UC San Diego Health

This policy applies to: UCSD Health	Last Approval Date: 10/4/2022
Name of Policy: Medical Staff Innovative Therapies	**Page** 1 **of** 9
Policy Number: MSP 027	
Departments Affected: All Departments	

I. PURPOSE:

To assist Practitioners on the UC San Diego Medical Staff ("Medical Staff") in appropriately identifying and distinguishing between established treatment, Innovative Therapy as defined herein, and research.

II. DEFINITIONS:

Innovative Therapy: Elective therapy that departs significantly from established, standard, or accepted therapy. Innovative Therapy meets all of the following criteria:

- Use of devices or technologies
- Limited number of individual patients
- Necessary because of unique circumstances or for a novel purpose
- Innovative approach is appropriate
- Primary objective is clinical treatment

For purposes of this Policy, Innovative Therapy does not include:

- FDA-approved procedures
- Research conducted under an Institutional Review Board ("IRB") protocol
- Unplanned or emergency therapy
- Medical diagnosis or prophylaxis
- Common/established therapies that are new to an individual Practitioner
- Incremental revisions of established practices that do not present significant risk
- Off-label drug use

Specific examples of Innovative Therapy can be found in ***Attachment A***. Questions regarding whether a treatment qualifies as Innovative Therapy should be directed to the Practitioner's Service Chief or Division Chief.

Practitioner: Practitioner means any currently licensed physician, dentist, clinical psychologist, podiatrist, or Advanced Practice Provider (*e.g.*, NP, PA, CRNA, etc.) who holds clinical privileges on the Medical Staff.

III. POLICY:

A. This Policy is intended to facilitate the delivery of Innovative Therapy at UCSDH, while minimizing the potential risks to both patients and Practitioners in the delivery of Innovative Therapy.

B. This Policy recognizes that research may effectively encompass Innovative Therapy and thus, Innovative Therapy should be conducted in a manner similar to research, with exceptions for emergency treatment and a lack of alternative therapy.

C. Practitioners on the Medical Staff who plan to engage in Innovative Therapy must request a review of the proposed Innovative Therapy prior to providing such therapy to patients at UCSDH.

D. The emergent or unplanned use of Innovative Therapy does not require pre-intervention review but does requires post-intervention review, as set forth in Section IV below.

E. This Policy is not intended to bypass the Medical Staff Pharmacy & Therapeutics Committee or its policies and procedures for medication management or off-label drug use (See UCSDHP 324.1).

F. In all such cases, the need to evaluate the therapy under a formal research protocol should at least be considered. However, the fact that the therapy is novel does not automatically place it in the category of research. If it is determined that the therapy should proceed as research, the Practitioner is required to engage the UCSD IRB as appropriate.

G. If the therapy is not determined to be Innovative Therapy, the Practitioner should engage with the Medical Staff Credentials Committee to determine whether the therapy should be incorporated on the Service's Delineation of Privilege Form.

IV. PROCEDURE:

A. *Request for Innovative Therapy*

i. To use an Innovative Therapy, the Practitioner must submit a request on the application as set forth in Attachment B to their Service Chief and if applicable, Division Chief. The request will include the following information:

a. A brief summary of the patient's clinical condition;
b. A description of the proposed Innovative Therapy;
c. A statement of the rationale for Innovative Therapy over standard therapies;
d. A statement of any known/potential risks and benefits;
e. Any literature in support of the Innovative Therapy;
f. The potential cost of the Innovative Therapy, if any;
g. A summary of the plans for informed consent (who will speak with the patient, when, where, etc.); and
h. A copy of a proposed written informed consent document containing a complete description of the Innovative Therapy, specifying known or unknown risks, benefits, and alternatives. The consent must be clear and specific to the patient and procedure.

ii. Any questions regarding the applicability of this Policy should be directed to the Practitioner's Service Chief and Division Chief.

B. *Service Chief and Division Chief Review*:

i. Requests to conduct Innovative Therapy must be reviewed by the Service Chief and if applicable, Division Chief. The request must be approved by the Service Chief and Division Chief before the Innovative Therapy may be used.

ii. Upon receipt of the application, the Service Chief and Division Chief will assess the information

provided to determine:

a. Whether the patient's safety can be maintained while engaging in the Innovative Therapy; and
b. The reasonableness of the Innovative Therapy.

iii. If the Service Chief and Division Chief approve the Innovative Therapy, both the Service Chief and Division Chief will document their approval in writing. The approval shall include the Service Chief and Division Chief's assessment that the Innovative Therapy is reasonable and safe given the information provided. Following written approval by the Service Chief and Division Chief on the Application for Innovative Therapy, the Practitioner may proceed with the proposed Innovative Therapy.

a. The Service Chief must advise the President of the Medical Staff ("POMS") of approved Innovative Therapies. The POMS will then notify the Chief Medical Officer ("CMO") and/or their designee, and the UCSDH Medical Staff Executive Committee ("MSEC") regarding the planned Innovative Therapy.
b. If there are potential billing concerns, either the Service Chief or Division Chief should also notify the Office of Compliance and Privacy ("OCP").
c. If specific equipment is required for the Innovative Therapy, the Practitioner will be directed to follow UCSDHP 703.1, the Centralized Purchasing Policy.
d. Any questions regarding documentation of the Innovative Therapy should be directed to UCSDH Risk Management.

iv. If the Service Chief and Division Chief do not approve of the Innovative Therapy, the Practitioner cannot move forward with the proposed Innovative Therapy.

v. The Service Chief and/or Division Chief may also include the Director of the IRB as part of the review process, as appropriate.

vi. If the Service Chief and/or Division Chief prefer to have the MSEC review and approve the proposed Innovative Therapy or if the Service Chief and/or Division Chief has/have a conflict of interest, the Chiefs will advise the POMS of the request and ask for review by the MSEC. The POMS, in coordination with the CMO, will determine how the request will be reviewed by the MSEC and whether the matter will be reviewed by a subcommittee of the MSEC. The POMS will also determine which individuals and hospital areas should be part of the review.

vii. In the event of emergent or unplanned uses of Innovative Therapy, the Service Chief and Division Chief must be notified by the Practitioner as soon as possible thereafter.

viii. All cases of Innovative Therapy, including those conducted under emergent or unplanned conditions, must be sent through the Medical Staff Peer Review process. The Practitioner is responsible for referring the case to the Medical Staff Patient Care and Peer Review Committee ("PCPRC") for review.

ix. Innovative Therapies that will be used for subsequent patients should be considered for submission to the MSEC for approval as an established practice or to the IRB for approval of a research protocol. Additionally, questions related to publishing information and/or data related to performed Innovative Therapy should be directed to the IRB.

x. A Practitioner's failure to obtain approval of planned Innovative Therapy prior to use may result in corrective action by the Medical Staff, including but not limited to, summary suspension, termination, and/or revocation of clinical privileges.

ATTACHMENTS:
Attachment A: Service-Specific Examples of Innovative Therapy
Attachment B: Application to Request Innovative Therapy

RELATED POLICIES:
UCSDHP 339.1,"Consent for Anesthesia, Surgery, Special Diagnostic, or Therapeutic Procedure"
UCSDHP 340.1, "Informed Consent for Human Research Subjects"

APPROVALS:

Credentials Committee:
Patient Care and Peer Review Committee:
Medical Staff Executive Committee (MSEC): 09/15/2022
UC San Diego Health Executive Governing Body (EGB): 10/4/2022

Attachment A

Service-Specific Examples of Innovative Therapy

The following Service-specific examples of Innovative Therapy may assist Practitioners with determining whether a proposed therapy should be reviewed under this Policy. This list is not exhaustive, and any questions regarding the applicability of the Policy should be directed to the Practitioner's Service Chief and Division Chief.

***Example No. 1*:** Right femur and tibia revision of endoprosthesis where tools associated with the specific implanted devices are not available. As an alternative, proposed Innovative Therapy includes the use of non-standard devices (*i.e.*, box wrenches) to address possibly infected hardware. No prior description in the peer-reviewed literature exists such that it is unclear whether the non-standard devices will have the intended effect. Intended use of the Innovative Therapy is limited to one patient.

***Example No. 2*:** Use of Radiation Therapy by Cardiology Practitioners to address ventricular arrythmia. Limited prior description in the peer-reviewed literature exists such that it is unclear whether the non-standard device will have the intended effect. Intended for the use of between 2-5 patients.

***Example No. 3*:** Use of ECMO in a neonate. A pulmonary mass and left mainstem bronchial obstruction are identified in an individual fetus. In the proposed Innovative Therapy, at the time of c-section delivery, the placental circulation would be preserved until a bronchoscope is obtained. If no safe and effective conventional respiratory support are feasible, the baby would be placed on ECMO prior to removal from placental circulation.

Attachment B

APPLICATION TO REQUEST INNOVATIVE THERAPY

Name of Requester: _____ **Date:**_____

Name and Innovative Therapy: _____

Please provide responses to the questions below. Please also attach any relevant literature. The completed form must be submitted to your Division Chief and Service Chief for approval prior to performing the Innovative Therapy.

1. Brief Summary of the Patient's Condition: _____

   _____

2. Description of Innovative Therapy:_____

   _____

3. Rationale For Innovative Therapy Over Standard Therapies:_____

   _____

4. Literature/Experience:_____

   _____

5. What Procedure Or Device Will This Be Replacing, If Any?_____

   _____

6. Possible Known Risks And Benefits: _____

   _____

7. Are There Other Medical/Surgical Specialties Involved In Pre- Or Post-Procedure Care That Should Be Aware?

   _____

8. Should This Be Evaluated By The IRB Such As Expanded Access Of An Investigational Device Or Used With In A Research Protocol? _____

   _____

9. What Are The New Equipment Needs (Personnel And/or Supplies), If Any?_____

   _____

10. Is There Is A Financial Impact To The Institution And/or The Patient?_____

    _____

11. Plan for Informed Consent (Who Will Speak With The Patient, When, Where, Etc.): _____

    _____

A copy of a proposed written informed consent document containing a complete description of the Innovative Therapy, specifying known or unknown risks, benefits, and alternatives, must be attached. The consent must be clear and specific to the patient and procedure.

Service Chief and Division Chief Review

Please review the information above and the attached materials to determine whether the Innovative Therapy is appropriate.

- ✓ *If you have a conflict of interest, or if you'd prefer this be reviewed by the UCSDH Medical Staff, please forward the form to the President of the Medical Staff (POMS) and/or the Associate Chief Medical Officer for Medical Staff Affairs (ACMO).*
- ✓ *If you believe the IRB should be involved in reviewing the proposed Innovative Therapy, please reach out to the Director of the IRB for their review.*

☐ **Approval of Innovative Therapy Request**

By my signature below, I attest to the following statement:

I have reviewed the patient's condition, the proposed innovative approach, and the literature supporting the reasonably safe use of this approach. Given the unique circumstances of the patient's condition, this approach is reasonable, and I approve for this patient.

_____

Signature Division Chief Name Of Division Chief Date

_____

Signature Service Chief Name Of Service Chief Date

Approvals must be sent to the POMS and/or ACMO and the case must be referred to peer review.

The following actions may also be appropriate:

- ☐ Contact the Office of Compliance and Privacy (OCP) to review billing implications of the Innovative Therapy
- ☐ Contact Medical Staff Administration to determine if your DOP requires any updates related to the proposed Innovative Therapy
- ☐ If specific equipment is required for the Innovative Therapy, direct the Practitioner to follow UCSDHP 703.1, the Centralized Purchasing Policy
- ☐ Contact UCSDH Risk Management with any questions regarding documentation and consent related to the Innovative Therapy

☐ **Denial of Innovative Therapy Request**

By my signature below, I do not approve of the Innovative Therapy for the following reasons:
_____
_____
_____

_____

Signature Division Chief Name Of Division Chief Date

_____

Signature Service Chief Name Of Service Chief Date