

## NIH Neurobiobank Federal Wide Assurance Requirement

A requirement of a NeuroBioBank (NBB) tissue access request is that it must come from an institution that has an active Federal Wide Assurance (FWA) on file with the U.S. Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP). FWA numbers for institutions can be searched for at <http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>. If an FWA does not exist for a specific institution guidance on the FWA request process can be found at <http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/file-a-new-fwa/index.html>. Additional guidance related to requesting an FWA is included in this document.

Under an FWA, an institution commits to DHHS that it will comply with the requirements set forth in [45 CFR part 46](#), as well as the [Terms of Assurance](#). The NBB understands that research using post-mortem tissue is generally not considered to be Human Subjects research. Having an active FWA is a requirement for NBB tissue access to ensure that tissue recipients understand and are prepared to abide by the requirements of Human Subjects research should the need arise. This includes having an IRB in place to review and approve research protocols when necessary.

### **The following information is intended to assist organizations with the FWA request process:**

Per OHRP guidance, *“before obtaining an FWA, an institution must either register its own Institutional Review Board (IRB) (an “internal” IRB) or designate an already registered IRB operated by another organization.”* If an institution does not have an internal IRB there are options that exist to identify an IRB for purposes of obtaining an FWA. The first option is to enter into an agreement with a collaborating institution to use their IRB. The second option is to enter into an agreement with a commercial IRB service. With either option, a written agreement between the organization and the IRB provider is required. Please see the [OHRP Terms of Assurance](#), item 6, for additional information regarding external IRBs.

Many commercial IRB service providers exist and can be found by searching the internet. The NBB is not able to provide information about IRB service providers or endorse any individual provider. Some IRB service providers may charge a fee for entering into an agreement with them for the purpose of requesting an FWA. **Please note that the NBB does not require IRB review and approval of a research protocol in order to accept a request for tissue.** Determining the need for IRB review and approval is the responsibility of the requester/requesting organization.

After securing an agreement with an external IRB, information regarding the FWA request process can be found at <http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/file-a-new-fwa/index.html>.