# “Institutional Review Board”

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**What is an Institutional Review Board (IRB)?**
The IRB is a body of professional and lay persons who review all ***research*** studies from an institution to assure that the investigator meets the federal guidelines for protection of human subjects. Each institution that performs human subject research “conducted, supported or regulated” by any federal agency that adheres to the Common Rule must have that research reviewed by a Review Board (Department of Health and Human Services, 1991). The Department of Health and Human Services is one of the 15 agencies that adheres to the Common Rule. The Code of Federal Regulations codified at 45 part 46 is known as the Common Rule. Subpart A of this federal policy describes the function and operations of an institutional review board. In this policy, an institution is required to maintain a review board to ensure the protection and rights of human subjects. The primary function of the IRB is to assist the investigator to meet these protective guidelines. It is necessary for others who are independent of the research to share the responsibility for determining the standards for ethical conduct of research involving human subjects. Investigators, however, carry primary responsibility for assuring that research protocols measure up to standards established by the IRB.

**What is research?**
As defined in the policy, research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

**What is a human subject?**
As defined by the same document, human subject means a living individual about whom an investigator obtains data through intervention, interaction or obtains identifiable private information. This definition uses the word *living* and such data on deceased individuals may not technically fall under the definition of research. In the organ procurement world, we must be conscious of two things that occur as we do research. 1) We may be performing research on a deceased person and thus feel that he/she is outside the federal policy; however, if data is collected prior to the declaration of death, then that subject (who is now dead) was not dead at the time of data collection and meets the criteria of living human subject. 2) We operate many of our activities holding the public trust and with that public trust we hold ourselves to a higher standard, and it is in our best interest to meet the guidelines of ethical practice (Ackerman & Winsett, 2002).

**What does oversight mean?**
Before a human subject research project is initiated, it must first be reviewed and approved by the IRB and then conducted in full compliance with Federal Regulations. There can be no exceptions to this requirement, since violations may result in serious repercussions for the institution and the investigator.

**What do I need to do?**
Once you have developed your research design, the first step in implementing the study is to have it reviewed by the IRB. This involves contacting the IRB and obtaining the forms and procedures for submission of a research proposal. If you have questions about the procedure, contact an IRB representative. While you may feel that this is a cumbersome process, if you do it early in your development phase, the process really helps you clarify your design. Prior to completing the IRB forms, you may be required to select what category your study meets. There are three categories: exempt, expedited, and full. If you are unsure, contact the IRB office and explain your study, and you will be directed to the correct set of forms to complete.

**Exempt Status**
Research activities that fall under exempt include studies that involve little or minimal risk to subjects (surveys, questionnaires, secondary analysis of existing data, data on deceased, or data with no identifiable information). Minimal risk means that the probability and magnitude of harm or discomfort

anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The investigator does not determine exempt status, but if you feel your study will meet these qualifications, your application process will be shortened.

**Expedited Status**
To be eligible for expedited review your study does not meet the eligibility criteria for exempt and also involves no more than minimal risk. You will have to build into your project descriptor the support for "no more than minimal risk". Types of studies that may qualify for expedited review are prospective studies that collect data trends or compare treatment regimens. Studies that involve simple blood draws or noninvasive procedures (blood pressure, mental acuity or voice taping) may also be eligible for expedited review.

**Full Board Review**
Studies that include procedures that involve more than minimal risk. This includes testing of an intervention (whether or not it is an invasive procedure), trials that have a control and an experimental group or if the procedure includes any procedure that is experimental in nature.

After your review you may be faced with modifying your design or justifying your procedure in such a way as to meet the guidelines to obtain approval. These provisos must be addressed and approved in writing before you can start your study. If at the beginning of your study idea you have a start time in mind, be sure to give yourself plenty of time to meet the IRB deadlines.

**What if I am not associated with a university and want to do research?**
This is the problem many in the OPO field face. Consider your study, your sample and your design and then work with someone from a facility that has an IRB. For example, your OPO medical director may be on staff at a university, so if he is on the study, the IRB will review it. University IRBs are not required by law to review outside research proposals, but if you have a staff member from the university on the study, they will most certainly want to protect the research that involves members of the faculty or staff. The safest and least frustrating experience is to talk to an IRB staff person before you develop any research study.

**References:**
Ackerman, T., & Winsett, R. P. (2002). Ethics and regulation in organ procurement research. *Progress in Transplantation, 12*(4), 257-265.

Department of Health and Human Services. (1991). Common rule, 56 federal register (45 cfr part 46 subpart a) (Vol. 56, pp. 28002-28032).