

**DREXEL UNIVERSITY
INSTITUTIONAL REVIEW BOARD**

POLICY ON CASE REPORTS AND CASE STUDIES

I. INTRODUCTION

Case reports, which generally consist of three or fewer patients, are prepared for the purpose of illustrating some points in the care of a patient, to educate and formulate new research questions which may eventually lead to generalizable knowledge. A resource guide published on the web⁽¹⁾ cites the following types of cases as worth reporting:

- Uncommon observations
- Report of a new condition, treatment and follow up
- Report of a familial condition with a proposed mode of inheritance
- A new theory
- Questions regarding a new theory
- Unusual combination of conditions or events that cause confusion
- Adverse responses to therapies
- Personal Impact

In addition, case reports may include:

- Very common observations or practices that has not been documented previously
- Unique aspects of the practice such as outreach and engagement into care, case management and collaborations, clinical adaptations to care
- The competing priorities of patients while homeless and how care needs to accommodate them.

This policy is developed to provide guidance on when publication of case reports constitute human subject research and review by IRB.

Case studies on the other are qualitative research methods⁽²⁾. It is the in-depth analysis, empirical inquiry, or investigation of a person or group in a natural, uncontrolled setting. This research method is done from the participants' perspective and studies how they make meaning of the world – not how researchers manipulate it. Qualitative researchers study things in their natural settings, attempting to make sense of, or to interpret, phenomena in terms of the meanings people bring to them.

II. POLICY ON MEDICAL CASE REPORTING

The boundaries between case reporting and formal medical records research may be unclear for a series of one's own patients. Researchers are advised to consult with the IRB when uncertainty exists and when formal and systematic collection of human subjects research will be occurring.

The Office for Human Research Protection regulations (45 CFR 46.102(d)) defines "research" as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. In general, the review of medical, educational or private records for publication of "case reports" typically involves three (3) or less subjects. In such circumstances, they are NOT considered human subject research and may not require IRB review since they do not formulate research hypothesis. However, administrative approval is required.

Formal retrospective or prospective records review involving a larger subject population [greater than three (3) subjects] qualify for either Exempt (if data is existing and anonymous) or Expedited IRB review. In these circumstances, researchers are beginning to ask questions and collect data either prospectively or retrospectively to systematically analyze data, making the study closer to deriving generalizable knowledge.

III. POLICY ON CASE STUDIES

A case study includes multiple data sources such as interviews, documents, archival records, direct observations, and physical artifacts. Analysis is through description, themes, and assertions. Researchers from many disciplines (e.g., social/behavioral, educational, epidemiological) use this method to build upon, produce new, and dispute current theory. A Case Study requires submission of an application to the Office of Human Research for administrative approval.

IV. CONFIDENTIALITY

Participant's rights to confidentiality must always be respected when using their personal or medical information. Please pay particular attention to the following when attempting to publish a case report:

- Patient's 18 HIPAA identifiers noted in HIPAA regulations or combinations of those identifiers, which might easily allow someone to identify a subject, should never be used in publications or presentations. In cases where data collection on behalf of the protocol requires access to protected health information (PHI), investigators must apply for a Waiver of HIPAA Authorization to the Privacy Board. The Privacy Board shall make the final decision on granting the Waiver of Authorization.
- Case Reports containing familial condition with a proposed mode of inheritance, unique family trees or pedigrees should be masked or disguised in the publication when such information could identify individuals or kindreds unless consent/permission has been obtained from those subjects.
- When photographs or other images are going to be used in the publication, identifiers should be appropriately masked to preclude identification of subjects. In some cases, the patient's permission may be necessary to publish such case reports.
- Investigators should be sensitive to unique or unusual diagnoses or illnesses, which when combined with the hospital name, state or city of residence might identify a subject with such rare diagnosis when published in research papers or text books.
- Investigators must abstract and retain only the minimum relevant clinical information. Investigators must not retain the links indefinitely. They must discard links between the source records and the human subjects as soon as the research goals have been completed and published, as applicable.

V. APPLICATION FORM

Go to www.research.drexel.edu/compliance to download the form.

References:

1. Burge SK. *Writing A Clinical Case Report*. Family and Community Medicine, The University of Texas Health Science Center at San Antonio site. 2004. [A PowerPoint presentation that can be reviewed in 15 minutes.] Available at <http://familymed.uthscsa.edu/education05/facdev/caseReportIntro.htm>
2. Hamel, J., Dufour, S., & Fortin, D.(1993). *Case study methods*. Newbury Park, CA: Sage.