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**Boston
Children's
Hospital**

Where the world comes for answers

Effective 9/1/2020
Next Review 8/29/2025

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

Case Studies/Series - Policy/Procedure

Internal Approval

SVP, Research

EVP & Chief Scientific Officer, Research

Scope

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.

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

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

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