

**NATIONWIDE CHILDREN'S HOSPITAL
COLUMBUS, OHIO**

MEDICAL STAFF

INNOVATIVE CARE POLICY

Adopted: 01/31/2025

MEDICAL STAFF OFFICE

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I. Purpose; Definitions

The purpose of this Innovative Care Policy is to establish a process whereby Practitioners on the Medical Staff of the Hospital shall obtain approval to provide Innovative Care. The definitions set forth in the Medical Staff Bylaws shall apply to this Innovative Care Policy unless otherwise provided herein.

Innovative Care means medical care, including any treatment, procedure, or intervention, that departs in a significant way from standard or commonly-accepted medical practice. Usually, Innovative Care includes a change from commonly-accepted medical practice that is based on scientific principles or observations. The primary purpose of Innovative Care is to benefit a single patient. Innovative Care is not provided for Research purposes. If a Practitioner proposes care that is planned to be disseminated or offered to other patients, such care is likely to be more appropriate to propose as a research protocol.

Research is carried out to collect data, test a hypothesis, or evaluate the efficacy of a particular medical/surgical procedure, drug, or device. The primary purpose of Research is to contribute to generalizable knowledge by seeking new knowledge, reordering existing knowledge, or applying existing knowledge to a new situation.

II. Procedure to Request Approval to Perform Innovative Care

A Practitioner who wishes to perform Innovative Care at the Hospital shall first obtain the approval of the Chief of the Practitioner's Section/Department. Upon approval by the applicable Section/Department Chief, the Practitioner shall request approval by the Chief Medical Officer and, if the Innovative Care involves a surgical procedure, the Surgeon-In-Chief.

The Practitioner's request should include:

- A description of the proposed Innovative Care, including evidence from existing studies, if applicable;
- Potential benefits to patient outcomes, safety, or operational efficiency;
- Risk assessment and mitigation strategies; and
- Required resources, including staffing, equipment, and training.

If a Practitioner's similarly-qualified multidisciplinary expert or colleague identifies care by a Practitioner that the multidisciplinary expert or colleague believes should be reviewed as Innovative Care under this policy, such individual may bring to the attention of the Practitioner's Section/Department Chief, and if the Chief agrees that the care should be reviewed under this policy, the Chief shall instruct the Practitioner performing the care to submit a request for review under this policy.

The Chief Medical Officer and the Surgeon-In-Chief (if the proposed Innovative Care involves a surgical procedure) will convene a committee (the “Review Committee”) to review the proposed Innovative Care. The Review Committee will contain such members as deemed appropriate by the Chief Medical Officer and the Surgeon-In-Chief and, if possible, should include a Practitioner with relevant medical expertise who is not involved with the patient’s care. A representative from Legal Services shall be included as an advisor to the Review Committee to provide relevant legal advice. Minutes from meetings of the Review Committee will be maintained.

The Review Committee will evaluate the proposed Innovative Care based on:

- Patient safety and ethical considerations (the Review Committee may request that the Practitioner obtain an opinion from the Ethics Committee if deemed appropriate);
- Alignment with the Hospital’s standard of care;
- Feasibility, including costs and required resources; and
- Evidence supporting the proposed Innovative Care’s effectiveness.

The Review Committee may request revisions or additional information before making a final recommendation.

After the Review Committee considers the proposed Innovative Care, the Chief Medical Officer shall inform the requesting Practitioner and such Practitioner’s Section/Department Chief of the final recommendation, which will be one of the following:

- If a determination has been reached that the proposed Innovative Care is innovative and reasonable, approval may be given to proceed with the Innovative Care as proposed.
- If a determination has been reached that potential benefits to the patient from the Innovative Care do not outweigh the risks of the proposed Innovative Care, the Chief Medical Officer will communicate that the Innovative Care shall not be performed at the Hospital. If the Practitioner nevertheless performs the proposed Innovative Care at the Hospital, such behavior will be grounds for corrective action under the Medical Staff Bylaws.
- If the Practitioner intends to perform the Innovative Care on more than one patient, the Review Committee may determine that the proposed care would be better undertaken as a Research project, and the Practitioner will be asked to consider developing a Research protocol for submission to the Hospital’s Institutional Review Board.
- If a determination has been made that the proposed care is not in fact Innovative Care and should be considered under the Hospital’s existing

privileging process, the Practitioner will be directed to request the applicable Privileges through the standard procedures established by the Medical Staff Office.

III. Informed Consent from Patients Receiving Innovative Care

As set forth in the Medical Staff Clinical Care Policy, it is the responsibility of the attending Practitioner to ensure that informed consent is obtained for all medical care provided to a patient. When providing Innovative Care, a Practitioner shall provide all necessary information to the patient and/or the patient's legal guardian to adequately inform them, including information about the Innovative Care, a detailed discussion of potential risks, and the alternative of receiving commonly-accepted medical care (i.e. not the Innovative Care).

IV. Multiple Requests for the Same Innovative Care

If the Chief Medical Officer and/or Surgeon-In-Chief receive multiple requests for approval of the same or similar Innovative Care (either repeatedly from the same Practitioner or from multiple Practitioners), the Chief Medical Officer and/or Surgeon-In-Chief may consider whether the proposed care should no longer be considered Innovative Care and whether it could be considered standard of care or appropriate for submission of a research protocol.

V. Recordkeeping

The Chief Medical Officer and/or Surgeon-In-Chief will notify the Medical Staff Office of requests received from Practitioners to perform Innovative Care. The Medical Staff Office will maintain records of:

- the number of requests received by Practitioners to perform Innovative Care;
- the type of Innovative Care requested to be performed;
- the outcome of each request for Innovative Care; and
- relevant cost analyses, including payer reimbursement for the Innovative Care provided.

All such records shall be maintained as confidential and subject to the peer review privilege pursuant to Ohio Revised Code § 2305.252.

ADOPTION & APPROVAL

Adopted by the Medical Executive Committee on January 21, 2025

Approved by the Hospital Board on January 31, 2025