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UM SIGB Innovative Therapies Guidelines

This process is not intended to replace formal Human Studies with small numbers of participants. Nor is it to be utilized to circumvent the Institutional Review Board's role in protecting human subjects.

Whenever innovative therapy is applied to patient care, it should be viewed as potentially experimental. In all such cases the need to evaluate the therapy/procedure under a formal research protocol should be considered. Such formal investigation should be undertaken as early as possible in the development of the therapy to determine if the therapy is efficacious and safe.

Definitions

Innovative Therapy

An innovative therapy is a newly introduced or modified therapy with unproven effect or side effect, and is undertaken in the best interest of the patient¹.

Categories of Innovative Therapies

- I. A non-standard treatment or approach that is used solely to attempt to enhance the well being of an individual patient.
- II. A change from a currently accepted practice by the medical community that is based on scientific observations and explicit rationale.
- III. The modification of commonly accepted procedures in small incremental steps²

Protocol

It is the ultimate responsibility of the involved Chair/s to determine which potentially innovative procedures fall into categories I and II and thus require oversight.

Clinicians anticipating the need to perform an innovative therapy in Category I and/or II should notify the Chair/s of the involved Departments and follow the steps below:

- I. Two or three medical staff members of each involved department (selected with input from the Chairperson), should conduct an independent peer review of the patient specific proposed therapy/procedure. These individuals must not be affiliated with the patient care team and must not be involved with the performance of the innovative therapy/procedure. The review must conclude that the proposed innovative therapy/procedure is a reasonable approach, given the patient's clinical situation and the alternatives available. The peer review group must also be assured that all

steps have been taken to assure patient safety and a favorable outcome. A written statement should be prepared that the group agrees with the proposed procedure or therapy. This group may consult with the appropriate institutional Ethics Committee for help in evaluating the proposed innovative procedure if the members feel that such consultation might be helpful.

- II. A separate written informed consent document should be drafted which is specific to the proposed procedure. This consent will contain at least the following elements:
 - A complete description of the procedures
 - The risks, benefits and alternatives.
 - The proposed process for obtaining consent
 - i) Who will obtain the consent
 - ii) When will the consent be obtained
 - iii) Where will the consent be obtained

- III. A letter containing the following elements must be submitted to the Department Chairs and the SIGB office prior to the proposed procedure. If the Department Chair is not part of the peer review process, he/she should also sign the letter. The letter should include the following elements:
 - a description of the clinical situation and the planned innovative diagnostic or therapeutic approach to treating or diagnosing the disease or condition
 - documentation of the peer review process, and supporting decision
 - a copy of the proposed consent, including who will obtain consent
 - The clinician's reasons why other standard therapies are not appropriate
 - The rationale for determining that the approach is "innovative therapy or diagnosis" rather than a "pilot study" or widely accepted "off-label" use of a drug or device
 - Supporting documentation (attachments), if relevant or helpful, e.g., case report from another institution, abstract, or other data supporting your proposal

- IV. The SIGB office will review and approve the consent document as soon as reasonably possible. This review will also consider the process by which informed consent is proposed to be obtained, to assure that the patient and family are adequately informed about the procedure before granting consent. The SIGB office will only approve the consent and will not be responsible for approving the performance of the procedure. In addition the SIGB office will maintain records of the peer review and consent documents.

- V. The Department Chair/s are responsible for approving the therapy/procedure and for monitoring the outcome after receipt of the

above documentation. The determination as to whether the procedure or therapy proves useful and should be attempted again remains the responsibility of the Chair/s of the involved Departments.

- VI. Approval for innovative therapies will only be given for one patient at a time.
- VII. Once approval for the innovative therapy is granted by the involved Chair/s, and the SIGB office has approved the consent form, the consent should be obtained in addition to the standard hospital consents.
- VIII. If the Chair/s or SIGB notes multiple submissions of the same innovative therapy, the Chair/s will contact the medical staff member performing the therapy/procedure to discuss whether a research protocol should be submitted or whether there are other mechanisms appropriate for the continued use of the therapy. It is also possible after adequate experience is gained with the procedure/therapy that the innovative therapy may become the accepted standard of clinical care. This decision will remain the responsibility of the Department Chair/s.

Adverse Events

Adverse events related to innovative therapies and procedures approaches must be reported in accordance with the UM adverse event reporting procedures. In addition, adverse events occurring within JHS hospitals must be reported in Quantros. This report must be completed by the clinician who has applied for approval for the procedure. Serious adverse events must be reported within 24 hrs of the event.

¹ **The ethics of using innovative therapies in the care of children.** Ayman Al Eyadhy, MD and Saleem Razack, MD, Paediatr Child Health. 2008 March; 13(3): 181–184.

² **Innovation Versus Research: Guidelines, Concepts and Procedures for Differentiation, Children's Hospital Boston Clinical Investigation Policy and Procedure Manual.**
http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_081_015_innovation_vs_rsrch.doc
Accessed July 16, 2009

³ **Innovative Therapy and Diagnosis Guidelines.** Partners Health Care Human Research Committee.
<http://healthcare.partners.org/phsirb/inntherp.htm>
Accessed July 16, 2009