MINUTES DRAFT
Thursday, July 11, 2002
Room LP 371

PRESENT:  M. Weiner (Chair), R. Malone, D. Deen, D. Kitterman, M. Shultz, J. Levine, P. Benner,
               H. Bourne, M. Schambelan, L. Sheiner

ABSENT:  S. Cummings, D. Rennie,

The meeting of the Conflict of Interest Task Force was called to order by Chair Weiner on July 11,
2002 at 3:08 p.m. in room LP 371. A quorum was present.

Announcements from the Chair

No announcements.

Approval of Minutes

The minutes of June 6, 2002 will be approved at the meeting of August 7, 2002.

Discussion of Motions Submitted for Inclusion in Final Task Force Report

Prior to the meeting, Task Force members submitted five motions (attached) for inclusion in the final
report of the task force. The Task Force agreed to discuss each of these motions prior to voting by
electronic ballot on their inclusion in the final report of the Task Force. A summary of the
discussion of these motions follows:

Motion 1 – Staffing Resources of the Chancellor’s Advisory Committee on Conflict of Interest
Forwarded by R. Malone
Seconded by P. Benner

The Task Force unanimously agreed to recommend inclusion of clauses $f$ through $h$ of this motion in
the final report. These clauses read:

$f)$ the number of conflict of interest disclosures is increasing and over 7000 disclosures and 200
positive disclosures are reviewed annually;
g) staffing for the Chancellor’s Committee on Conflict of Interest, the body charged with managing COI issues for UCSF, is currently limited to one person; and

h) staffing for the UC campus with the next highest number of disclosures (2460/130 positive) is three FTEs;

THEREFORE, the COITF recommends that:

• Staffing resources for the Chancellor’s Committee on COI be immediately and significantly increased.

The Task Force discussed clauses a through e extensively and agreed to put two motions forward for a vote by electronic ballot. The first motion will include clauses a through h and will read:

Whereas the COITF finds that:
  a) relations between scientific investigators at the university and private industry are increasing in number and complexity;

  b) the university wishes to encourage innovation and dissemination of research products through such collaborations;

  c) the increase in these relationships creates potentially serious conflict of interest issues; d) issues of conflict of interest are increasingly matters of public and media concern;

  e) ensuring protection of research subjects, preserving the public’s trust in its institutions, and protecting the integrity, objectivity, rigor and openness of the scientific community while encouraging research productivity and dissemination are linked goals of the university;

  f) the number of conflict of interest disclosures is increasing and over 7000 disclosures and 200 positive disclosures are reviewed annually;

  g) staffing for the Chancellor’s Committee on Conflict of Interest, the body charged with managing COI issues for UCSF, is currently limited to one person; and

  h) staffing for the UC campus with the next highest number of disclosures (2460/130 positive) is three FTEs;

THEREFORE, the COITF recommends that:

• Staffing resources for the Chancellor’s Committee on COI be immediately and significantly increased.

The second motion will include only clauses e through h and will read:

Whereas the COITF finds that:
  e) ensuring protection of research subjects, preserving the public’s trust in its institutions, and protecting the integrity, objectivity, rigor and openness of the scientific community while encouraging research productivity and dissemination are linked goals of the university;
f) the number of conflict of interest disclosures is increasing and over 7000 disclosures and 200 positive disclosures are reviewed annually;

g) staffing for the Chancellor’s Committee on Conflict of Interest, the body charged with managing COI issues for UCSF, is currently limited to one person; and

h) staffing for the UC campus with the next highest number of disclosures (2460/130 positive) is three FTEs;

THEREFORE, the COITF recommends that:

• Staffing resources for the Chancellor’s Committee on COI be immediately and significantly increased.

Motion 2 – Ethical Considerations in Conflict of Interest Policy Discussions
Forwarded by R. Malone
Seconded by M. Shultz

The Task Force discussed at length the motion to include the following statement of ethical considerations as a preamble to the Task Force report and to be incorporated into the final UCSF policy statement on Conflict of Interest.

The following considerations relate to COI issues concerning clinical trials with human subjects:

1. Conducting scientific research at a publicly funded institution is a privilege that constitutes a public trust and creates certain obligations for researchers. Conflict of interest policies at such institutions have at least three linked primary purposes: ensuring protection of research subjects; preserving the public’s trust in its institutions, and protecting the integrity, objectivity, rigor and openness of the scientific community.

2. Changes in existing conflict of interest policies are ethically justified if they enhance protection of research subjects, enhance public trust in the university, enhance the integrity, objectivity, rigor and openness of the science conducted under university auspices, and are necessary to facilitate effective working relationships with commercial interests in order to enhance public benefit.

3. An appointment at a publicly supported university creates an obligation among scientists to put public interests before personal or private commercial interests. COI policies are designed to provide procedural as well as substantive assurances that this obligation will be respected. The effectiveness of disclosure (of financial ties) alone is limited by disparities in power and communications gaps between the scientific community and the public. Disclosure procedures should clearly identify the nature of financial or other relationships that could create conflicts of interest, reach those who might be most likely to be affected by such relationships (including but not limited to research subjects, journal editors and readers, attendees at scientific meetings, developers of clinical practice guidelines and pharmaceutical formularies, and institutional review bodies), and be effectively monitored on a systematic and ongoing basis by the university. When in doubt, the default position must be the protection of research subjects and the public.

4. The university serves public interests and acts independently from private commercial interests, which have as their primary aim provision of profit. Sustaining independence in the
conduct of research, regardless of its funding source, is essential to retaining public trust in science conducted at publicly supported institutions. This is, in fact, one of the very reasons companies seek affiliations with university researchers, and COI policies should be designed to provide and ensure institutional support for researcher independence by building in safeguards aimed to avert possible undue influence as well as the appearance of such influence. Public trust is not merely an issue of “perception” but is a substantive issue which bears on both the willingness of the public to provide ongoing support for its institutions and the scientific reputation of the entire research community at such institutions.

5. Issues of technology transfer and diffusion of innovation create different ethical issues and obligations in their own right and should be considered separately from the scientific development and testing of procedures, technologies and therapies.

The Task Force considered whether the language of this motion should be changed to reflect that these considerations apply to all areas of scientific research, not just those which are clinical in nature. The Task Force further considered to what extent a conflict of interest policy should regulate human subject research and whether regulation related to conflict of interest, should be generated by the Committee on Human Research. The Task Force extended this discussion to include consideration of:

Motion 3 – Clinical and Basic Science Research
Forwarded by Dennis Deen
Seconded by Morris Schambelan

This motion reads:

The members of the Task Force on Conflict of Interest believe that policies concerning conflict of interest should not apply different standards to different types of research, i.e. policies concerning conflict of interest should not differentiate between clinical and basic science research.

The Task Force acknowledged the complexity of the issues involved in a discussion of conflict of interest policies and agreed to extend further discussion of all motions until the meeting of August 7, 2002 prior to voting. Members recognized that there is a need to establish within the UCSF Guidelines on Conflict of Interest a minimum regulatory guideline which will apply to all areas of scientific research. This guideline may be supplemented by more stringent guidelines related only to clinical research. Task Force members acknowledged that there may be an inherent dichotomy between freedom of research and maintenance of research integrity. The Task Force believes that this dichotomy may be addressed by regulations within the UCSF Guidelines which are incrementally restrictive according to the type of research to which they apply.

L. Sheiner and D. Kitterman will work to provide the Task Force with revised motions relating to guidelines regulating clinical research prior to the meeting of August 7, 2002.

The meeting adjourned at 4:55 p.m.