Purpose: Jackson Health System (JHS) Policy on Innovative therapies is intended to help JHS Leadership and physicians understand the difference between innovative practice and actual research and apply the guidelines/requirements as appropriate**.**

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 patient.[1] Innovative care may be proposed as an intermediary step between clinical care and formal research. This is intended to *cover a very limited number of patient***s (no more than three)** in whom unusual, innovative approaches are used for the primary goal of clinical diagnosis or therapy. Per this JHS Policy all planned innovative procedures must be brought to the Chief Medical Officer (CMO) for review and approval (clinical feasibility & financial feasibility) before the procedure is scheduled.

Innovative therapy is not intended to replace formal human studies research protocols involving small numbers of patients. Also, these guidelines do not apply to:

- The planned or emergency use of an investigational drug or device;
- The common, accepted "off label" uses of Food and Drug Administration (FDA)-approved medications; or
- **"pilot"** studies of approaches where additional larger studies are needed (submitted to Institutional Review Board -IRB).

Distinction between clinical care and research: Many innovative therapies and diagnostic techniques are developed at the interface between well-established clinical practice and research. These activities do not, however, become research until they are carried out in a systematic fashion to develop or contribute to “general knowledge.

Submission requirements (forward to the Chief Medical Officer for the JHS):

1. Letter from treating physician co-signed by the division chair.
2. The letter submitted should include the following:
   - Description of the clinical situation and the planned innovative diagnostic or therapeutic approach to treating or diagnosing the disease or condition
   - Why other standard therapies are not appropriate or as beneficial.
   - 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

3. **Consent form requirements**: A formal Informed Consent Form as in research consent form should not be submitted as these submissions are describing clinical diagnosis or treatment and not research. You may use a standard clinical procedure consent form or a customized JHS consent form that includes the standard sections of a research consent form (purpose,

1 The Ethics of Using Innovative Therapies on the Care of Children. AymanAl Eyadhy, MD and Saleem Razack, MD, Paediatr Child Health. 2008 March; 13 (3); 181-184

procedures, contacts, costs, risks, benefits and alternatives) without any reference to "research." The JHS Clinical Trials Office (CTO) administrative staff is available to assist in the development and review of the consent forms for innovative therapy or innovative diagnosis.

4. The JHS Clinical Trials Office will review the clinical protocol to conduct a Medicare coverage analysis, review compliant billing, financial and resource impact for the JHS.

5. **Adverse event reporting**: Adverse events related to innovative therapeutic or diagnostic approaches must be reported to the CMO within 72 hours.

   An *adverse event (AE),* as defined by Good Clinical Practice, is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease having been absent at baseline, or if present at baseline, appearing to worsen and is temporally associated with medical treatment or procedure, regardless of attribution (i.e., relationship of event to medical treatment or procedure).

   Serious adverse events (SAE) must be reported with 24 hours of occurrence of event, by telephone, fax or email followed by a full written report via email within 10 business days. SAE is defined as any adverse event occurring at any dose that results in any of the following outcomes: Death, Life threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, congenital anomaly/birth defect OR

   Important Medical events (IME) that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse drug experience when they may: jeopardize the patient AND May require medical or surgical intervention to prevent one of the outcomes above.

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6. **Follow-up reporting on the outcome**: A follow-up report may be submitted when the procedure or therapy is complete.
   - A summary report on the outcome of the patients receiving the innovative therapeutic or diagnostic approach must be submitted to the JHS CMO within one year of approval.

OPTIONS

The CMO may consult the IRB for further review if he/she deems it necessary in determining if the innovative therapy is appropriate and safe.

A final report (signed off by JHS CMO) on the experience with the innovative approach and further plans should be submitted to the IRB.

If the physician wishes to continue to treat patients using this innovative therapeutic or diagnostic approach, he/she must file a request through the CMO and the JHS Clinical Research Review Committee (CRRC) to have the innovative approach adopted as a standard or acceptable therapy.

Use of Data: Data obtained as a result of these few cases will not be considered IRB-approved thus may not be used in grants, publications, or future IRB protocol submissions.

APPROVED:

Eve Sakran, Director, Clinical Trials Office, Jackson Health System

AUTHORIZED:

Carlos A. Migoya, President and CEO, Jackson Health System

REQUIRED STEPS ON THE NEXT PAGE

Innovative therapy guidelines
Required steps

1. Letter from treating physician cosigned by division chair should include:

    a. Description of the clinical Situation and the planned innovative diagnostic or therapeutic approach to treating or diagnosing the disease or condition.
    b. Why other standard therapies are not appropriate or as beneficial.
    c. Rational for determining that the approach is 'innovative or diagnosis' rather than a "pilot study" or widely accepted "off label' use of the drug or device.
    d. Supporting documentation (attachments), if relevant or helpful, e.g., case report from another institution, abstract, or other data supporting your proposal.

2. Consent Form: The Informed consent will include purpose, procedures, contacts, costs, risks, benefits and alternatives.

3. Billing plan: JHS CTO has approved the submitted billing plan.

4. Once the CMO has given approval the physician may begin to perform the innovative procedure.

5. Adverse events: Any incident must be placed in the JHS Quantros system and reported to the CMO within 72 hours. Serious Adverse event must be reported to the CMO within 24 hours and placed in Quantros.

6. Summary Report: A summary report must be submitted to the CMO with in one year of approval.