

## **Project: Clinical Research: Treatment versus Research**

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Team: Health

### **Project name**

Medical Research versus Medical Treatment

### **Clients & collaborators**

Berman Institute of Bioethics, Johns Hopkins University

The increasing integration of medical research with medical treatment has significantly blurred distinction between the two areas, resulting in a gap within mechanisms for research ethics and oversight. This project is intended to support the advancement of policy and regulatory frameworks to account for the research-treatment interface– in order to ensure adequate human subject protection.

### **Goals & objectives**

Purpose: To Ensure adequate protection of persons subject to medical research given the increasing integration of research and treatment in the U.S. healthcare system.

Goal:

- Advance the policy and regulatory frameworks that govern research activities involving human beings, so that they reflect the increasing integration of research with treatment (the “research-treatment interface”).
- Influence key actors (policymakers, medical practitioners, and Institutional Review Boards) to update regulations, policies and ethics guidelines.

Objectives:

- Bring mechanisms for research oversight up to speed so the research-treatment interface is accounted for:
  - Analyze how the law/regulations currently distinguish medical research from medical treatment
  - Provide clear conceptual, ethical, and policy recommendations as to what should constitute research versus treatment

### **Stages of work**

- Analytical work products

- Table summarizing definitions of key human subject research oversight concepts/terms in Federal and State law
- Table summarizing definitions of key human subject research oversight concepts/terms Federal regulations/preambles
- Table summarizing definitions of key human subject research oversight concepts/terms Federal and State case law
- Memo describing any noticeable evolution or change over time in:
  - The legal definitions of key concepts/terms
  - The way medical research was distinguished from medical treatment in law