

Institutional Review Board (IRB) Policies & Procedures Manual



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Case Studies/Series

Purpose

This policy provides guidance to Boston Children's Hospital (BCH) researchers for determining if a case study report constitutes human subject research and requires prospective IRB review and approval.

Policy

Boston Children's Hospital defines **case study** and **case series** as found below.

Case Study: A report of a person with a unique disease or condition, associated treatment or outcome.

Case Series: A report of 3 or less persons with a unique disease, condition, associated treatment or outcome.

Procedure

Specific considerations for developing and publishing case studies/series

Case studies/series of 4 or more patients/subjects are considered human subject research and prospective IRB approval must be obtained prior to review of patient records and data collection.

While not considered human subject research, case studies involving 3 or less patients should be reviewed by the BCH Privacy Office prior to publication for any HIPAA/PHI considerations.

Examples that do not require IRB review or approval:

- The review of records for 3 or less patients to report as a case study or case series is not considered human subject research under the jurisdiction of the IRB.
- A case study/series involving 3 or less patients is considered anecdotal and not generalizable. As such, it does not meet the definition of human subject research. For more information see IRB Policy: *Research and Human Subject Definition*.

Related Content

IRB Policy

Research and Human Subject Definition

Document Attributes

Title	Case Studies/Series
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