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Owner	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies
Department	HRPP/Research

Research: Case Report Publication Policy- AD.0163

PURPOSE

The purpose of this policy is to provide guidance to the IRB, Privacy Office and clinicians/investigators on how to approach **case reports/case series** for publication purposes. It is intended that this case report publication policy be consistent with the 2018 Common Rule, OHRP Guidance and the HIPAA Privacy Rule, each as amended from time to time. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and **Research** Personnel engaged in research.

POLICY

I. Single case reports and limited case series (three (3) or less patients), are not required to be submitted to the LRH IRB for review and approval. To the extent that a journal or other publication requests a consent document please contact the IRB Office to request documentation or help with determination. If there are more than three (3) patients in the project/study in question, follow relevant policies and procedures for human subject research; see: **Research: Research that Must be Reviewed by the IRB AD.0162**.

II. All case reports/series must adhere to the **HIPAA Privacy Rule requirements** in the use and disclosure of **PHI**. LRH regards case reports as activities for educational purposes, which may be disseminated outside of LRH from time to time. HIPAA Privacy Rule requirements apply to the use and disclosure of PHI within a case report.

III. Investigators who submit de-identified case reports (three (3) or less patients) for publication do not need to obtain the patient(s) HIPAA authorization(s) prior to submission for publication. However, because a case report is usually interesting or unique, it is often difficult for clinicians to de-identify a case report. For de-identification, the clinician must strip the single case report or limited case series of any and all of the eighteen (18) HIPAA identifiers and be unrecognizable to someone who knows the patient, including the patient themselves. If a case report contains **indirect identifiers** or significant details about the patient, medical treatments, history, procedures,

hospital stay, etc., then it is possible the patient can be identified and a HIPAA authorization and a signed Consent for Case Report form is needed (see form attached to this policy).

IV. HIPAA Authorization and consent may be needed in certain single case reports and/or limited case series:

A. Single case reports or limited case series may require HIPAA authorization and a signed Consent for Case Report in certain circumstances. When a patient cannot be de-identified in the report or the researcher is unsure if complete de-identification is possible, contact the Office of Research and Sponsored Studies for HIPAA guidance. Contact the IRB Administrator for a Consent for Case Report form.

B. When a project involves more than three (3) patients and meets the definition of human subjects research, the IRB must be used for review (see Research: Research that Must be Reviewed by the IRB- AD.0162).

C. In the instance that a HIPAA authorization is needed, it must be stored in the patient's medical record. If there is any doubt regarding if a description is identifiable, contact the Office of Research and Sponsored Studies at least ten (10) days prior to your intended submission date.

V. IRB Review and Letter for Journal/Publication Requests

A. If an investigator wishes to have a single case report or limited case series reviewed by the LRH IRB, the clinician may do so by submitting a request in IRBNet, where the IRB Administrator will then guide the investigator appropriately.

B. Upon request, the IRB Administrator may provide a form letter to share with external entities (i.e. a publisher requesting permission from the organization) pending appropriate level of review and criteria met in this policy. The form letter will specify that the single case report or limited case series has been reviewed by the LRH IRB and is approved for external dissemination.

C. Investigators/clinicians should inform the LRH IRB if the journal does not accept the IRB's decision. The issue will then be discussed with the IRB Administrator, IRB Chair, Legal, Privacy, and Compliance Offices to determine a resolution.

PROCEDURE

I. In the instance that a single case report or limited case series, meets the definition of human subjects research, the project must be reviewed and approved by the IRB before beginning any research activities.

II. If the investigator must obtain a HIPAA Authorization and/or Consent for Case Report from the patient or guardian/representative, the following steps should be taken:

A. A signed HIPAA Authorization from the subject(s) of the single case report or limited case series is required if there is disclosure of PHI in the manuscript. Any questions regarding PHI should be directed to the Office of Research and Sponsored Studies prior to submission of the case report to assure proper authorization was obtained.

B. The patient should be informed that while a reasonable effort will be made to anonymize the single case report or limited case series, complete anonymity is not possible. If a patient can identify themselves in the report, then it cannot be considered completely anonymous.

C. All aspects of consent must be explained to the patient in their own language,

understood by the patient and agreed to by the patient.

D. In the event that a patient is deceased, a signed Consent for Case Report form must be attempted to be obtained from their next of kin or a legal representative. A HIPAA authorization form from the legally authorized representative of the deceased is required if there is disclosure of PHI in the Case Report publication.

E. If the patient is a child, consent must be obtained from their parent or legal guardian.

F. The eighteen (18) elements of PHI which are direct HIPAA identifiers must not be included in a single case report or limited case series when possible. To help avoid the use of PHI, use an age group instead of exact age, use season instead of exact month, avoid using a specific race (i.e. use Asian instead of Vietnamese), and make sure the totality of information given, including the author's institutional address do not provide enough information to potentially identify a patient.

G. A consent is executed when it is signed by the patient or patient's legal representative and the requesting author.

    1. Consent shall be obtained as soon as possible after consent to treatment and prior to the presentation or publication of the single case report or limited case series.
    2. To consent the patient or legal representative, the consent document must have basic information about how their treatment information may be used in the article, presentation, or poster presentation.
    3. The requestor must be available to answer the patient's questions.
    4. The patient must be able to understand the personal implications of providing consent.
    5. The patient must voluntarily consent without of an element of force, deceit, duress, overreaching, or coercion. The patient should be instructed that their decision to consent will not affect the medical care and treatment they receive. The patient should be informed that they can withdraw their consent any time before there is a commitment to publish an article or give a presentation based on their information.
    6. Documentation of the patient consent will be made in the patient's medical record as a provider entry detailing the Consent for Case Report of the patient or by uploading a separate Consent for Case Report document signed by the patient into the patient's medical record.
    7. Any use or disclosure of PHI will be authorized by the patient, or if the patient is deceased, the patient's legal representative.

H. A copy of the signed Consent for Case Report will be given to the patient or the patient's legal representative.

I. If the case report contains photography, video or recording, a specific authorization section in the Consent for Case Report form for photography, video, and/or recording must be signed.

J. If a patient requests to withdraw their Consent for Case Report, the request should be submitted in writing to the individual who obtained the Consent for Case Report. This information or revocation of consent should also be included in the Consent for Case Report form the patient or representative signed.

K. In the event that a journal requires a specific consent form, both the LRH and journal consent may be required.

L. In the event that the author is unable to reach the patient to obtain consent and the case report contains important scientific information that would significantly benefit other patients, and no PHI will be reported, consult with the Office of Research and Sponsored Studies.

M. For case reports that have been de-identified of all eighteen (18) HIPAA identifiers, the author may obtain and document verbal consent for publication, with a witness present, from the patient on the Consent for Case Report form.

DEFINITIONS

Case Report or Case Series: A formal summary of a unique patient and their illness, including the presenting signs and symptoms, diagnostic studies, treatment course, and outcome which did not involve the investigator having any research intent at the time of the intervention [i.e., no prospective plan to systematically evaluate the outcome for purposes other than treating the particular patient(s)].

Indirect identifiers: In conjunction with other information, could potentially identify a patient. These indirect identifiers might include: gender, hospital, hospital affiliation of the author, extremely rare disease or treatment, sensitive data such as illicit drug use or "risky behavior", place of birth, "rare" occupations, place of work, anthropometry measures, multiple pregnancies and information which can potentially be used to uniquely identify, contact, or locate a single person.

PHI (Personal Health Information): Means information, including demographic information, which relates to: the individual's past, present, or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, and that identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.

HIPAA Privacy Rule requirements: lists the following eighteen (18) HIPAA identifiers below; all of these identifiers must be removed or masked for a single case report or a limited case series to be considered de-identified:

1. Names;
2. All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three (3) digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three (3) initial digits contains more than 20,000 people; and (2) The initial three (3) digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;

7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

Case Reports: Single Case Reports – Limited Case Series - Duke University Health System, Health Research Protection Program https://irb.duhs.duke.edu/sites/irb.duhs.duke.edu/files/Case%20Reports%20Policy%2005-30-2008.pdf

Guidance for Investigators HIPAA Requirements for Case Reports Office of Human Subjects Research - Institutional Review Board, John Hopkins Medicine http://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/hipaa_case_reports.html

Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule - http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/

COLUMBIA UNIVERSITY INSTITUTIONAL REVIEW BOARD/ PRIVACY BOARD POLICY CASE REPORTS DRAFT—MAY 31, 2005 (columbia.edu)

OHRP Scholarly and Journalistic Actvities Deemed not to be Research: 2018 Requirements. Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements | HHS.gov

ATTACHMENT

Lakeland Regional Health

CONSENT FOR CASE **REPORTS**

Title of Case Report:

Principal Investigator (PI): Name, degree(s)
Contact Phone Number

Person Obtaining Consent (if Different from PI): Name, degree(s)
Contact Phone Number

Dr. (insert name) would like to use information about your (insert condition/disease/experience) to write a case report. Case reports are usually written to share new information based on a patient's experience during medical treatment. This new information may help other physicians and healthcare providers. A case report may be published in print or on the internet, or it might be presented at a medical conference. This form explains the purpose of this case report. Please read this form carefully and take your time to make your decision and ask questions.

The purpose of this case report is to inform other physicians that (insert specific reason, including outcomes of interest). For this case report, the information your physician would like to use includes (insert detailed information here. Specify materials that will be submitted including photographs, video, recordings, text, etc.). This case report will discuss the information listed and how it affects (insert details surrounding the outcome that was previously listed).

Your personal information will be removed to protect your privacy to the furthest extent possible. This means Dr. (insert name) will not share your personal information (including your name, date of birth, and medical record number). **When the case report is published or presented, your personal information will not be revealed.** Although Dr. (insert name) will do everything possible to keep your personal information confidential there is a small risk that publication of this case report could result in a loss of confidentiality due to your unique experience as a patient (insert examples relevant to case).

Your participation in this case report is completely voluntary and will not affect the care you receive from Dr. (insert name). You will not receive any different treatment than you already were if you choose to participate or not. You may withdraw your consent at any time before the case report is published; however, once it is published, you will no longer be able to withdraw your consent. Even though you will not directly benefit from participating in this case report, the information may help other patients in the future. You will not incur any additional costs by allowing your information to be included in this case report, nor will you receive any compensation.

To revoke your authorization, please write to:

Principal Investigator

For IRB Study # *[Insert your IRB Study # or Title of Case Report/Series]*

[Insert complete business mailing address and email]

Dr. (insert name) will also share with you any new information learned related to this case report that could affect your medical care.

Please feel free to ask Dr. (insert name) any questions you have before you give your permission for your information to be used in this case report. Your signature below means that you understand how your information will be used and that you give permission for your information to be used in this case report.

Case Report Title: _____

Name of Participant: _____

Participant Guardian/Representative (if participant is unable to give consent):

_____

Relationship of Guardian/Representative to Participant (if participant is unable to give consent:

_____

Materials (text, photo, video, recording, other) to be included in case report:

_____

By signing this form, I confirm that:

- The case report has been fully explained to me and all of my questions have been answered to my satisfaction.
- I have been informed of the risks and benefits, if any, of allowing my information to be used in this case report.
- I have been informed that I do not have to participate in this case report.
- I authorize access to my personal health information (medical record) as explained in this form.
- I can revoke my consent at any time before publication, but once the article has been committed to publication it will not be possible to revoke the consent. I may revoke my consent by contacting the author.
- A copy of this consent has been provided to me and a copy will be retained in my medical record.
- I have agreed to participate in this case report.

Name of Participant/Guardian	Signature	Date (print)
Name of Person Obtaining Consent	Signature	Date (print)

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	03/2024
	Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	03/2024
	Timothy Regan: 0009 President - LRMC/Chief Medical Officer	03/2024
	Renee Reed: 4064 Senior Attorney	03/2024
	Deana Nelson: 4080 SVP - Administration and Corporate Initiative	03/2024
	Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	03/2024
	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	12/2023