



Document: ref\_innovative\_therapies\_toolkit.doc

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](#)

## 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.
- Whenever innovative therapy differs significantly from routine practice, it should be viewed as experimental.
- 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.

Any procedure that is determined not to require oversight should proceed in accordance with generally accepted departmental policies and practices. (e.g., [Novel Interventions in the Cardiovascular and Critical Care Programs](#)).

## Related Content

- [Patient Care Manual](#)
- [Cardiovascular and Critical Care Manual](#)
- [Program for Patient Safety and Quality](#)
- [Office of Clinical Investigation](#)
- [Innovative Therapy Reference](#)

# Innovative Therapy Tool Kit



Boston Children's Hospital

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. Briefly describe the outcome:
  - b. Describe the rationale for performing additional innovative therapy on more patients?
  
5. Innovative therapies must be approved by the Department Chair or Division Chief.
  
6. Peer Review written statements required (see [page 4](#))  
 Yes  No
  
7. Signed Innovative Therapy Checklist is attached (see [page 5](#))  
 Yes  No  
**Note:** If you are a Division Chief, approval from your respective Physician/Surgeon-in-Chief is required.
  
8. It is recommended 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.
  - a. Consent document (if used) is attached  
 N/A  Yes  No
  - b. Addendum to the hospital's general consent form is attached  
 N/A  Yes  No

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

Please submit to your appropriate leader (Department Chair/Division Chief).

Also provide copies to:

- Program for Patient Safety & Quality  
c/o Elise Woodard MS, RN, Manager
- Administrative Office of IRB

Please also forward patient outcome and lessons learned from the innovative therapy to the PPSQ contact and Administrative Office of IRB.

If you have questions with the innovative therapy review process, please contact either:

**Email:** [susan.kornetsky@childrens.harvard.edu](mailto:susan.kornetsky@childrens.harvard.edu) Director, Clinical Research Compliance

**Dial #:** 57053

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

**Email:** [elise.woodard@childrens.harvard.edu](mailto:elise.woodard@childrens.harvard.edu) Nurse Manager, Program for Patient Safety & Quality

**Dial #:** 58065

**Direct Dial #:** 617-355-8065

**Pager Id:** 3920

# Innovative Therapy Tool Kit



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## 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.
- Department Chair/Division Chief **may not** be involved in the procedure or patient care team
- 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:

# Innovative Therapy Tool Kit



Boston Children's Hospital

## Innovative Therapy Checklist

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

Department Chair or Division Chief Sign-off

Date

**Please remember to close the loop by sending PPSQ the patient outcome and lessons learned from the innovative therapy!**