

## DISCLOSURE OF FINANCIAL INTERESTS FOR IRB REVIEW

Version Date: February 20, 2007

The Office for Protection of Research Subjects (OPRS) has modified its application forms to simplify the disclosure of financial interests to the campus Institutional Review Boards (IRBs). In the past, OPRS has asked for copies of the financial interest forms (Form 700-U and/or Form 740) that are completed in conjunction with sponsored research. **As of March 15, 2007, OPRS and the IRBs will no longer require nor accept these financial interest forms** (although the forms will continue to be used by other offices, such as the Office of Contract and Grant Administration and the Office of Clinical Trials).

As of March 15, Principal Investigators (PIs) will disclose information directly on the application for IRB review or exemption. This change is intended to reduce the administrative burden on investigators, research staff and OPRS staff while yielding more consistent and complete information for the IRBs.

For example, Form HS-1 (*Application to Involve Human Subjects in Research*) has been modified as follows:

- Section II, Question 3 now describes the IRB's financial disclosure requirements and then asks one simple "Yes or No" question: whether the Principal Investigator (PI) or any Co-Investigators or Key Personnel have any financial interests in the research. **This question must be answered whether or not the research is supported by extramural funds.**
- A new section, Section VIII, is designed to collect additional detailed information *only* if the answer to Section II, Question 3 is "Yes" and *only* from the individual(s) with financial interests. If the answer to Section II, Question 3 is "No," then no additional information is needed and Section VIII should remain blank.

Corresponding changes have been made to Form HS-7 (*Claim of Exemption from IRB Review*) and Form HS-9 (*Application for Research Review of Medical Records*). For the sake of simplicity, "Form HS-1" is used throughout this document to refer to whichever initial application is appropriate to your research. Where the Medical IRBs and General Campus IRBs have separate versions of items (such as checklists), both versions have been modified.

To remind PIs to report changes to financial interests over the life of the project, OPRS has also modified the addendum submission checklist and Form HS-4 (*Continuing Review Application*).

New and revised materials, such as forms and checklists, are being released with this guidance and appear on the Forms section of the OPRS website. **Old versions of these materials may not be used for any submissions to the IRBs after March 14, 2007.**

## **HOW WILL THE TRANSITION WORK?**

### ***Studies Already Approved or Under Review as of March 14, 2007:***

These studies will be “grandfathered” under the old disclosure procedure. You will not be required to update financial disclosure information *except* if there are new financial interests or changes to previously reported financial interests. Changes or new interests will need to be reported according to the procedures below for addendum or continuing review submissions.

If you have a new submission undergoing review and you have not yet responded to a request for Form 700-U and/or Form 740, you may choose to either submit those forms or to follow the new procedure, depending on which is most convenient for you. To follow the new procedure:

- Complete and submit the new Form HS-1, Section II (the new Section II is available from the OPRS website as a stand-alone item).
- If there is a positive disclosure, complete and submit the new Form HS-1, Section VIII (the new Section VIII is available from the OPRS website as a stand-alone item)

### ***New Studies Submitted On or After March 15, 2007:***

You may only use the new version of Form HS-1. **Use of an old version of Form HS-1 and/or use of Form 700-U or Form 740 on or after March 15 may lead to delays in the processing and review of your submission.** The following documents are new or have been revised:

- Checklist for New Submissions
- Form HS-1
  - Section II (revised)
  - Section VIII (new)(also available as a stand-alone document for distribution to multiple personnel or for disclosure of interests in multiple entities).

### ***Addendum Submissions On or After March 15, 2007:***

You are expected to report any changes in financial interests, so it is important that you check with colleagues and staff for updates whenever you are preparing an addendum. If there are no changes or new interests to report, you do not have to take any action.

The Checklist for Addendum Submissions has been modified to include a reminder about new or changed financial interests. In the event that you, or your colleagues or staff, have new or changed financial interests to report:

- Indicate in the cover letter that new or changed financial interests are being reported.
- Modify the answer to Section II, Question 3 of Form HS-1 accordingly.
- Complete Section VIII of Form HS-1 as needed.

The Checklist for Addendum Submissions has also been modified to include reminders about disclosing the financial interests of new personnel or any financial interests in new funding sources. It is important that you actively check whether these situations involve any new financial interests. If yes, then follow the above steps for reporting new or changed interests.

***Continuing Review Applications Submitted On or After March 15, 2007:***

When applying for continuing review, you are required to report whether or not there have been any changes in financial interests since the last review of the study. A new question has been added to Form HS-4. As when preparing addenda, it is important that you actively check with colleagues and staff for updates.

If there are changes or new financial interests to be reported as part of an application for continuing review:

- Modify the answer to Section II, Question 3 of Form HS-1 accordingly.
- Complete Section VIII of Form HS-1 as needed.

**MAY I USE THE NEW PROCEDURE BEFORE MARCH 15, 2007?**

Yes. You do not have to wait until March 15 to start using the updated forms and procedure.

**WHAT DO THESE CHANGES MEAN?**

The PI has always been responsible for the conduct of research and the IRB review process, including the disclosure to the IRB of the financial interests of relevant personnel. These changes will allow PIs to establish their own procedures for collecting and maintaining the information from colleagues and staff and then provide one clear answer to the IRB.

Also, detailed reporting is now limited to those individuals with a financial interest, thereby eliminating the burden of collecting multiple forms when there are no interests to disclose. The IRBs will also now be able to collect the complete range of information needed, instead of receiving information that varies according to funding source or the role of the individual.

The use of Form 700-U and Form 740 for the IRB process and for other purposes produced a great deal of confusion about where originals should be sent, whether one set of forms takes care of all requirements, where an investigator's completed forms end up, etc. Form 700-U and Form 740 will no longer be used for IRB purposes, eliminating a key source of this confusion.

**TO WHOM DO THE DISCLOSURE REQUIREMENTS APPLY?**

The IRBs need information about financial interests held by any UCLA employee who has or shares responsibility for the design, conduct or reporting of results of a project. Such an individual is also considered to have a financial interest if a spouse, registered domestic partner or dependent child of that individual has a financial interest. For example, if a co-investigator's spouse owns shares in the company sponsoring the study, the co-investigator is considered to have a reportable financial interest.

The disclosure requirement will typically apply to anyone named in the consent form as the PI or a Co-Investigator, but may apply to research staff as well. The PI is most familiar with the roles and contributions of everyone involved with the research and is therefore best able to determine who qualifies as Key Personnel.

**MY PROJECT ISN'T EXTRAMURALLY FUNDED/MY FUNDING COMES FROM THE FEDERAL GOVERNMENT, SO WHY DOES THIS APPLY TO ME?**

An individual can still have a financial interest in the outcome of the study whether or not there is an outside sponsor, or whether or not an outside sponsor is a for-profit entity. For example, an investigator may hold a patent on a product and test the product in a study funded out of his own pocket- the investigator still has a financial interest in the outcome of the study. As another example, an investigator who has a financial interest in the manufacturer of a drug being tested in an NIH-funded study has a financial interest in the outcome of the study. The previous procedures and forms did not always capture information about such interests.

If you do not have any financial interests to disclose, the only additional action you need to take is to check one box to indicate as much.

**DO THE DISCLOSURE REQUIREMENTS EXTEND TO COLLABORATORS AT OTHER SITES?**

If one of the UCLA IRBs serves as the designated IRB for research activities at another site, the UCLA PI is also responsible for collecting information about financial interests from researchers and staff at that site.

If collaborators at another site are overseen by that site's IRB, then the disclosure requirements of that IRB apply and the UCLA PI is not responsible for collecting information about financial interests from researchers and staff at that site.

**IF ONE OF MY CO-INVESTIGATORS IS OUT OF TOWN, DO I HAVE TO WAIT FOR HER DISCLOSURE BEFORE SUBMITTING MY APPLICATION?**

You may still submit your application for review. However, you should indicate in a cover memo that you do not yet have disclosure information for that co-investigator. If you are not able to provide the relevant information before IRB approval of the study, a codicil will appear on the approval notice. The codicil will prohibit her involvement until the IRB has received and acknowledged information about her financial interests.

**ARE THE IRBS COLLECTING THE SAME INFORMATION I SUBMIT WITH GRANT PAPERWORK?**

No. Although investigators and staff are accustomed to completing Form 700-U and Form 740 according to the definitions in the University's conflict of interest policies, the IRBs require that **any** financial interest be disclosed, regardless of the amount, the type of sponsor or the role of the individual. With this new method of collecting information, the IRBs will be better able to evaluate financial interests in terms of human subjects protection.

**CAN I GIVE THE IRB COPIES OF FORM 700-U, FORM 740 OR MY SPONSOR'S FINANCIAL DISCLOSURE FORMS INSTEAD?**

As of March 15, the IRBs will not accept any other disclosure forms. Since the IRBs are collecting information that might be different from what other review bodies require, the IRB review process will be smoother if all disclosures are made on the HS-1.

**IF I ANSWER THE DISCLOSURE QUESTIONS OF THE HS-1, WILL THAT TAKE CARE OF REQUIREMENTS FOR THE CONTRACTS AND GRANTS PROCESS?**

Completing the disclosure questions of the HS-1 will not satisfy any other University of California, state, federal or sponsor disclosure requirements. The IRBs collect this information for the purposes of IRB review only. The IRBs do not share this information, except when interests appear to cross the University's thresholds for review by the UCLA Conflict of Interest Review Committee (CIRC).<sup>1</sup>

**WHAT IS DIFFERENT ABOUT THE INFORMATION THE IRBS COLLECT?**

There are five key differences:

- Any financial interest is reportable, regardless of amount (except in the case of gifts, which must cross the \$50 threshold before being reported to the IRB).
- An interest is reportable to the IRB regardless of who holds the interest. For example, there is not a lower threshold for a PI than there is for a co-investigator.
- An individual is expected to report recent, current and anticipated financial interests.
- Interests in intellectual property related to the research are reportable, even if the intellectual property is licensed to The Regents of the University of California.
- Interests are reportable regardless of funding status or type of funding entity, even if there is no extramural funding or if extramural funding is provided by a non-commercial entity.

A sponsor's support for the proposed project (including salary support paid by the University from the grant or the reimbursement of study-specific travel costs) is not considered a financial interest. However, all sources of funding should be clearly noted in the IRB application and consent form.

**WHAT ABOUT INCENTIVE PAYMENTS, SUCH AS ENROLLMENT BONUSES?**

Please be reminded that campus policy does not allow acceptance of incentive payments. See the memo at [http://www.research.ucla.edu/researchpol/memos/incentive\\_pay\\_guidance.pdf](http://www.research.ucla.edu/researchpol/memos/incentive_pay_guidance.pdf).

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<sup>1</sup> For information regarding conflicts of interest and the CIRC review process, see <http://www.research.ucla.edu/researchpol/coi.htm>

## **IF I DISCLOSE A FINANCIAL INTEREST, DOES THAT MEAN I HAVE A CONFLICT OF INTEREST?**

Collection of this information doesn't mean that the IRB is determining that there is a conflict of interest. The new process is designed to consistently collect information the IRBs need for determining what might be important to potential subjects. The new process does not change the University's standards or processes for identifying and managing conflicts of interest.

## **WHAT SHOULD I DISCLOSE IN CONSENT FORMS?**

If a PI discloses a financial interest to the IRB, the interest does not necessarily need to appear in the consent form. The IRB will make a determination based on the nature of the interest and the context of the project. If necessary, the IRB will then request that a specific disclosure be made.

Whether or not there is a financial interest, the introductory section of a consent form should always identify sources of extramural funding. This is typically accomplished with a statement such as "X is the sponsor of this study." A sponsor may be defined in the consent form as the organization covering UCLA's costs of running the study.

Statements about the sponsor "paying" UCLA or the PI to conduct the study should be avoided. Such statements may create the impression that UCLA conducts research on a for-profit basis.

In addition to financial interests, please note the requirement that the potential conflict between a doctor's roles as a subject's health care provider and as a researcher must be disclosed in consent forms. See the April 20, 1999 memorandum from the Executive Vice Chancellor at [http://www.oprs.ucla.edu/human/news/item?item\\_id=119763](http://www.oprs.ucla.edu/human/news/item?item_id=119763) for further details.

## **WHO CAN HELP ME WITH QUESTIONS?**

Questions about the procedures may be directed to the staff of the IRB handling your study. Medical IRB staff may be reached through (310) 825-5344 and General Campus IRB staff may be reached through (310) 825-7122. Questions about financial disclosure policy may be directed to OPRS Assistant Director Kip Kantelo at [kkantelo@oprs.ucla.edu](mailto:kkantelo@oprs.ucla.edu). See <http://www.oprs.ucla.edu/human/irbstaff> for additional contact information.

## **GLOSSARY**

- *Anticipated Interests*: interests expected at any point in the next 12 months.
- *Key Personnel*: all UCLA employees, including the Principal Investigator and any co-investigators or research staff who share responsibility for the design, conduct or reporting of results of a project. For IRB purposes, this includes all individuals who will be named in an informed consent form for a project.
- *Recent Interests*: interests held at any point in the previous 12 months.
- *Significant Financial Interest*: definitions by type of funding source are available in the corresponding policy at [http://www.adminvc.ucla.edu/appm/entry\\_900.html](http://www.adminvc.ucla.edu/appm/entry_900.html).