

Status **Active** PolicyStat ID **17413569**



**Boston
Children's
Hospital**

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Effective 3/1/2025
Next Review 2/29/2028

Owner Susan Kornetsky:
Manager
Department Research
Applicability Boston Children's
Hospital- Policies
& Procedures

Case Studies/Series - Policy/Procedure

Internal Approval

SVP, Research Administration

EVP, Chief Scientific Officer

Scope

This policy applies to the Boston Children's Hospital (BCH) Research department and the respective staff.

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.

Policy Statements

This policy applies to all Boston Children's Hospital (BCH) licensed locations, BCH operational and clinical departments, and staff (inclusive of W-2 employees, contracted staff, and members of the medical staff irrespective of their appointment category or employer). As applicable, the policy also applies to foundation practices leasing space at hospital-licensed locations.

Specific considerations for developing and publishing case studies/series

1. **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.

2. 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.

Procedures

Examples that do not require IRB review or approval

1. 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.
2. 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.

Related Content

- IRB Policy: Research and Human Subject Definition (For more information on human subject research definition)

Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	3/1/2025
Site Administrator: Education/ Training Requirement	Dwight Mayfield	2/26/2025
Steering Committee	Dwight Mayfield	2/26/2025
Required Departmental Review/Approval	August Cervini	1/17/2025
Committee Chair(s)	Susan Kornetsky: Manager	1/17/2025
Contributor(s)	Susan Kornetsky: Manager	1/17/2025
Document Owner	Susan Kornetsky: Manager	1/17/2025

Applicability

Boston Children's Hospital- Policies & Procedures