Innovative Practice

Overview:

An innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. Innovative or newly-introduced clinical procedures or therapies do not require IRB review and approval, **except when they meet the definition of 'research'**.

According to the federal regulations, "research" includes activities designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). "Research" is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective (45 CFR 46.102).

Two passages from the Belmont Report are particularly relevant to any discussion of what constitutes 'innovative practice'.

> For the most part, the term "practice" refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to particular individuals. By contrast, the term "research" designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.
>
> When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is "experimental," in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project

Considerations:

Proposed innovative clinical practices that are not being investigated in the context of a formal research study are not subject to IRB review and approval. Rather, the introduction of innovative procedures or therapies into clinical practice should be reviewed with the applicable UPMC oversight committee (e.g., Pharmacy and Therapeutics Committee; Innovative Practices Subcommittee of the Technology Assessment Committee) prior to their implementation. The contact person for the Innovative Practices Subcommittee is Mary Gardner at 412-647-6883.

If you are unsure whether your project requires IRB review, email us (askirb@pitt.edu) or call the IRB office at 412-383-1480.

Additional Information or Resources:

IRB Policies and Procedures: http://www.irb.pitt.edu/pandp/default.aspx

UPMC Policy and procedures

UPMC Pharmacy and Therapeutics Committee

UPMC Innovative Practices subcommittee of the Technology Assessment Committee

The Belmont Report: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Ryan, C. M. & Swanson, D. P. (2007). Clinical research, innovative practice, and IRB review: Identifying and respecting boundaries. American Journal of Transplantation **7**: 748-780.