Gina Anderson

From: Gina Anderson
Sent: Thursday, September 26, 2013 5:08 PM
To: Gina Anderson
Subject: FW: PPM Review Request; Due 6/19/13

From: Gina Anderson
Sent: Friday, May 31, 2013 2:09 PM
To: Molly M. Theodossy
Cc: Academic Senate Chair
Subject: RE: PPM Review Request; Due 6/19/13

Dear Molly,

Once again, the Division is unable to facilitate a review of the enclosed draft policy so late in spring quarter. We will review the section in fall 2013.

Best,
Gina

Gina Anderson
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From: Molly M. Theodossy
Sent: Friday, May 31, 2013 1:46 PM
To: Gina Anderson; Wendi Delmendo; Karl M Engelbach; Sandi Glithero; Cindy M Kiel; Daniel Redline; Karl Mohr; Yvonne Sundahl; Michael F. Sweeney; Jeremiah J Maher; Leslyn Kraus
Subject: PPM Review Request; Due 6/19/13

Policy and Procedure Manual
Review Request

Date: 5/31/2013

Response requested by: 6/19/2013

To: Internal Audit
G. Anderson, Academic Senate
W. Delmendo, Compliance
K. Engelbach, Office of the Chancellor

S. Glithero, Academic Personnel
C. Kiel/D. Redline, Office of Research
K. Mohr, Office of the Provost
Y. Sundahl, UCDHS Policy
M. Sweeney, Campus Counsel

Section: 240-61, Distribution of Investigational Drugs, Devices, or Biologics

Purpose: New; describes the appropriate use of investigational drugs, devices, or biologics to ensure the safety of human subjects.

A draft of the section is attached for your review. Please review the draft, entering your edits and comments in the attached file.

Return the edited file directly to me, via email, by the response date indicated above. In your return email, indicate any additional individuals in your office who have reviewed the draft.

No response by the deadline above will be interpreted as your concurrence with the proposed manual section.

Reviewers' comments and suggestions will be compiled, and I will work with the policy/process originator to resolve any issues. Once the comments are reconciled, I will prepare a final draft for approval by the originator, the department head and the appropriate vice chancellor or vice provost prior to publication.

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Molly M. Theodossy
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Chapter 240, Research Involving Human Subjects
Section 61, Distribution or Use of Investigational Drugs, Devices, or Biologics
Date: Draft 5/31/13
Supersedes: New
Responsible Department: Institutional Review Board Administration
Source Document:

I. Purpose

This section describes the appropriate use of investigational drugs, devices, or biologics to ensure the safety of human subjects.

II. Definitions

A. Biologic—any therapeutic serum, toxin, antitoxin, or analogous microbial product applicable to the prevention, treatment, or cure of a disease or injury.

B. Device— an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

C. Dietary supplements—a product taken by mouth that contains an ingredient intended to supplement the diet but does not claim to treat, prevent, or cure a specific disease or condition; including but not limited to vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars and metabolites.

D. Drug—any chemical compound that may be used on or administered to humans as an aid in the diagnosis, treatment, cure, mitigation, or prevention of disease or other abnormal conditions.

E. Investigational use—a non-FDA approved drug, device, or biologic; an approved drug, device, or biologic used for non-FDA approved indication; or any other compound or placebo permitted by the FDA to be tested in humans but not yet determined to be safe and effective for a particular use in the general population.

III. Policy

A. The investigational use of drugs, devices, or biologics must be approved by the Institutional Review Board (IRB) prior to use.

1. An investigational drug, device, or biologic may be used without IRB approval only in the following emergency circumstances:
   a. When the subject is in a life-threatening situation requiring intervention before the next convened meeting of the IRB for review of the drug, device, or biologic is feasible.
   b. When there is no standard alternative treatment available that may save the life of the subject.

c. Physicians should notify the IRB in advance of its use to determine if the situation meets the requirements of emergency use.

d. The patient or the legally authorized representative must provide written informed consent prior to emergency use.

e. Unapproved investigational drugs and biologics require an IND prior to emergency use.

B. Investigational drugs or biologics are distributed by the UC Davis Medical Center (UCDMC) Investigational Drug Services (IDS) pharmacy.

C. The IRB, with the assistance of the Research Compliance and Integrity (RCI) unit, conducts ongoing monitoring of all investigational drugs, devices and biologics used in human subjects research under its jurisdiction.

D. Research involving dietary supplements must be reviewed by the IRB, but the supplements may not require distribution through the UCDMC pharmacy.

IV. Responsibilities

A. Principal Investigator (PI)

1. Ensures that the investigation is conducted according to contractual agreement with the sponsor, if applicable, and the IRB-approved protocol.
2. Ensures protection of the rights, safety, and welfare of prospective subjects.
3. Ensures pertinent laws and regulations as required by the University are observed.
4. Provides training of co-investigators and personnel who prescribe, distribute, or administer the test article.
5. Notifies the IRB of any amendments or unanticipated problems to participants or others that occur while conducting the research or during follow-up.
6. Submits a report to the IRB within five working days after emergency use of a test article, including description of the medical emergency, date the IRB was notified, current status of the patient, date and time administered, and any adverse events or unanticipated problems.

B. IRB

1. Reviews PI requests for exemption from IND or IDE requirements.
2. Seeks clarification or requests literature review from the Pharmacy regarding any concerns that may affect the risk/benefit assessment for investigational products.

C. UCDMC IDS Pharmacy

1. Stores, distributes, and logs test articles in accordance with the International Conference on Harmonization's (ICH E6) Guideline for Good Clinical Practice.
2. Provides the standard operating procedures to PIs.
3. Approves and monitors the storage or distribution of investigational drugs outside of the pharmacy, reporting deficiencies to the PI and IRB.
4. Maintains a current copy of the IRB-approved protocol.
5. Provides training to staff who distribute investigational drugs or biologics.

V. Further Information

Additional information is available from IRB Administration; http://research.ucdavis.edu/c/cs/hrp.

VI. References and Related Policies

A. Code of Federal Regulations:

1. 21 CFR Part 56, Institutional Review Boards.
2. 45 CFR Part 46, Protection of Human Subjects

B. UC Office of the President: Protection of Human Subjects in Research.

C. UCD Policy and Procedure Manual:

1. Section 220-05, Integrity in Research.
2. Section 230-02, Eligibility to Undertake Sponsored Research.
3. Section 230-05, Individual Conflicts of Interest Involving Research.
4. Section 230-07, Public Health Service Regulations on Objectivity in Research.
5. Section 240-30, Data Safety Monitoring Plans.
6. Section 240-50, General Policy Regarding Human Research.