3/18/2008

Guidelines for Completing the Clearance of NIH Personal Investigator Financial Holdings

The Clearance of NIH Personal Investigator Financial Holdings is to accompany a protocol submitted to the IRB for initial review, continuing review or an amendment adding an investigator, any changes related to the use of commercial products, or any change to an IND/IDE. After completing the PFH Clearance, submit the form electronically to the appropriate ethics office for review and approval. Directions for completing each numbered section of the form are detailed below.

1) Date Received by Ethics Office: The date the Ethics office receives the form.

2) Date of Memo: The date the memo is submitted to the IC Ethics office

3) Date of IRB Meeting: The date the new protocol, or continuing review is scheduled to be reviewed by the IRB.

4) Date Protocol Expires: Date when continuing review must be completed to allow continued accrual of patients.

5) New Protocol (attach précis): Include the protocol precis when submitting the COI packet to the ethics office. NIH ethics staff generally is not scientists. The summary will assist in understanding the basic premise of the protocol in order to perform a conflicts analysis. However, the ethics staff may contact the PI for additional information or clarification.

6) Continuing Review: A protocol that is currently active, and will be reviewed by the IRB to ensure compliance with human subject's research policies and procedures.

7) Amendment: Check the appropriate box to indicate if the ethics review is based on the addition of an NIH investigator or a change related to the use of commercial products or to an IND/IDE.

8) To: Send this completed form electronically to the Deputy Ethics Counselor for the PI's Institute **(including institute top five).** For a listing a Deputy Ethics Counselors, please refer to http://ethics.od.nih.gov/decs.htm
IC ethics staff will forward protocols for top five on to the NIH Ethics Office for the signature of the NIH Deputy Ethics Counselor.

9) From: Include the name of the PI as well as another point of contact (when applicable). When the IC DEC has signed the PFH Clearance, both individuals will receive a signed electronic copy of the document for submission to the IRB via e-mail.

10) Protocol Number: Provide protocol number if assigned. For new protocols, this field may be left blank.

11) Research Type/Phase: Indicate the type of protocol. This helps ethics staff determine potential conflicts with pre and post market issues, and use of commercial products for standard of care versus research.

12) Title: Include the full title of the protocol.

13) Principal Investigator's IC: The institute affiliation for the principal investigator.

14) Responsible IRB: The Institute IRB that will review protocol.

15 Product(s) made by a commercial entity that is the subject of the study: List all drugs, biologics or devices used as the variable (intervention) or control of the study. The product list is not limited to just those covered by an IND/IDE; these products may have been obtained through a technology transfer agreement such a cooperative research agreement (CRADA), a clinical trial agreement (CTA), a public-private partnership, NCI CTEP or through the Clinical Center Pharmacy. Drugs, biologics or devices that are commercially available but used "off-label" for research must be listed with their manufacturer, even if they are obtained through a technology transfer agreement or the Clinical Center Pharmacy. This requirement applies to all research types including natural history studies, screening or training protocols as well as phased clinical trials.

16) Manufacturer of study product(s) (drugs, biologics or devices): The commercial entity (public or private) producing or manufacturing the drug, biologic or device. For assistance with drug manufacturers, you may refer to the Clinical Center Pharmacy website http://www.thomsonhc.com/hcs/librarian or the FDA website http://www.fda.gov/cder/drug/default.htm

17) IND/IDE # (if applicable) and 18) IND/IDE Sponsor (if applicable): This applies to products in development and "off-label" products under study for new indications. The IND holder should be the name of a commercial entity, an academic provider or collaboration or an NIH employee.

19) Do you know of competitors for study drug or device manufacturer(s) for purposes related to this protocol?
A competitor can be considered in the following ways:

a) A product is used for diagnosing or treating an indication or diagnosis. Other commercial entities make a product that is used to diagnose or treat the same indication or diagnosis using the same scientific principles or mechanisms. In the marketplace, they would be competing for use by the same patient population.

b) A product is used for diagnosing or treating an indication or diagnosis. Other commercial entities make a product that is used to diagnose or treat the same indication or diagnosis using different scientific principles or mechanisms. In the marketplace, they would be competing for use by the same patient population.

20) Key words as per 1195: Words used to describe the study and not contained in the study title

Investigators: New NIH clinical investigators must file a form 717-1 within 30 days of being named as a participant on a protocol. NIH employee investigators with "significantly affected organization" (SAO) holdings must provide an update on their holdings to their IC ethics office every six months using a Form 717-1. If an investigator acquires a new personal financial holding in a "significantly affected organization" (SAO) or the value of an SAO has changed, he/she is required to notify the IC Ethics office with a Form 717-1 within 30 days of the change. Current SAO's are listed at http://ethics.od.nih.gov/Topics/SAO/sao-intro.htm A copy of the financial disclosure form for clinical investigators can be found at http://ethics.od.nih.gov/forms/hhs-717-1.pdf

21) List individuals serving on the protocol as an: Accountable Investigator, Adjunct PI, Medical Advisory Investigator, Lead Associate Investigator, Associate Investigator and/or Research Contact. For each identify their affiliation (i.e., outside entity) and if an NIH Employee or Non-NIH Employee.

Adjunct Principal Investigator: an individual serving as the principal investigator who is not an NIH employee. If the protocol has an Adjunct Principal Investigator, there must be a named NIH Principal Investigator who is an employee and who will be responsible for the conduct and conflicts analysis of the protocol. The relationship between the Adjunct PI and the NIH PI will allow for the conduct of collaborative protocols between the intramural and extramural/outside medical community.

Accountable Investigator: defined as a tenure or tenure-track investigator who is responsible and accountable for the scientific quality and expenditure of resources for the conduct of a clinical research protocol.

Medical Advisory Investigator: When the PI is not a physician, or when the Clinical Director, the IRB or the Director NIH CC considers it warranted, a medical advisor (MA) shall be identified in the protocol. The MA must be a member of the CC's Junior or Senior Medical Staff. There may be only one MA per protocol.

Lead Associate Investigator: An associate investigator who plays a leading role in the formulation, writing and implementation of a clinical research protocol under the mentorship of the protocol's principal investigator. A lead associate investigator may be a physician, a dentist, a Ph.D., an RN, a member of the allied health professions or a trainee.

Associate Investigators: Name each associate investigator, their affiliation and employment status. For NIH employees (e.g. FTE), Fellows, IRTA's, or special volunteers include their status as listed in the e-mail global directory (E, F, V etc) and their institute. For extramural or outside investigators include academic affiliation, contractor affiliation, or commercial affiliation.

Research Contact: Individual managing logistics for the protocol, and to who the Patient Recruitment and Public Liaison Office will refer potential participants to, when contacted.

22) No conflicts identified for NIH employees, or conflicts have been resolved through divestiture or waiver: Checked by the Institute or NIH Deputy Ethics Counselor when the NIH employees listed do not have a personal financial interest in the manufacturer of the drug, biologic or device used in the study (or their conflicts have been resolved by divestiture or waiver).

23) No conflicts exist however one or more NIH employees have a de minimus holding in the manufacturer of the product(s) used in the study. Checked by the Institute or NIH Deputy Ethics Counselor when an NIH employee holds a de minimus amount of stock (under $15,000) in the manufacturer of the drug, biologic or device used in the study and list the name of the manufacturer. A statement should be included in the informed consent document as per suggestions below.

24) No conflicts exist however one or more NIH employees have an over the deminimus holding in the manufacturer of the product(s) used in the study and has been cleared to participate by waiver. Checked by the Institute of NIH Deputy Ethics Counselor when an NIH employee holds over the deminimus amount in the manufacturer of the product(s) in the study, but the investigator has a waiver on file. A waiver ensures that all conflicts related to this holding have been considered and deemed to be a minimal risk based on the employee's federal position and role in the protocol. A statement should be included on the informed consent document as per the suggestions below.

Conflict of Interest Statements for NIH Protocol Consent Forms

In a Section called **Conflict of Interest** suggested **standard statements**:

1. The National Institutes of Health reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process http://ethics.od.nih.gov/forms/Protocol-Review-Guide.pdf You may ask your research team for additional information or a copy of the Protocol Review Guide.

2. One or more investigators participating in this study may have less than $15,000 of stock in the manufacturer of the product(s) used in this study. Under federal regulations, however, this is permissible and does not create a conflict of interest.

3. This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to adhere to the principles of the Protocol Review Guide but are not required to report their personal financial holdings to the NIH.

Optional statements:

Use this statement if developing a new drug or device:

1. The National Institutes of Health and the research team for this study have developed (a drug, imaging agent, device) being used in this study. This means it is possible that the results of this study could lead to payments to NIH scientists and to the NIH. By law, government scientists are required to receive such payments for their inventions. You will not receive any money from the development of _____.

Use this if the protocol is part of a CRADA:

2. The National Institutes of Health and the research team for this study are using (a drug, imaging agent, device) developed by (company name) through a joint study with your researchers and the company. This means it is possible that the results of this study could lead to payments to NIH scientists and to the NIH. By law, government scientists are required to receive such payments for their inventions. You will not receive any money from the development of _____.

Use this if an investigator has a waiver:

3. No conflicts of interest exist among NIH investigators based on federal regulations. One or more NIH employees have a personal financial holding in the manufacturer of the product(s) used in the study, but the conflict has been resolved by NIH ethics staff and Institute Leadership.