

Article courtesy of Terry Reser, SNL

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By IRBFORUM Listserv

OHRP ON FWAS AND REGISTRATION

OHRP has posted clarifying language on its website regarding OHRP-approved assurances and OHRP-registered Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs). Regarding registered IRBs, the fact that an IRB or an IEC is registered with OHRP does not mean that OHRP has determined that the IRB reviews research in accordance with the requirements of the Department of Health and Human Services (HHS) Protection of Human Subjects regulations, 45 CFR part 46, and does not mean that the IRB or IEC has the appropriate competence or expertise to review a particular research project.

Regarding approved assurances, the fact that OHRP has approved an institution's assurance does not mean that OHRP has determined that the institution is complying with the requirements of the HHS Protection of Human Subjects regulations, 45 CFR part 46. It means that an institution has submitted all of the documentation OHRP requires to constitute a commitment by the institution to comply with the requirements of 45 CFR part 46 when its employees or agents engage in non-exempt human subjects research conducted or supported by HHS or other research covered by the assurance.

These clarifications are now included on several of OHRP's web pages related to IRB registration and assurances (e.g. <http://www.hhs.gov/ohrp/assurances/> and [http://www.hhs.gov/ohrp/assurances_index.html](http://www.hhs.gov/ohrp/assurances/assurances_index.html) and as a frequently asked question (FAQ) in OHRP's set of FAQs on IRB registration <http://www.hhs.gov/ohrp/IRBfaq.html> and OHRP's set of FAQs on assurances, <http://www.hhs.gov/ohrp/FWAfaq.html>