OHRP Revises Federalwide Assurance

July 7, 2011

The Office for Human Research Protections recently revised its Federalwide Assurance application form. Institutions engaged in federally funded human subject research should take note of these changes and consider making appropriate modifications to internal policies and procedures.

The U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) announced on June 20, 2011, a revised Federalwide Assurance (FWA) form and process, which is applicable to institutions participating in federally funded human subject research activities. Institutions that engage in human subject research that is conducted or supported by any U.S. federal department or agency that has adopted the Common Rule are required to hold current FWAs, unless otherwise exempt from this requirement. Institutions that either currently hold or anticipate requiring an FWA should carefully review the Terms of Assurance and consult legal counsel to address compliance with regulatory requirements under the FWA prior to submitting an FWA application.

Entities that currently hold FWAs do not need to submit a new application, but may voluntarily submit an FWA application on the new form. Entities that do not currently hold an FWA and entities that are nearing the end of the three-year term of their current FWA should take particular note of these changes.

On September 23, 2010, OHRP published a notice in the *Federal Register* soliciting public comment to proposed changes to the FWA, with the goal of simplifying and shortening the FWA form and Terms of Assurance. The new FWA documents approved by OHRP are available on the OHRP website.

The changes focus on the designation by institutions of institutional review boards (IRBs) charged with reviewing research at that institution. Previously, an institution was required to designate each IRB that the institution would use as a supervising IRB for human subject research regulated by the Common Rule. This requirement applied to both internal and external IRBs. Institutions were also required to submit updates to OHRP when the institution wished to rely on a previously undesignated IRB. For example, if the institution participated in a multi-site trial that was Common Rule-regulated to be overseen by a centralized IRB, the institution would need to first update its FWA to list this new IRB. The new FWA application requires institutions that host internal IRB(s) to designate all internal IRB(s), and institutions that do not have an internal IRB to designate just one external IRB, even if that institution uses multiple external IRBs. Moreover, no updates for any future designations are required for institutions relying upon IRBs not already designated on the FWA application.

Nevertheless, while institutions are not required to formally submit designations to OHRP when utilizing new IRBs, institutions are still required to utilize IRBs on the OHRP's list of approved IRBs for oversight of any federally supported or conducted studies. Similarly, institutions that have made a 4(b) election on the FWA application agreeing that the Common Rule will govern all human subject research, not just human subject research that is federally supported or conducted, may only have their research overseen by OHRP-approved IRBs. Though OHRP no longer mandates designation of new, additional IRBs, institutions should still implement policies and procedures to formalize how and when the institution will rely on IRBs in order to minimize opportunities for "IRB shopping" by the institution or investigators.

A summary of key changes to the previously utilized FWA and Terms of Assurance is set forth in Table 1.

Table 1

<table>
<tr><th>Old FWA</th><th>Revised FWA</th><th>Impact</th></tr>
<tr><td rowspan="2">Institutions required to designate any institutional review board (IRBs) relied upon for research oversight and approval</td><td>If institution has internal IRB(s), institution must designate all internal IRB(s) on FWA application</td><td rowspan="2">Institutions no longer required to designate all IRBs relied on for oversight of federally supported or conducted research studies on FWA application</td></tr>
<tr><td>If institution does not have an internal IRB, institution must designate one external IRB on FWA application</td></tr>
<tr><td>Institutions required to update any new IRB designations to OHRP</td><td>Institutions no longer have to designate IRBs with OHRP when utilizing an IRB not described in the original FWA application</td><td>No updates required to OHRP

All IRBs used for oversight of covered research must be registered with OHRP

Can lead to potential IRB shopping concerns</td></tr>
<tr><td>FWA approval period is three years</td><td>FWA approval period is five years</td><td>Institutions will have a longer term before an FWA renewal is required

Notably, IRB registration period is three years, which means FWA</td></tr>
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		and IRB registration renewal schedules will no longer be aligned
Separate FWA forms for U.S. and non-U.S. institutions to complete	Both U.S. and non-U.S. institutions utilize the same FWA application	
FWA signature page required to be submitted in hard copy	FWA must be submitted through the electronic submission system; only if the institution does not have ability to submit electronically can the application be submitted in hard copy	Institutions must be careful to maintain copies of electronically submitted information
Terms of Assurance required for FWA submission	Terms of Assurance have been shortened and simplified to eliminate duplication.	
FWA form required submission of the HHS Institution Profile code or Federal Entity Identification Number	FWA form no longer requires submission of these numbers	