1 PURPOSE

1.1 This guidance establishes the process for the submission and publication of single case reports and limited case series at Sharp HealthCare (SHC).

1.2 The guidance begins with the consultation to determine if the report meets the definition of human subjects' research.

1.3 The guidance ends with the SHC Institutional Review Board (IRB) determination.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions available in Human Research Protection Program Change Log.

3 POLICY STATEMENT

3.1 A Case Report or Limited Case Series is a description of the clinical characteristics or treatment(s) provided to a single patient or a small group of patients that share a common condition, which did not involve activities defined as research.

3.2 Federal regulations (45 CFR 46.102(d) and 45 CFR 164.501) define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The review of medical records for publication of a single case report or a limited case series involving data from three or fewer patients is not considered by the IRB to be research involving human subjects, and therefore such a report does not require IRB review and approval. The report of a small series of patients does not typically involve a systematic investigation, including defining a hypothesis that is investigated prospectively.

3.3 A case series (more than three cases) meets the definition of human subjects' research and requires the submission of a new protocol application to the IRB.

3.4 The IRB regards case reports or a limited case series as an educational activity, and therefore it is permissible under the Health Insurance Portability and Accountability Act (HIPAA) as a part of health care operations (45 CFR 164.501). However, from both the Common Rule and the Privacy Rule perspective, a case series involving more than three cases does meet the definition of research, and such research requires IRB approval.

3.5 Medical education or medical consultation, including the presentation of a difficult case or case series at a teaching conference, does not require IRB review and approval. Generalizing comments presented in an accepted educational setting by a caregiver who describes the outcome of his/her clinical care of a group of patients is also not considered research requiring IRB review if the generalizing is restricted to the specific local educational setting. Such a presentation may occur outside the local setting, and even in published form, as in a regional meeting on continuing education, or in an editorial in a medical journal, as long as the comments are clearly identified as representing the personal experience of the presenter and not the result of formal clinical research. In such a case, a summary of the opinion may be offered, but specific supporting data would not be presented.

3.6 Case reports for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Any use or disclosure of Protected Health Information (PHI) must be authorized by the patient, or, if the patient is deceased, the patient's family using TEMPLATE: Consent Form for Case Report (HRP-508). Publication of a case report containing PHI is a disclosure of PHI. The privacy officer or designated HIPAA authority at the applicable location should be consulted prior to submission of the case report to assure proper authorization was obtained (*POLICY: HIPAA Policy [16508.00]*)

4 RESPONSIBILITIES

4.1 Investigators, sub-investigators, or study coordinators must fulfill the requirements set forth in this guidance.

4.2 IRB specialists carry out this guidance.

5 PROCEDURE

5.1 Investigator or designee completes *FORM: Case Reports Using Existing Data (HRP-229)* and submits to the IRB for a determination of research versus case report or limited case series

should they wish to report on an experience or set of experiences, as well as when determination by the IRB is required by journals prior to publication or presentation.

5.1.1 If the report involves more than three (3) cases or become a systematic investigation at any time, investigator or designee submits an application under 45 CFR 46.101(b)(4), see *GUIDANCE: Initial IRB Review Application (HRP-211)*.

5.1.2 If the report qualifies as a single case report, the IRB will send *TEMPLATE: Letter: Not Human Research Determination (HRP-513)* to the investigator or designee stating IRB review is not required.

5.2 *TEMPLATE: Letter: Not Human Research Determination (HRP-513)* may be used as an acknowledgment letter as required by journal editors for publication of case reports or limited case series.

5.2.1 Should the journal not accept the IRB's determination that reporting a case or a limited case series does not constitute research, the investigator or designee should contact the IRB and the issue will be discussed and resolved by the IRB chair or designee.

5.3 The investigator obtains a signed HIPAA authorization from either the patient or their legally authorized representative prior to submission of the case report or limited case series for publication using *TEMPLATE: Consent Form for Case Report (HRP-508).*

6 MATERIALS

6.1 POLICY: HIPAA Policy (16508.00)
6.2 GUIDANCE: Initial IRB Review Application (HRP-211)
6.3 FORM: Case Reports Using Existing Data (HRP-229)
6.4 TEMPLATE: Consent Form for Case Report (HRP-508)
6.5 TEMPLATE: Letter: Not Human Research Determination (HRP-513)

7 REFERENCES

7.1 45 CFR 46.102(d); 45 CFR 45.101(b)(4)

This document is available on www.sharp.com/research, IRBANA, or by contacting research@sharp.com.