Non-FDA Regulated Innovative Therapy Tool Kit

Boston Children's Hospital

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The term innovative therapy covers a large spectrum of situations. It may include a minor modification to an established procedure or a new interventional approach for a particular patient. When a proposed innovative therapy/procedure:

- Represents a significant increase in risk, above the alternative approaches that could have been offered; or
- When the procedure is so novel that the risks and benefits are unknown the following forms contained within this toolkit are to be completed:
  - ***Innovative Therapy Form***
  - ***Innovative Therapy Peer Review***
  - ***Innovative Therapy Checklist***

* Approval and sign off by your Department Chair/Chief as well as the Physician /Surgeon in Chief is required. After all sign offs are obtained the forms must be provided to Peter Laussen, MBBS, EVP, Health Affairs and IRB Administrative Office (Susan Kornetsky).

Defining Innovative Therapy

- Innovative therapy occurs when a practitioner proposes to use a treatment, procedure or intervention in a way that deviates from commonly accepted practice in a clinical encounter.
- In all such cases the need to evaluate the therapy/procedure by a scientifically sound methodology under a formal research protocol should at least be considered although the fact that the procedure is novel does not automatically place it in a category of research.
- However, when new procedures are used repeatedly, they should be made the object of formal research at an early stage, in order to determine whether the innovation is both safe and effective.

Innovative therapy can be characterized by one or more of the following principles:

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

In ambiguous cases, members of the medical and surgical staff who propose to implement novel procedures should consult with their Department Chair or Division Chief to determine whether the proposed innovative therapy/procedure requires oversight by an independent professional. This policy applies to innovative therapies that are not FDA regulated. All FDA regulated therapies are covered under the policy and procedure 8.1 Drugs, Biologics and Dietary Supplements Regulations. Any procedure that is determined not to require oversight should proceed in accordance with generally accepted departmental policies and practices.

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Use Plate or Print:

MRN#:

DOB:

Pt Name:

Gender:

Innovative Therapy Form

1. Provide a brief summary of the clinical history of the patient.

2. Describe the proposed innovative therapy and provide the rationale for innovative therapy.

3. Provide a statement on any known/potential risks and benefits.

4. Has this innovative therapy been performed before at Boston Children's Hospital?
☐Yes ☐ No

If YES, please answer the following questions:

a. Please describe what has been learned so far in the use of this innovative therapy.

b. Describe the rationale for performing additional innovative therapy on more patients?

5. Innovative therapies must be peer-reviewed, approved initially by the Department Chair or Division Chief with final approval by Physician-in-Chief or Surgeon-in-Chief.

6. Peer Review written statements required (see ***page 4***)

☐Yes ☐ No

7. Signed Innovative Therapy Checklist is attached (see ***page 5***)
☐Yes ☐ No

8. It is required that a separate written informed consent document containing a complete description of the procedures, specifying known or unknown risks, benefits and alternatives, be extremely clear and specific to the patient and procedure. This form should be completed in addition to the hospital's general consent forms and reviewed by the administrative office of the IRB.

a. Consent document is attached N/A
☐ ☐Yes ☐ No

b. Addendum to the hospital's general consent form is attached
☐N/A ☐Yes ☐ No

9. Please provide a brief summary of the plans for informed consent (who will speak with the patient, when, where, etc.).

Please obtain approval from your appropriate leader (Department Chair/Division Chief) and the Surgeon in Chief or Physician in Chief. The attached checklist has a location for these signatures. Alternatively, you may attach copies of emails with their approval.

After the treatment, please forward patient outcome and lessons learned from the innovative therapy to Peter Laussen MBBS, EVP, Health Affairs

Provide copies to:

Email: **Susan.Kornetsky@childrens.harvard.edu** Director, Clinical Research Compliance

Dial #: 57053 **Direct Dial #:** 617-355-7053

Email: Peter Laussen MBBS, EVP, Health Affairs

Dial #: 56617 **Direct Dial #:** 617-355-6617

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Gender:

Non FDA Regulated Innovative Therapy Peer Review

Peer Reviewer Guidelines

- Peer review is required by 2 individuals.
- Peer reviewers may not be involved in the procedure or patient care team.
- Department Chair/Division Chief may serve as one of the peer reviewers.
- Review must conclude that proposed innovative therapy/procedure is reasonable given:
    - Patient's clinical situation
    - Available alternatives
- Peer reviewers must be assured that all steps are taken to assure patient safety and a favorable outcome.
- Peer reviewers signed written statement specifies agreement with proposed procedure or therapy.

Patient Name:

☐ see addressograph

Practitioner performing therapy/procedure:

Procedure:

Peer Reviewer Statement:

Use Plate or Print:

MRN#:

DOB:

Pt Name:

Gender:

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Non-FDA Regulated Innovative Therapy Checklist

Post Submission Reviews/Requirements:			Approval/Receive Date
☐ *Required*	Peer Review Complete		
☐ *Required*	Consent Document (supplement to standard consent) or Addendum to general hospital consent form with explicit language		
☐ *Required* ☐ *Not Required*	Multidisciplinary Team Review Pre-procedure		
		Contact Information	
☐ *Involved* ☐ *Not Involved*	Radiation Safety		
☐ *Involved* ☐ *Not Involved*	Pharmacy		
☐ *Involved* ☐ *Not Involved*	Laser Use		
☐ *Involved* ☐ *Not Involved*	OR Team/Anesthesia (pre or intra-op care specific to particular case)		
☐ *Involved* ☐ *Not Involved*	Nursing (post-op care specific to particular case)		
☐ *Involved* ☐ *Not Involved*	Critical Care Provider (post-op care)		
☐ *Involved* ☐ *Not Involved*	Respiratory Therapy		

Department Chair or Division Chief Sign-off **Date**

Department Chair or Division Chief Sign-off_____ Date

Please remember to close the loop by sending outcomes to Peter Laussen MBBS, Office of Medical Affairs.