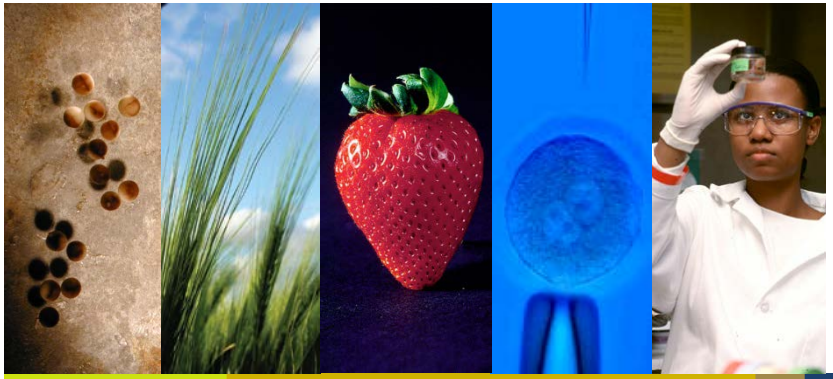

UC DAVIS OFFICE OF RESEARCH

Reviewing International Research

January 13, 2015
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Outreach, Training & Education Analyst

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Outline

- Expectations
- Protocol Template Locations
- Topics to Consider
- Resources

Expectations

UC Davis Researchers who wish to conduct human subjects research in countries outside the United States or its territories must obtain approval from the host country's IRB/ethics committee and from the UC Davis IRB

Expectations

UC Davis Requirements:

- Greater than minimal risk research, the IRB requires a copy of the local IRB/ethics committee approval (or equivalent) before approving the research.

- No more than minimal risk research, the IRB adds an administrative requirement to the approval letter stating that the researcher may not begin the research until the local IRB/ethics committee (or equivalent) approves the research.

❖ *If there is no collaboration and/or ethics review in the foreign country, the IRB uses local 'officials' and/or representatives to provide the local approval.*

Expectations

✓The standards for human subjects protection are no less than those that apply to US-based research.

✓For clinical trials, we apply the "International Conference on Harmonization – Good Clinical Practice (E6)" Guidance

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Protocol Template Locations

During the Review – What to Look For and Where

Question 20: Multi-Site Research

If this is a multi-site study where you are the lead investigator, describe the process to ensure communication among sites, such as:

- All required approvals have been obtained at each site (including approval by the site's IRB of record).

Protocol Template Locations

During the Review – What to Look For and Where

Question 23: Setting

Describe the sites or locations where your research team will conduct the research.

- For research conducted outside of the organization and its affiliates describe:
  - Site-specific regulations or customs affecting the research for research outside the organization.
  - Local scientific and ethical review structure outside the organization.

Protocol Template Locations

During the Review – What to Look For and Where

Question 24: Resources Available

Describe your staff by roles. Describe the qualifications required to perform each role. When applicable describe their knowledge of the local study sites, culture, and society.

Topics to Consider

During the Review

1. Cultural differences that influence study design and the consent process

2. The rationale for conducting the study with an international population.

3. A description of the host country's ethics review and oversight mechanism for participant protection.

Resources

- OHRP's International Compilation of Human Research Standards
- ICH Guideline for Good Clinical Practice (GCP)
- Council for International Organizations of Medical Sciences
- World Medical Association
- International Association of Bioethics

Program Evaluation

- This process will be evaluated by our RCI Analyst in 6-9 months (based on volume) to ensure all procedures are being followed, and to make any changes, as necessary.

Questions?

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