National Institute on Alcohol Abuse and Alcoholism

Human Subject Protection

All who request the limited access data set must comply with the DUA for ensuring study subject confidentiality. The IRB at the institution of each requester is responsible for determining whether the project satisfies the requirements for protection of human subjects. **The NIAAA will accept an IRB letter stating that the proposed study is exempt from review or an IRB letter of approval obtained through expedited or convened review**. The IRB, whether within or outside of the U.S., must operate under the Office of Human Research Protections (OHRP)–approved assurance. The Web Site for OHRP provides information regarding the process to obtain project assurances (http://www.hhs.gov/ohrp/). Investigators who do not agree to sign the DUA or do not submit an IRB exemption letter or IRB approval letter will not be sent the limited access data set.

If the requester's IRB determines the project must be reviewed, the requester should inform the IRB of the need for review each of the following items in considering approval of the request:

1. Have all reasonable personal identifying items been removed from the data set, or modified appropriately?
2. Will the recipient investigators provide appropriate safeguards for protection of participant confidentiality?
3. Has the recipient investigator signed the data DUA with the NIAAA pledging to protect confidentiality, not to contact individuals in any way, and to use the data in the manner specified in the agreement?

A copy of either the IRB exemption letter or the IRB approval document, including the OHRP assurance number, should be sent to the NIAAA along with the signed DUA.