

What does the Department Chairperson's Assurance Statement on the IRB application mean?

Research involving investigation and/or collection of data from living human subjects require review by the Institutional Review Board prior to initiation of a project. The IRB focuses its principal attention on human subjects protections when evaluating a research proposal. In the full, expedited and exempt IRB applications, there is a requirement for the Department Chair's Assurance Statement/signature, or that of an authorized designee. The IRB assumes that research conducted as part of the University mission is designed and carried out in a manner that meets the highest scientific standards and with a commitment to human subjects protections. Each academic department is free to choose a mechanism to assure human study proposals or protocols meet these rigorous scientific and human protections guidelines. By reviewing the IRB application and signing the Assurance statement, a Department Chair or designee has assumed certain responsibilities and signifies that the science is meritorious and deserving of conduct in humans.

The following is a list of the responsibilities reflected by signing the Assurance statement:

1. **Scientific validity:** The Department Chair or designee has reviewed the research proposal submitted to the IRB and ensured that the science represented in the research protocol is valid and is likely to achieve its aim. He/She has also ensured that the knowledge expected as a result of the research has importance.
2. **Qualifications:** The Department Chair or designee has ensured that the researcher(s) has sufficient time to conduct and complete the research and that persons listed as study personnel on the research protocol have the proper expertise and training necessary to carry out the research being proposed. The Chair or designee has also ensured that the investigator has an appropriate number of qualified staff that are adequately informed about the protocol and their research related duties and functions.
3. **Subject population:** The Department Chair or designee has ensured that the investigator has access to a population that will allow recruitment of the required number of participants within the proposed recruitment period. The Chair or designee also has ensured that if participants need ancillary resources as a consequence of taking part in the research (psychological counseling or emergency treatment), the researcher has a process to make these available.
4. **Facilities:** The Department Chair or designee has ensured that the facilities and equipment necessary to conduct the research study are adequate and appropriate for the type of research proposed to the IRB.
5. **Mentoring – Direct:** The Department Chair or designee has and will continue to provide guidance to the researcher(s) during the course of study conduct ensuring adherence to established standards of scientific integrity, as appropriate.