

## Correspondence on “Non-engaged” Scenarios

As noted in OHRP’s October 16, 2008 *Guidance on Engagement of Institutions in Human Subjects Research*, the scenarios of when an institution is not engaged in human subjects research are not all-inclusive (see <http://www.hhs.gov/ohrp/policy/engage08.pdf>). Since the guidance document was issued, on a case-by-case basis in response to specific requests from institutions, OHRP has found some institutions in certain circumstances to be not engaged, even though the exact non-engaged scenario is not included in OHRP’s October 16, 2008 guidance document.

Since these exceptions have been granted on a case-by-case basis in certain circumstances, institutions should not extrapolate from these descriptions and determine they are not engaged. If investigators or institutions have questions about whether their involvement in a non-exempt human subjects research study would make them engaged in the research, contact OHRP by phone at (866)447-4777 (toll-free within the U.S.) or (240)453-6900, or by e-mail at [ohrp@hhs.gov](mailto:ohrp@hhs.gov). When OHRP receives requests that institutions be considered “not engaged”, the analysis will be guided by consideration of whether the institution's participation is so limited or marginal that considering them to be “engaged” would not meaningfully add to protection of the human subjects in research. The following are descriptions of the activities that OHRP determined did not make the institution engaged in the specific non-exempt human subjects research projects that were in question:

### **Awardee Institution**

The institution received a grant award from the National Institutes of Health (NIH) for the conduct of non-exempt human subjects research (i.e. was an awardee institution), but no specific human subjects research studies were described in the grant application. In this case, the awardee institution planned to solicit research proposals that would be funded under the awardee institution’s NIH grant. Institutions other than the awardee institution could receive these sub-awards from the awardee institution. The institution receiving the NIH award would have no involvement in the conduct of the research conducted at the other institutions.

Note that in this case, OHRP determined that the awardee institution of the NIH award was not engaged in the non-exempt human subjects research studies that were to be carried out by other institutions under the award. This was an exception to the “engaged” scenario described in section III.A.(1) of OHRP’s October 16, 2008 *Guidance on Engagement of Institutions in Human Subjects Research*.

## **Data Center**

The institution's employees helped to maintain and operate a data center that had been approved by an institutional review board (IRB), and these employees also obtained individually identifiable private information from the data center to assist investigators from engaged institutions with any of the following activities, provided the activities had been described in the IRB-approved data center protocol:

1. Consulting with an investigator from an engaged institution on elements within the dataset that would meet the investigator's needs;
2. Consulting with an investigator from an engaged institution on analytic strategy;
3. Designing the analysis for an investigator from an engaged institution;
4. Developing analytic code for an investigator from an engaged institution; and
5. Interpreting the results of analyses run in the data center for an investigator from an engaged institution.

Note that OHRP determined that the institution operating the data center was not engaged in the human subject research being carried out by other institutions, even though the services provided by the institution operating the data center were not typically performed by the institution for non-research purposes. This is in contrast to the "non-engaged" scenario described in section III.B.(1) of OHRP's October 16, 2008 Guidance on Engagement of Institutions in Human Subjects Research. The "non-engaged" scenario described in section III.B.(1) of OHRP's guidance document is limited to commercial or other services that are typically performed by an institution for non-research purposes, and identifies other conditions that need to be satisfied.

## **Magnetic Resonance Imaging (MRI) Research Facility**

The MRI research facility's involvement in human subjects research was limited to the following:

1. Permitted use of their MRI research facility for intervention or interaction with subjects by investigators from another institution that was engaged in the research; and
2. Involved their employees or agents interacting or intervening with human subjects in the research by providing investigators from the engaged institution with only technical assistance in operating the MRI equipment.

Note that OHRP determined that the MRI research facility was not engaged in the human subjects research being carried out by other institutions even though the MRI services being provided were not typically performed by the MRI research facility for non-research purposes. This is in contrast to the “non-engaged” scenario described in section III.B.(1) of OHRP’s October 16, 2008 Guidance on Engagement of Institutions in Human Subjects Research. The “non-engaged” scenario described in section III.B.(1) of OHRP’s guidance document is limited to commercial or other services that are typically performed by an institution for non-research purposes, and identifies other conditions that need to be satisfied.