



## Case Studies/Series

### Purpose

The purpose of this document is to provide 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.

### Definitions

**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.

### Specific considerations and procedures for developing and publishing case studies/series

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. These reviews may proceed without IRB review.

A case study/series involving 3 or less patients is considered anecdotal and not generalizable, and does not meet the definition of human subject research (please refer to the policy Definition of Human Subject and Research), or require IRB review or approval. 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.

Case studies/series of four (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.

### Related Content

IRB Policy and Procedure

Research & Human Subject Definition

### Document Attributes

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