1 PURPOSE

1.1 This guidance establishes the process for the submission and publication or presentation of a Case Report or Limited Case Series involving Sharp HealthCare (SHC) patients.

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

1.3 The guidance ends with the SHC Institutional Review Board (IRB) clearance of the proposed publication or presentation.

2 REVISIONS FROM PREVIOUS VERSION

2.1 If applicable, previous versions are available via the Human Research Protection Program (HRPP) Change Log.

3 POLICY STATEMENT

3.1 Medical education or medical consultation, including the presentation of a difficult case or case series at an educational 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 patient or 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, in a textbook, or in an editorial in a medical journal, provided the comments are clearly identified as representing the personal experience of the author or 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.

3.2 Definitions and IRB Review Requirements

3.2.1 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.

3.2.2 Case Report (1-3 patients) - A description (i.e., publication or presentation) of the clinical characteristics or treatment(s) provided to three or fewer patients that share a common condition, which did not involve activities defined as research. A Case Report is a medical/educational activity that does not meet the Department of Health and Human Services (DHHS) definition of "research" ("a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge") because a report of a small group of 1-3 patients does not typically involve a systematic investigation or defining a hypothesis that is investigated prospectively.

3.2.3 Limited Case Series (≥4 patients) - A description (i.e., publication or presentation) of the clinical characteristics or treatment(s) provided to four or more patients that share a common condition. This activity is defined as research.

3.2.3.1 IRB submission and approval is required prior to submission to the journal or conference at which the limited case series will be published or presented.

3.2.4 Review of Proposed Publication or Presentations – Authors will submit to the SHC IRB Office all proposed publications or presentations for Case Reports or Limited Case Series that were reviewed by the SHC IRB. The SHC IRB Office provides written clearance to the author or designee. Proposed publications or presentations do not require SHC IRB review when a Case Report was not reviewed by the SHC IRB.

3.3 Informed Consent Requirements

3.3.1 When a Case Report or Limited Case Series involves the publication or presentation of images and/or audio/visual recordings (i.e., photography (still images), audio recordings, videotaping, and any other type of filming or recording that produces any of these media types) and associated health information, informed consent must be obtained from each patient or their Legally Authorized Representative (LAR), prior to submission of the proposed publication or presentation to a journal or conference. The

author must obtain a signed/dated *Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use*, per POLICY: Consent to Photograph & Publication (01601).

3.3.1.1 Images and/or audio/visual recordings must be taken or recorded on Sharp HealthCare owned equipment.

3.3.2 When a Case Report or Limited Case Series involves publication or presentation of:

3.3.2.1 **Only** de-identified health information (no images and/or audio/visual recordings), the patient's or patient's LAR's informed consent **is not** required.

3.3.2.2 Identifiable health information (no images and/or audio/visual recordings), the patient's or patient's LAR's informed consent and Health Insurance Portability and Accountability Act (HIPAA) authorization **is** required.

3.4 HIPAA Privacy Rule Requirements

3.4.1 The author of a Case Report or Limited Case Series must comply with HIPAA. Images, audio/visual recordings, and health information to be shared via a proposed publication or presentation should be de-identified in accordance with the HIPAA Privacy Rule's de-identification standard and implementation specifications (45 CFR 164.514(a-b)), prior to dissemination outside SHC.

3.4.1.1 Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission of the proposed publication or presentation do not need to obtain a signed PHI (privacy) authorization.

3.4.1.2 Authors who wish to publish or present Case Report or Limited Case Series data with HIPAA identifiers will need to obtain from the patient or their LAR a signed/dated *Sharp HealthCare Authorization for Use or Disclosure of Protected Health Information*.

3.4.1.3 If the author strips off all HIPAA identifiers, but the information associated with a patient of the proposed publication or presentation includes a "unique characteristic" which would make it identifiable to that patient, or the author has actual knowledge that the information about the patient(s) could be used alone or in combination with other information to identify the patient(s), the author must contact Corporate Compliance to discuss the required steps to take prior to publication or presentation.

4 RESPONSIBILITIES

4.1 Authors and/or their designees and IRB Specialists carry out this guidance.

5 PROCEDURE

5.1 Case Reports (1-3 patients)

5.1.1 If the journal or textbook publisher or conference organizer **does not** require documentation of IRB review, **do not** submit the Case Report to the SHC IRB.

5.1.1.1 In advance of submission of the proposed publication or presentation to the journal or textbook publisher or conference organizer, the author or designee obtains the following from each patient or patient's LAR:

- When the Case Report involves the use and sharing of **de-identified** images or audio/visual recordings, with or without associated de-identified health information, signed/dated *Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use* when the Case Report. The author or designee:
  - Files the signed/dated consent in the patient's electronic medical record; and
  - Should provide a copy of the signed/dated consent to the patient or their LAR.

- When a Case Report involves the use and sharing of **identifiable** health information, signed/dated informed consent and *Sharp HealthCare Authorization for Use or Disclosure of Protected Health Information*. The author or designee:
  - Files the signed/dated consent and authorization in the patient's electronic medical record; and
  - Should provide a copy of the signed/dated consent and authorization to the patient or their LAR.

5.1.2 If the journal or textbook publisher or conference organizer **does** require documentation of IRB review:

5.1.2.1 Author or their designee submits the following electronically to the SHC IRB via research@sharp.com:

- Completed FORM: Case Report Review Request (HRP-229)
- If the Case Report involves the use of de-identified images or audio/visual recordings with associated de-identified health information, signed/dated *Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use* for each patient included in the Case Report / presentation. The author or designee:
  - Obscures all patient identifiers (i.e., patient name; LAR name; MRN; etc.) prior to IRB submission; and
  - Files the signed/dated consent in the patient's electronic medical record; and
  - Should provide a copy of the signed/dated consent to the patient or their LAR.
- If the Case Report involves the use of identifiable health information (including unique characteristics as defined by HIPAA), signed/dated *Sharp HealthCare Authorization for Use or Disclosure of Protected Health Information* when identifiable information and/or images and/or audio/visual recordings will be shared via the proposed publication or presentation. The author or designee:
  - Obscures all identifiers (i.e., patient name; LAR name; MRN; etc.) prior to IRB submission; and
  - Files the signed/dated authorization in the patient's electronic medical record; and
  - Should provide a copy of the signed/dated authorization to the patient or their LAR.
- If the Case Report involves only use of health information (i.e., no images or audio/visual recordings), customize *TEMPLATE: Consent Form for Case Report or Case Series (HRP-508)* for use with the proposed Case Report prior to IRB submission.

5.1.2.2 An IRB Specialist:

- Reviews the submission for completeness and notifies the author or designee if additional information or changes are needed.
- Uses *WORKSHEET: Human Research Determination (HRP-310)* to document the not human subjects research determination. *WORKSHEET: Human Research Determination (HRP-310)* is maintained in the IRB's agenda item file.
- Issues TEMPLATE: Letter: Not Human Research Determination (HRP-513) and, if applicable, the IRB cleared TEMPLATE: Consent Form for Case Report or Case Series (HRP-508) to the author or designee.

- Documents the not human subjects research determination via *TEMPLATE: Non-Committee Review Notification (HRP-501b)*.

5.2 Limited Case Series (≥4 patients; considered research)

5.2.1 Sharp HealthCare Requirements (before SHC IRB submission)

5.2.1.1 When the Limited Case Series involves the use and sharing of de-identified images or audio/visual recordings, with or without associated de-identified health information and prior to IRB submission, the author or designee obtains from the patient or patient's LAR a signed/dated *Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use*. The author or designee:

- Files the signed/dated consent in the patient's electronic medical record; and
- Should provide a copy of the signed/dated consent to the patient or their LAR.

5.2.1.2 When a Limited Case Series involves the use and sharing of identifiable health information, the author or designee obtains from the patient or patient's LAR a signed/dated *Sharp HealthCare Authorization for Use or Disclosure of Protected Health Information*. The author or designee:

- Files the signed/dated authorization in the patient's electronic medical record; and
- Should provide a copy of the signed/dated authorization to the patient or their LAR.

5.2.2 SHC IRB Submission

5.2.2.1 The author or designee submits the following to the SHC IRB electronically, via research@sharp.com:

- Completed FORM: Initial IRB Review Application (HRP-211)
- Completed, signed/dated FORM: Principal Investigator's Attestation (HRP-219)
- When applicable, signed/dated Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use.
  - Author or designee obscures all patient identifiers prior to IRB submission.
- When applicable, signed/dated *Sharp HealthCare Authorization for Use or Disclosure of Protected Health Information* for each patient included in the Limited Case Series.
  - Author or designee obscures all patient identifiers prior to IRB submission.
- When the Limited Case Series involves only use and sharing of health information (i.e., no images or audio/visual recordings), *TEMPLATE: Consent Form for Limited Case Series (HRP-508)*, customized for use with the proposed Limited Case Series. The author or designee
  - Files the signed/dated consent document in the patient's electronic medical record; and
  - Should provide a copy of the signed/dated consent to the patient or their LAR.
  - When the IRB cleared *TEMPLATE: Consent Form for Limited Case Series (HRP-508)* is used, the signed/dated document does not need to be submitted to the IRB after consent is obtained from the patient or their LAR.

5.2.2.2 An IRB Specialist:

- Reviews the submission for completeness and notifies the author or designee if additional information or changes are needed.
- Uses *WORKSHEET: Human Research Determination (HRP-310)* to document the not human subjects research determination and saves the completed worksheet in the agenda item file.
- If applicable, uses *CHECKLIST: Exemption Determination (HRP-428)* to document the exempt category of review and saves the completed checklist in the agenda item file.
- Issues TEMPLATE: Letter: Not Human Research Determination (HRP-513) and, if applicable, the IRB cleared TEMPLATE: Consent Form for Case Report or Case Series (HRP-508) to the author or designee.
- Documents the not human subjects research determination via *TEMPLATE: Non-Committee Review Notification (HRP-501b)*.

5.3 Proposed publications or presentations

5.3.1 Proposed publications or presentations **do not** require SHC IRB review when the Case Report **was not** reviewed by the SHC IRB.

5.3.2 Proposed publications or presentations **do** require SHC IRB review when the case report **was** reviewed by the SHC IRB.

5.3.2.1 Prior to the author's submission to the publisher or conference organizer, the author submits the proposed publication or presentation to research@sharp.com.

5.3.2.2 An IRB Specialist sends the proposed publication or presentation to the Director of Research or designee for administrative clearance.

5.3.2.3 The Director of Research or designee notifies the IRB Specialist of their clearance, requested changes, or rejection of the proposed publication or presentation.

5.3.2.4 An IRB Specialist notifies the author and/or their designee of administrative clearance via e-mail.

6 MATERIALS

6.1 POLICY: Research and the HIPAA Privacy Rule (16508.00)
6.2 POLICY: Consent to Photograph & Publication (01601)
6.3 Sharp HealthCare Consent for Collection and Sharing of Images and/or AV Recordings for External Use
6.4 Sharp HealthCare Authorization for Use or Disclosure of Protected Health Information
6.5 FORM: Initial IRB Review Application (HRP-211)
6.6 FORM: Principal Investigator's Attestation (HRP-219)
6.7 FORM: Case Report Review Request (HRP-229)
6.8 WORKSHEET: Human Research Determination (HRP-310)
6.9 CHECKLIST: Exemption Determination (HRP-428)
6.10 TEMPLATE: Non-Committee Review Notification (HRP-501b).
6.11 TEMPLATE: Consent Form for Case Report or Case Series (HRP-508)
6.12 TEMPLATE: Letter: Not Human Research Determination (HRP-513)

7 REFERENCES

7.1 DHHS: 45 CFR 46.102(l); 45 CFR 45.101(b)(4)

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