DEPARTMENT OF HEALTH & HUMAN SERVICES

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April 27, 2000

TO: OPRR Staff

FROM: Director, OPRR

SUBJECT: Human Subject Research Compliance Oversight Procedures

As you know, the Office for Protection from Research Risks (OPRR) is responsible for oversight of compliance by awardee institutions with the Department of Health and Human Services (HHS) Regulations for Protection of Human Subjects (45 CFR Part 46) . This memorandum summarizes the procedures utilized by OPRR staff in conducting compliance oversight activities. These procedures have been developed over a period of years, and their effectiveness has been demonstrated in a number of investigations. Deviations from these procedures should occur only in extraordinary circumstances and must be approved by the Director, OPRR.

Background

Institutions engaged in human subject research that is conducted or supported by HHS, must provide written Assurances of Compliance to HHS describing the means they will employ to comply with the HHS Regulations. OPRR negotiates and approves these Assurances on behalf of the Secretary, HHS. Each Assurance incorporates the individual institution's needs, research practices, and procedures. It must be consistent with the HHS Regulations. An Assurance approved by OPRR commits the institution(s) and its personnel to full compliance with the Regulations.

In carrying out its oversight responsibility, OPRR evaluates all allegations or indications of noncompliance with the HHS Regulations derived from any source. All compliance oversight evaluations are predicated on the HHS Regulations and the institution's Assurance of Compliance.

OPRR holds accountable and depends upon institutional officials, committees, research investigators, and other agents of the institution to assure conformance with the institution's Assurance and thus with the Regulations. Only through the partnership established by the Assurance can the shared responsibility to protect the rights and welfare of human subjects be discharged in accordance with Section 491 of the Public Health Service Act.

Compliance Oversight Evaluations

When OPRR initiates a compliance oversight evaluation, appropriate institutional officials are so advised in writing, and they are informed as to the likely administrative course of events. Activities expected of the institution are explained initially and at appropriate times during the course of the evaluation. Except in rare circumstances when sound ethics dictates the need to act immediately, OPRR takes no action against any institution without first affording the institution an opportunity to offer information which might refute or mitigate adverse determinations.

Under HHS regulations at 45 CFR Part 5, documents related to compliance oversight evaluations may be subject to the provisions of the Freedom of Information Act (FOIA). In most cases, such documents are exempt from the disclosure provisions of the FOIA while the evaluation is in progress, and OPRR treats them confidentially. However, determination letters are available for release under FOIA at the time they are provided to the institution. In addition, most other documents become publicly available once the compliance evaluation is closed. OPRR routinely advises appropriate HHS officials concerning the status of its evaluations and may be required to inform members of Congress and provide to Congress some or all of the information or documents in its files.

Under HHS regulations at 45 CFR Part 5b, records that are retrieved by an individual's name or other personal identifier are subject to the provisions of the Federal Privacy Act. Information regarding OPRR's compliance oversight activities is maintained only in a system of records identifying the institution under evaluation. Records can be retrieved by institutional name or Assurance number. OPRR maintains no system of records related to compliance oversight activities through which records can be retrieved by individuals' names or other personal identifiers.

Possible Outcomes

Corrective actions based on compliance oversight evaluations are intended to remedy identified noncompliance with the HHS Regulations and to prevent reoccurrence. Because each case is different, OPRR tailors its corrective actions to foster the best interests of human research subjects, and to the extent possible, the institution, the research community, and HHS. Most compliance oversight evaluations and resultant corrective actions are resolved at the OPRR level. In some instances, however, OPRR recommends actions to be taken by other HHS officials.

OPRR's compliance oversight evaluations may result in one or more of the following outcomes:

(1) OPRR may determine that protections under an institution's Assurance of Compliance are in compliance with the HHS Regulations.

(2) OPRR may determine that protections under an institution's Assurance of Compliance are in compliance with the HHS Regulations but that recommended improvements to those protections have been identified.

(3) OPRR may restrict its approval of an institution's Assurance of Compliance. Affected research projects continue to be supported by HHS only if the terms of the restriction are being satisfied. Examples of such restrictions include, but are not limited to,

   (a) suspending the Assurance's applicability relative to some or all research projects until specified protections have been implemented;

   (b) requiring prior OPRR review of some or all research projects to be conducted under the Assurance;

   (c) requiring that some or all committee members and institutional officials, as well as investigators conducting research under the Assurance, receive appropriate human subject education;

   (d) requiring special reporting to OPRR.

(4) OPRR may withdraw its approval of an institution's Assurance of Compliance. The institution's research projects cannot be supported by any HHS component until an appropriate Assurance is approved by OPRR.

(5) OPRR may recommend to appropriate HHS officials

   (a) that an institution or an investigator be temporarily suspended or permanently removed from participation in specific projects, and/or

   (b) that peer review groups be notified of an institution's or an investigator's past noncompliance prior to review of new projects.

(6) OPRR may recommend to HHS that institutions or investigators be declared ineligible to participate in HHS-supported research (Debarment). (NOTE: A suspension of eligibility for Federal funding may precede a Debarment.) If OPRR makes this recommendation, the Debarment process will be initiated in accordance with the procedures specified at 45 CFR Part 76. Any Debarment is Government-wide, and not just applicable to HHS funding.

Sequence of Events

The typical sequence of events to be followed in an OPRR compliance oversight evaluation is as follows:

(1) OPRR discovers or receives an allegation or indication of noncompliance with the HHS Regulations (45 CFR Part 46). OPRR may receive such allegations or indications from a variety of sources, including the institution itself. (Under the HHS Regulations, institutions are required to report any serious or continuing noncompliance to OPRR.)

(2) OPRR determines that it has jurisdiction in the matter on the basis of HHS support and/or an applicable Assurance of Compliance. (NOTE: Once jurisdiction has been established, OPRR may, at any time, require interim corrective actions under an Assurance of Compliance, or should it find noncompliance during the course of its evaluation, restrict or temporarily suspend the Assurance, when it considers such actions necessary to protect human research subjects.)

(3) OPRR either (i) acknowledges the institution's report of noncompliance or (ii) notifies the institution's Assurance Signatory Official of the possible noncompliance and, as necessary, initiates a compliance evaluation and requests that the institution investigate the matter and report to OPRR by a specified date. Depending upon the circumstances involved, OPRR may communicate directly with other affected institutional officials or personnel. Where the allegations of possible noncompliance involve a specific research investigator, OPRR will notify the investigator involved.

(4) OPRR evaluates the institution's report and any other pertinent information to which it has access. OPRR may request additional information from the institution or conduct an on-site evaluation of protections under the applicable Assurance of Compliance. (NOTE: On-site evaluations of protections under an Assurance of Compliance may also be conducted in the absence of specific allegations or indications of noncompliance.)

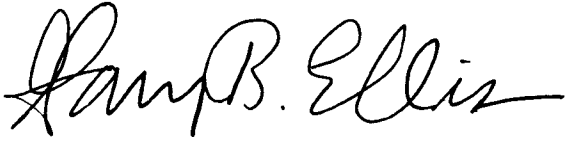
(5) OPRR issues in writing a determination for each evaluation to the Signatory Official and other appropriate institutional officials. The determination letter to the institution summarizes (i) findings of noncompliance with the HHS regulations, if any; and/or (ii) the corrective actions proposed and or/implemented by the institution that appropriately address the findings of noncompliance. In such circumstances, the complainant(s) are ordinarily informed in writing of OPRR's determination upon completion of its evaluation.

(6) Except as noted above, OPRR ordinarily makes no official announcement that a final determination of compliance oversight findings has been issued to the institution and

complainant. Once issued, however, the final determination becomes available under the FOIA, as do other related documents.

(7) An OPRR determination document may be made accessible on the OPRR website (http://grants.nih.gov/grants/oprr/oprr.htm) once it has been released pursuant to a request made under the Freedom of Information Act.

(8) An institution may request review by the Director of OPRR of determinations and findings resulting from a compliance oversight evaluation.



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