BayCare Institutional Review Board

Surgical Innovation vs. Research Activities Subject to IRB Review

The Human Research Protection Program (HRPP) has developed local guidance to help our investigators distinguish the 'grey area' between surgical innovation and research activities that involve patients, their data, and/or their biological specimens.

This guidance is based on the ethical guidelines articulated in the Belmont Report which provide the framework for the conduct of human subject research in the United States: (a) respect for persons, (b) beneficence, and (c) justice; and the ethical guidelines for innovative surgery: (a) potential harms to patients, (b) compromised informed consent, (c) unfair allocation of healthcare resources, and (d) conflicts of interest. Lack of adequate data on innovations and lack of regulatory oversight contribute to these ethical challenges.

A. Definitions: The following definitions should be used when applying this guidance

Non-Experimental Surgical Innovation: a new variation on accepted techniques, consistent with accepted principles and practices of surgery, and regarded as having predictable clinically beneficial results for patients.[1]
Experimental Surgical Innovation: a new variation on accepted techniques, consistent with accepted principles and practices of surgery, but where clinical benefit is unpredictable or unknown.[1]
Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
Institutional Review Board (IRB): a committee constituted in compliance with DHHS regulations at 45CFR46 and FDA regulations at 21CFR50 that has been formally designated by an institution to review and monitor biomedical research involving human subjects. In accordance with regulations, an IRB has the authority to approve, require modifications in, or disapprove research. The purpose of IRB review is to assure, both in advance and by periodic continuing review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.
IRB Approval: the written determination of an IRB that the proposed research plan has been reviewed and may be conducted at the institution within the constraints set forth by the IRB and by other institutional and federal requirements.

B. Research Activities

All research conducted with **human subjects** at any BayCare Health System facility must have prior appropriate administrative, clinical ***and*** IRB approvals before such research is undertaken. No research with human subjects may be initiated without the advanced approval of an authorized Institutional Review Board (IRB).
Planned Experimental Surgical Innovations regardless of the number of subjects or Surgical Innovations designed to contribute to generalizable knowledge are generally categorized as 'research' and consequently require prospective IRB review and approval before the surgery can occur. However, surgical procedures often include planned and unplanned innovation that might or might not constitute research with human subjects subject to IRB review. This guidance attempts to help the IRB Committee,

Baycare Health System regulatory support staff, and surgeons determine if an innovative surgical activity is research.

Note: Regardless of the need for IRB review and approval, innovative surgical procedures may require ethics committee or department approval or notification as well as informed consent from patients. All planned surgical innovations should be submitted to the related Medical Director or Chief Medical Officer for review.

C. Is a given surgical activity "Research" requiring IRB review?

Non-Experimental Surgical Innovation: is not subject to IRB review and approval if it meets the definition articulated above and **ALL of the following** are also true:

- ☐ The innovation is being made for the care and treatment of an individual patient or class of patients at BayCare Health System facilities. It may be planned or unplanned.
- ☐ There are no plans to collect data and/or analyze results for general applicability or knowledge (i.e., to write up or provide to outside entities).

Experimental Surgical Innovation is not subject to IRB review and approval if its meets the definition articulated above and **ALL of the following** are also true:

- ☐ The innovation was unplanned. For example the surgical innovation occurred due to an emergency or to remove an immediate hazard to the patient.
- ☐ There are no plans to collect data and/or analyze results for general applicability or knowledge (i.e. to write up or provide to outside entities).

The following activities **are** considered Research and therefore **do** require prospective IRB review and approval before beginning research activities:

- Any planned Experimental Surgical Innovation or planned prospective evaluation of a Non-Experimental Surgical Innovation.
- Any Surgical Innovation (Experimental or Non-Experimental) designed to **develop** a standard of care or benchmark **for general applicability** (i.e., not only for operations within Baycare Health System, but for outside entities as well).
- Collection and submission of data to a registry or database to track the outcomes of the Surgical Innovation (Experimental or Non-Experimental) for generalizable knowledge.
- Use of surgical data from any registry or database that was established for clinical care but will now be used for the purpose of measuring, improving or developing a standard or benchmark or to describe the procedures or outcome of the Surgical Innovation (Experimental or Non-Experimental).
- Any activity that proposes comparisons of one or more prospective interventions that are deliberately administered or made available (through a randomization or other process) to some patients or some hospitals and not to others.

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D. Single Case Reports

A report of a small number of cases (generally not more than three), created for presentation or publication, are not considered research if the following conditions exist:

- ☐ The report is compiled by persons already involved in the patient's care;
- ☐ The information is presented in de-identified form; and
- ☐ No changes were made in the patient's care or diagnostic testing for the sake of reportability.

Case reports become a research activity if any of the previous three stipulations are not met, or if multiple cases are systematically analyzed for presentation or publication or to test a hypothesis.

E. Off-label Use or Non-Standard Medical Practices

Off-label use of a marketed drug or device, or non-standard medical or surgical practices, may be pursued with the sole intent of enhancing the well-being of an individual patient.

Off-label use or non-standard practices may become a research activity when one or more of the following is true:

- ☐ There is a clear intent, before treating the patient, to systematically collect data on a series of patients receiving similar treatments;
- ☐ The physician keeps separate data sheets for reviewing patient outcomes or has other organized methods of gathering data;
- ☐ Extra tests are performed that are not directly related to the patient's benefit;
- ☐ The care under consideration is delivered consistently across a series of patients according to an "unwritten" protocol in order to keep processes and procedures uniform.

For any 'problematic' activity not described above, please consult with the IRB Office for assistance.

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[1]L. B. McCullough, "Standard of Care, Innovation and Research in Surgery: A Problem in Research Ethics or in Professional Ethics?", Ethical Guidelines for Innovative Surgery, Reitsma and Moreno (2006)
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