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BERKELEY: DONNER LABORATORY

June 30, 1977

TO: Donner Staff

RE: Research Involving Human Subjects

This memo is to advise you of several important procedural changes relating to timing and documentation on human subject matters. In addition, it sets forth information concerning several aspects of human subject involvement which, based on our experience during the past year, are in need of greater attention. Please read this material carefully. All investigators should consider these points during their proposal-planning process. Questions should be directed to James L. Born, Baird Whaley, or Jan DeMoor.

Timing

Both NIH and ERDA rules now require that certification of human subject approval be secured from the Institutional Review Board (the Berkeley Campus Committee for the Protection of Human Subjects) no later than two months following the deadline for which the proposal is submitted. This is a change from the previous "grace" period of three months. For virtually all of our protocols, this will require completion of the documentation, and submission to the LBL Human Use Committee for initial review, not later than the week preceding the proposal deadline. Preparation and timely submission are the responsibility of the investigator.

Timely submission is vital. While we have not yet lost a grant from failure to comply with human subject procedural requirements, we have had a very close call relating to interruption of ongoing support. It is clear that funding agencies are going to treat human subject deadlines with the same rigidity as application deadlines. Since we are able to observe the latter deadlines, there is no reason for us not to meet the former ones. But to do so, we will have to relegate to the past any attitudes that human subject matters are an administrative burden of secondary concern. They are as integral and important a part of the proposal process as the scientific protocol and the budget.

Central Filing of Consent Forms

CPHS regulations now require that the consent forms signed by the subjects be filed centrally in each major administrative unit. Effective at once, the original of each consent form should be forwarded immediately after signature to Ms. Janice DeMoor, Room 468 Donner, who will maintain our central repository. Investigators who need to retain a copy for patient records may do so, provided there is secure storage to preserve confidentiality.

Changes in Consent Forms

A question arose recently as to whether a minor change might be made, "on the spot", in a consent form to accommodate the wishes of a subject. The answer

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is "No". The consent form is approved by CPHS, along with the protocol. Any change in the consent form, regardless of who makes it, creates a new form which has not been approved by CPHS. The use of an unapproved form would violate the regulations under which we are obliged to operate, and would place the investigator in potential legal jeopardy. A subject who is unwilling to sign the consent form, as presented, may be exercising his/her prerogative not to participate in the activity, and this right must be respected regardless of any inconvenience that might be caused the investigator. In every instance, it is the responsibility of the investigator, or appropriate professional personnel designated by him/her, to be sure that the subject has obtained the full understanding necessary to agree or decline to participate.

Consistency of Human Subject Protocols with Proposals

All activities involving human subjects set forth in a research project or proposal should be covered by protocol(s)/consent form(s), or explained in a covering memorandum. When human subject documents for a project are submitted to CPHS, they are accompanied by a copy of the proposal (NIH application, 189 form, etc.). Be assured that the CPHS staff reads every proposal word-for-word, and is fully capable of identifying human subject activities not covered by the documentation. The CPHS certification form (which the funding agency must receive before an award is made) will indicate explicitly any activity set forth in the proposal which has not been reviewed and approved.

In some proposals there may be statements of prospective human subject involvement for which it is not possible to prepare a specific protocol until the project has been underway for some time, as human studies may depend on the outcome of animal research, or instrument development, etc. Such cases can and should be explained in an accompanying memorandum stating that there is no human involvement in the initial phase of the study, and that the proper protocol and consent form will be submitted for approval prior to initiating human use involvement. CPHS will issue approval for the preliminary phase of such a study, and will annotate the certification form accordingly.

Likewise, activities which are clearly not to be undertaken during the first year of a project need not have a protocol/consent form when the proposal is originally submitted, but the investigator must provide an explanation in an accompanying memo.

The recitation in a proposal of activities involving human subjects which are not covered by either a protocol/consent form or a memo, will certainly generate a processing delay, and may cause reduced, delayed, or zero funding from the agency.

Approval for Cooperative Studies

In some instances access to subjects or materials of human origin is gained through another institution. This requires submission to our CPHS of the cooperating institution's protocol and consent form.* along with evidence that the activity has current approval from the cooperating organization's Institutional

* For cases involving only residual material, it may be sufficient to provide a copy of the surgical consent form, provided the form gives the pathologist complete discretion in disposition of severed material.

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Review Board

This is in addition to your own protocol. Our recent experience has shown that some of our investigators' potential collaborators do not have current approval at their own institution. You should be mindful of this possibility, and request the necessary material from your collaborators far enough in advance of the deadline to insure that your own approval here will not be delayed. Other types of collaboration involve provision of materials of human origin by LBL to another institution, participation in human subject activities at LBL by a staff member of another institution, or participation in human subject activities at another institution by an LBL staff member. Most of these activities require approval by both the Berkeley Campus CPHS and the cooperating institution's Institutional Review Board.

Annual Review and Renewal

Each approved protocol/consent form requires annual review and renewal, usually at the same time the project is being submitted for continued funding. Investigators should submit a copy of each protocol/consent form that they wish renewed (it is the investigator's responsibility to furnish these documents), along with a brief progress report on human subject activities under each protocol during the past year: number of subjects; absence of untoward effects (if untoward effects occurred during the year, they should be reported immediately); feedback (both positive and negative) from the subjects on their participation; the extent to which the research objectives were achieved, etc.

If any changes are being requested in the protocol or consent form, these should be clearly stated, along with the reasons therefor.

Care in Preparation of Protocol(s)/Consent Form(s)

Complete, well written protocols/consent forms, which fulfill all requirements of the CPHS, will expedite the approval process by eliminating the delays which arise when we must return documents to the investigator for correction of deficiencies. A written statement of CPHS guidelines can be obtained from Jan DeMoor.

Final Reminder

You must submit protocols and consent forms for all research and development involving human use regardless of funding or source of support.

ELA:gw

Edward L. Alpen