DDIR memorandum

DATE: June 12, 2006

TO: Clinical Research Protocol Principal Investigators
Clinical Research Protocol Associate Investigators
NIH IRB Chairs

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Research Use of Stored Human Samples, Specimens or Data

This memorandum is to clarify and strengthen the NIH Intramural Research Program's (IRP) requirements for the research use of stored human samples, specimens and data consistent with DHHS requirements. Please review the attached OHSR Information Sheet. It has been updated to clarify these requirements and provides definitions that I use in this memorandum. I want to emphasize the following points:

1) NIH IRB-approved research protocols in which IRP researchers intend to collect and store human specimens or data: All such protocols must include a written description of the intended use of the samples; how they will be stored; how they will be tracked; what will happen to the samples/specimens/data at the completion of the protocol, and what circumstances would prompt the PI to report to the IRB loss or destruction of samples. New protocols should include this information at the time of initial review. For ongoing protocols, this information may be added at the time of the next continuing IRB review.

2) Research involving stored identified or coded samples, specimens or data when IRP investigator can identify the subjects: Such research must receive prospective and continuing NIH IRB review and approval. Continuing IRB review and approval is required as long as research analyses are ongoing. This means that: 1) even after a protocol's subject enrollment and research-related interventions are complete, continuing IRB review and approval are required for ongoing research analyses and, 2) the research use of stored specimens or data collected under now-terminated IRP protocols may occur only with prospective and continuing NIH IRB review and approval.

3) Research involving stored unlinked or unidentified specimens or data: Such research may be exempt from the requirement for IRB review and approval. NIH requirements for obtaining exemptions have not changed. The NIH Office of Human Subjects (OHSR) is authorized to determine whether a research activity is exempt. IRP investigators must submit a formal request to OHSR by completing Form #1 found on the OHSR website at **http://ohsr.od.nih.gov/info/info.html**.

4) Research collaborations involving sending or receiving stored specimens or data: For discussion of IRP guidelines on research collaborations, please review the information in The Gray Booklet at **http://ohsr.od.nih.gov/guidelines/guidelines.html**. Prospective and continuing NIH IRB review and approval is required for research collaborations in which IRP researchers send coded samples (for which they maintain the key) to non-NIH investigator(s). The protocol must identify the names of the collaborating researchers and their affiliated institutions. Before sending the samples, IRP investigators should contact an IC technology development coordinator for guidance on an appropriate NIH transfer agreement. IRP researchers whose collaborations involve the receipt of samples collected and sent by non-NIH researchers from non-NIH subjects should contact OHSR for guidance.

Action Items:

1) All new IRP research activities must fulfill the requirements set forth in this memorandum.

2) IRP researchers are requested to stop research activities involving the use of stored identified or coded specimens or data that are not consistent with the requirements set forth in item 2), above. Please submit to the appropriate NIH IRB, a completed NIH form 1195 along with a written request (i.e., protocol or memorandum) containing the items outlined in Information Sheet #14 (IV. 3). Research may take place after IRB review and approval.

3) IRP investigators whose research activities involving unidentified or unlinked stored specimens or data that are not consistent with the requirements set forth in 3), above should contact OHSR as soon a possible to request an exemption from IRB review.

If you have questions, contact your NIH IRB Chair or OHSR. OHSR is located in Building 10, Room 2C146 and the phone number is 301-402-3444. For questions involving transfer of biological materials into and out of the NIH, please contact your IC technology development coordinator.

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CC: Dr. Gallin
NIH IRB Administrators
NIH Principal Investigators
Institute Directors
Clinical Directors
Scientific Directors