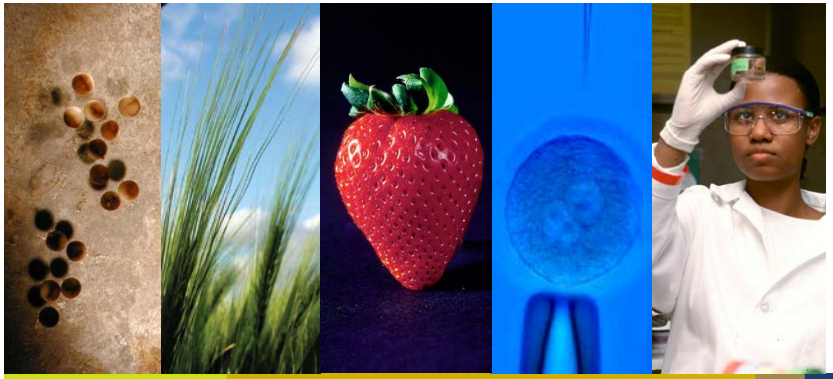

UC DAVIS OFFICE OF RESEARCH

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

Miles McFann
Outreach, Training, and Education Analyst
October 14, 2013

UCDAVIS OFFICE OF RESEARCH

AAHRPP is coming to UC Davis early next year

The team will be interviewing people in various roles









UCDAVIS OFFICE OF RESEARCH

The AAHRPP site visit team includes members who are your peers

What is the training plan?

1. UC Davis HRPP Plan
2. Applicable UC Davis SOPs
3. UC Davis IRB Worksheets and Checklists
4. Review

HRP-101:

Human Research Protection Program Plan

research.ucdavis.edu/irbadmin

UCDAVIS OFFICE OF RESEARCH

Let’s get started…

What do you do if you don't know the answer a question asked by an AAHRPP site visit teammember?

Acknowledge that you don’t know the answer and offer:

1. You would use the UC Davis website and other resources to access SOPs and other information;
2. You would call the IRB office if you cannot find the answer

What do we mean when we say UC Davis is “engaged” in human subject research?

1. If UC Davis is the grant recipient – even if all research activities are done at other organizations
2. If for purposes of human subject research, UC Davis employees/agents obtain:
(a) Data about subjects through intervention or interaction;
(b) Identifiable private information
(c) Informed consent from a research subject

What is the difference between a “clinical investigation” and “research” (FDA vs. OHRP definitions)

Clinical Investigation: An experiment involving a test article and control when the results must meet requirements for prior submission to the FDA or are intended to be later submitted to or held for inspection by the FDA

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

What are the three principles of the Belmont Report?

1. **Respect for persons** – autonomy

2. **Beneficence** – do no harm

3. **Justice** – distribution of risks and burdens

According to the UC Davis Federal Wide Assurance (FWA), when must UC Davis apply the regulations of a federal agency that are relevant to human subject protections?

When UC Davis is engaged in research that is conducted, funded or other wise subject to the regulations of that agency that are relevant to human subject protections.

What is UC Davis's policy regarding finder's fees and bonus payments?

UC Davis prohibits payments to professionals in exchange for referrals of potential subjects and also prohibits payments designed to accelerate enrolment if the payment is tied to the rate or timing of enrollment.

Thank you – Don’t miss Part II of this continuing series!