NOTE: THIS GUIDANCE HAS BEEN REPLACED BY OHRP'S OCTOBER 16, 2008 GUIDANCE ENTITLED, "ENGAGEMENT OF INSTITUTIONS IN RESEARCH." CLICK HERE FOR THE OCTOBER 16, 2008 GUIDANCE.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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December 23, 1999

TO: Division of Human Subject Protections, OPRR

FROM: Director, Division of Human Subject Protections, OPRR

SUBJECT: Engagement of Pharmaceutical Companies in HHS-Supported Research

Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(a) require that each institution "engaged" in HHS-supported human subjects research provide OPRR with a satisfactory Assurance to comply with the regulations, unless the research is exempt under 45 CFR 46.101(b).

An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

A pharmaceutical company is automatically considered to be "engaged" in human subjects research whenever it receives a direct HHS award to support such research. In such cases, an Assurance is required because the awardee company bears ultimate responsibility for protecting human subjects under the award.

Pharmaceutical companies may also become "engaged" in HHS-supported human subjects research without receiving a direct HHS award. This memorandum clarifies when an Assurance is required from pharmaceutical companies that (i) provide test articles regulated by the US Food and Drug Administration (FDA) for use in HHS-supported research; (ii) supply other materials or support for HHS-supported research; or (iii) otherwise collaborate in HHS-supported research.

Examples

(A) Pharmaceutical companies are considered "engaged" in human subjects research (and must provide an Assurance) if their non-exempt involvement in HHS-supported research includes either or both of the following:

(1) Companies whose employees or agents intervene or interact (e.g., by performing invasive or noninvasive procedures or manipulating the environment) with living individuals for research purposes.

(2) Except as described in (B) below, companies whose employees or agents obtain, receive, or possess private information that is individually identifiable (either directly or indirectly through codes) for research purposes (e.g., obtaining or receiving private information from medical records in an individually identifiable form; receiving coded data that can be linked to individual subjects by members of the HHS collaborative research team).

Where a pharmaceutical company's engagement in research is limited to receiving or possessing individually identifiable private information, OPRR will accept an Assurance from the pharmaceutical company wherein the company simply agrees to comply with the determinations of all Institutional Review Boards (IRBs) overseeing the research. In such cases, the IRB-approved protocol must clearly describe (i) the role of the pharmaceutical company in the research; (ii) the company's access to identifiable private information; and (iii) the extent to which confidentiality will be maintained.

(B) Pharmaceutical companies are not considered "engaged" in human subjects research (and do not need an Assurance) if their involvement is limited to the following:

(1) Companies whose employees or agents neither interact or intervene with living individuals nor obtain, receive, or possess identifiable private information about living individuals (e.g., company employees receive and/or analyze data that cannot be linked to individual subjects, either directly or indirectly through codes, by any member of the HHS collaborative research team).

(2) Companies whose employees or agents receive coded, or other potentially identifiable, private information only in accordance with a written agreement that unequivocally prohibits release of identifiers to the company.

(3) Companies whose employees or agents access or review identifiable private information solely for purposes of on-site quality auditing, where (i) a written agreement unequivocally prohibits use or release of such information for other purposes; and (ii) the IRB-approved protocol and informed consent document clearly describe this practice.

(4) Companies whose employees or agents receive identifiable private information solely for purposes of satisfying FDA reporting requirements, where (i) a written agreement unequivocally prohibits use or release of such information for other purposes, and (ii) the IRB-approved protocol and informed consent document clearly describe this practice.

Assurance Coordinators within the Division of Human Subject Protections (DHSP) retain the authority to determine whether companies are "engaged" in human subjects research consistent with the above guidelines. The DHSP Director and the Assurance Branch Chief should be consulted if Coordinators require assistance in applying these guidelines to specific situations.

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