibited the Human Research Protection Program and would be a conflict of interest.

Thank you – Don't miss Part III of this continuing series – the UC Davis Investigator Manual!

