Community Memorial Health System

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Community Memorial Health System

Institutional Review Board

Case Report Determination/Assessment Form (Application)

Case Report Determination/Assessment Form

Application Packet

Community Memorial Health System
Institutional Review Board

Case Report

A "single case report", defined by the IRB is a retrospective analysis of three or fewer clinical cases does not require IRB review/approval. A case report is a medical/educational activity that does not meet the DHHS definition of research, which is - "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

Single case reports that involve a prospective analysis are eligible for expedited review by the IRB.

A "case series" (more than three cases) meets the definition of research and an IRB application must be submitted for review and approval.

Principal investigators may contact the IRB if he/she wishes to have the project assessed to see if it meets the definition of a single case report and/or does not meet the DHHS definition of research.

HIPAA Privacy Rule Requirements

Although IRB approval is not required, certain HIPAA Privacy Rule requirements apply to the use and disclosure of PHI for a single case report:

- Investigators who remove HIPAA identifiers from the case report data prior to disclosure of the data (e.g., prior to submission of the case report to a journal) do not need to obtain a signed privacy authorization from the subject of the case report.

Please note that in addition to removing the 18 listed HIPAA identifiers (attached), the investigator must determine that no photo or illustration in the case report could lead to identification of the patient, and that the case(s) described are not so unique as to be identifiable with reference to other public sources such as media accounts.

- Investigators who wish to publish a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule (i.e., that contains any direct or indirect identifiers), must first obtain each patient's signed HIPAA-compliant authorization. It is *not* necessary to submit this authorization form to the IRB for review.

The HIPAA authorization form used to obtain a patient's authorization to use and disclose PHI for a single case report may be found at the HIPAA web site at:

https://www.hhs.gov/hipaa/index.html

Publication of a Case Report

Many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case. If an investigator wishes to have the project assessed by the CMHS IRB to see if it meets the definition of a single case report, the investigator should complete and submit the Case Report Determination/Assessment Form to the CMHS IRB Coordinator. If the project qualifies as a single case report, the CMHS IRB will send to the investigator an acknowledgement letter stating that the case report was reviewed and was determined that it does not meet the DHHS definition of research, thus IRB review is not required for the activity.

Investigators should inform the IRB if a journal does not accept the IRB's decision. The issue will then be brought to an IRB Chair and co-chair for resolution.

Again, please be advised that case reports for publication must be prepared in accordance with the requirements of the HIPAA privacy regulations. Any use or disclosure of PHI must be authorized by the patient, or if the patient is deceased, the patient's Legally Authorized Representative. Publication of a case report containing PHI is a disclosure of PHI. It is the responsibility of the investigator to consult with the CMHS Privacy Officer or designated HIPAA authority prior to submission of the case report to assure authorization was obtained.

IMPORTANT
As with all IRB applications, incomplete applications will <u>not</u> be accepted. It is the responsibility of the Principal Investigator to ensure the application is complete prior to submission. On the application, do not leave any lines blank, if they do not apply please *mark* N/A.

Report Publication Guidance: IRB Review and HIPAA Compliance
Frequently Asked Questions

Q: What constitutes a "case report"?

A case report for IRB purposes is a retrospective analysis of one, two, or three clinical cases. If more than three cases are involved in the analytical activity, the activity will constitute "research."

Q: Do investigators who prepare a case report as an article for submission to a journal require IRB approval prior to preparation?

No. A case report is a medical/educational activity that does not meet the DHHS definition of "research", which is: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, the activity does not have to be reviewed by an IRB.

Q: Are there HIPAA implications associated with publication of case reports?

Yes. Under HIPAA, a case report is an activity to develop information to be shared for medical/educational purposes. Although the use of protected health information to prepare the paper does not require IRB review, the author of a case report must comply with HIPAA. Ideally, the author of the article will obtain the signed authorization of the patient, or of the patient is deceased, the patient's legally authorized representative, to use the patient's information in the article. If it is not possible to obtain authorization, the author should be aware that one of the identifiers described by HIPAA as requiring written authorization is, "Any other unique identifying number, characteristic, or code...." Moreover, HIPAA requires that, at the time of publication, "[t]he covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information." (See attached: Definition of De-Identified Data.)

- Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization.
- Investigators who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed HIPAA compliant authorization. This authorization does not need to be submitted to the IRB for review. The appropriate authorization form for use with a single case report may be found on the HIPAA web site: https://www.hhs.gov/hipaa/index.html
- If the author strips off all HIPAA identifiers, but the information associated with the patient of the article includes a "unique characteristic" which would make it identifiable to the patient, or the author has actual knowledge that the information about the patient could be used alone or in combination with other information to identify the patient, the author must contact the HIPAA Privacy Officer to discuss the required steps to take prior to publication.

DEFINITION OF DE-IDENTIFIED DATA

Identifiers That Must Be Removed to Make Health Information De-Identified

(i) The following identifiers of the individual or of relatives, employers or household members of the individual must be removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three 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 initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) 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;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

DEFINITION OF DE-IDENTIFIED DATA (continued)

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

IMPORTANT!

Please Read

At the time an application and required materials are received, all documents will be examined for compliance with submission requirements. The CMHS IRB Coordinator will perform a preliminary review of the application and may send questions to the Principal Investigator (PI) directly on any concern before the actual IRB review. The PI must respond to the comments before the application is forwarded for IRB review.

If the application is **incomplete**, the PI will be notified of any outstanding documentation or information required for IRB review and that the application is being returned. Once the application is complete it may be resubmitted for IRB review.

Community Memorial Health System Institutional Review Board

Case Report Determination/Assessment Form

Submission Checklist

The purpose of the checklist is to assist you in ensuring your application is complete. (Please submit this checklist with your application.) Please be reminded, it is the PI's responsibility to submit a complete application. ***Incomplete will be returned to the PI.***

TITLE OF CASE REPORT: _____

Principal Investigator: _____

☐ Completed CMHS Case Report Determination/Assessment Form, including:

- ☐ Case Report Team Roster (Pages 10-11 of this packet) with required documents:
  - ☐ CVs for Principal Investigator, all Co-Investigators, Faculty Advisor and Research Team Members
  - ☐ Good Clinical Practice (GCP) Certification for all
  - ☐ Principal Investigator's Assurance (*for GME studies only*)
  - ☐ Faculty Advisor's Assurance (*for GME studies only*)

Please submit this checklist with your application.

FOR IRB USE ONLY
Date Received: _____
☐ Complete
☐ Incomplete

PLEASE

COMPLETE

ALL

PAGES

OF THE

APPLICATION

Community Memorial Health System
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Case Report Determination/Assessment Form

LEAVE BLANK – FOR IRB USE ONLY.
IRB Number: _____ Date Received: _____
Review/Board Action:
☐ Incomplete. Returned to Principal Investigator. Date: _____
☐ Project meets criteria of being a research project. **Project must be submitted and approved by the IRB as a Research Protocol before it can move forward. Returned to Principal Investigator.** Date: _____
☐ Project does not meet the DHHS definition of "research" as determined by the CMHS IRB Chair/Co-Chair on: _____.

A single, retrospective case report (three or fewer cases) is a medical/educational activity that does not meet the DHHS definition of "research", which is: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, the activity does not have to be reviewed by the IRB. However, many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report. To obtain a letter or acknowledgement of IRB review for your case report, please complete this form and submit with required documents to the CMHS IRB Coordinator. **If your project does meet the criteria of "research" you will need to complete and submit a Human Subjects Research Protocol Application to the CMHS IRB Coordinator.**

Date: _____

Case Report Title: _____

Principal Investigator: _____ E-Mail: _____

Co-Investigator: _____ E-Mail: _____

1. Are you (Principal Investigator project leader and co-investigator) a clinician of record for the patient(s) about which the case report(s) is being prepared?

☐ Yes
☐ No (if "no" case report criteria is not met). **This project must be submitted and approved by the IRB as a Research Protocol before it can move forward.**

2. Indicate the number of patient(s) about which the case report(s) will be prepared.

☐ One (1)
☐ Two (2)
☐ Three (3)
☐ More than three (3). If more than three (3) patients, **case report criteria is not met. This project must be submitted and approved by the IRB as a Research Protocol before it can move forward.**

3. Describe the disorder/disease and/or related observation (e.g. treatment, outcome, etc.) that will be discussed in the case report(s). If your report is complete, please attach a copy.

4. Describe the purpose of preparing the case report(s) for this particular disorder/disease and/or observation (e.g. involves a rare disorder/disease and/or a unique treatment and/or outcome):

5. Describe what will be done with the results of the case report(s) (e.g. submitted for publication):

6. HIPAA Privacy Rule requirements apply to the use and disclosure of PHI for a single case report.
Investigators who remove HIPAA identifiers from the case report prior to disclosure of the data (e.g., prior to submission of the case report to a journal) do not need to obtain a signed privacy authorization from the subject of the case report.

Will your case report(s) contain any Protected Health Information (PHI) from Community Memorial Health System patients? (A de-identified data set may not include any of the following.) Please indicate either "Yes" or "No" for each element below:

➢ **PHI includes any of the following 18 elements:**

☐ Yes ☐ No	1. Names
☐ Yes ☐ No	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 digits of the zip code if according to the current publicly available data from the Bureau of Census: a) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and b) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
☐ Yes ☐ No	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.
☐ Yes ☐ No	4. Telephone numbers
☐ Yes ☐ No	5. Fax numbers
☐ Yes ☐ No	6. Electronic mail addresses
☐ Yes ☐ No	7. Social security numbers
☐ Yes ☐ No	8. Medical record numbers
☐ Yes ☐ No	9. Health plan beneficiary numbers
☐ Yes ☐ No	10. Account numbers
☐ Yes ☐ No	11. Certificate/license numbers
☐ Yes ☐ No	12. Vehicle identifiers and serial numbers, including license plate numbers.
☐ Yes ☐ No	13. Device identifiers and serial numbers
☐ Yes ☐ No	14. Web Universal Resource Locators (URLs)
☐ Yes ☐ No	15. Internal Protocol (IP) address numbers
☐ Yes ☐ No	16. Biometric identifiers, including finger and voice prints
☐ Yes ☐ No	17. Full face photographic images and any comparable images
☐ Yes ☐ No	18. Any other unique identifying number, characteristic, or code that allow you to link the information collected to a specific patient.

7. Additional HIPAA Requirements for Case Reports

Please note that in addition to removing the 18 HIPAA identifiers listed on page 2, the investigator must determine that no photo or illustration in the case report could lead to identification of the patient, and that the case(s) described are not so unique as to be identifiable with reference to other public sources such as media accounts.

Investigators who wish to publish a case report that is not completely de-identified to the standards of the HIPAA Privacy Rule (i.e., that contains any direct or indirect identifiers), must first obtain each patient's signed HIPAA-compliant authorization. The HIPAA authorization form used to obtain a patient's authorization to use and disclose PHI for a single case report may be obtained by contacting the CMHS Privacy Officer at x3073.

Principal Investigator's Assurance

- I will make every effort possible to exclude protected health information (PHI) from the publication.
- I will consult with the CMHS Privacy Officer to verify that the data and photographs to be used in the report are adequately de-identified. The Privacy Officer has the final authority to make this final determination.
- Should identifiable information be required, I will ensure written permission (informed consent) is obtained from the individual if the data or the pictures are not-de-identified.
- I certify that the information supplied on this form is complete and correct.

_____ _____

Principal Investigator's Signature Date

Case Report Team Roster
(for submission with the Determination/Assessment Form)

List Principal Investigator, Co-Investigator and all project team members engaged in the project. All team members must submit a copy of their Curriculum-Vitae (CV) and Good Clinical Practice (GCP) certification as the IRB is required to review the qualifications of all project team members. Project team members are those persons who are involved in data collection, data analysis, chart review or report preparation.

Principal Investigator			
Last Name	First Name	Academic Degree(s)	
Office Address	City	State	Zip Code
Phone	Fax	E-mail	
CMHS Affiliation (Mark One) ☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ GME Faculty ☐ CMHS Employee ☐ Other: _____			
Attachments: ☐ Curriculum-Vitae (CV) ☐ Good Clinical Practice Certification			

Co-Investigator			
Last Name	First Name	Academic Degree(s)	
Office Address	City	State	Zip Code
Phone	Fax	E-mail	
CMHS Affiliation (Mark One) ☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ CMHS Employee ☐ Other: _____			
Attachments: ☐ Curriculum-Vitae (CV) ☐ Good Clinical Practice Certification			

Co-Investigator/Project Team Member			
Last Name	First Name	Academic Degree(s)	
Office Address	City	State	Zip Code
Phone	Fax	E-mail	
CMHS Affiliation (Mark One) ☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ CMHS Employee ☐ Other: _____			
Attachments: ☐ Curriculum-Vitae (CV) ☐ Good Clinical Practice Certification			

Project Team Member				
Last Name		First Name	Academic Degree(s)	
Office Address	City		State	Zip Code
Phone		Fax	E-mail	
CMHS Affiliation (Mark One)	☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ CMHS Employee ☐ Other: ____________			
Attachments:	☐ Curriculum-Vitae (CV) ☐ Good Clinical Practice Certification			

Project Team Member				
Last Name		First Name	Academic Degree(s)	
Office Address	City		State	Zip Code
Phone		Fax	E-mail	
CMHS Affiliation (Mark One)	☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ CMHS Employee ☐ Other: ____________			
Attachments:	☐ Curriculum-Vitae (CV) ☐ Good Clinical Practice Certification			

Project Team Member				
Last Name		First Name	Academic Degree(s)	
Office Address	City		State	Zip Code
Phone		Fax	E-mail	
CMHS Affiliation (Mark One)	☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ CMHS Employee ☐ Other: ____________			
Attachments:	☐ Curriculum-Vitae (CV) ☐ Good Clinical Practice Certification			

For additional Project Team members use attached sheet, make copies if needed.

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Principal Investigator Assurance
(For GME Studies Only)

The Resident/Student Investigator must agree to accept the responsibilities and roles of Principal Investigator.

Principal Investigator (Resident/Student) Assurance:

I, as Principal Investigator, accept responsibility for the following:

- I have reviewed the conflict of interest statement submitted with my application and the information disclosed is correct.
- The information provided in this application represents an accurate description of the study.
- All project personnel will conduct the study in compliance with all applicable federal, state, and local regulations and CMHS IRB and CMHS requirements and policies. All project personnel will be properly trained in their respective responsibilities, licensed as required, and have requisite hospital privileges.
- Only the current CMHS IRB approved informed consent documents and recruitment scripts will be used.
- No changes will be made to the protocol without prior CMHS IRB approval except when necessary to eliminate immediate hazards to the subject in which case the CMHS IRB will be notified as soon as possible.
- Valid informed consent/assent will be obtained and documented from all research subjects on their legally authorized representatives unless these requirements have been waived by the CMHS IRB.
- Timely written reports of unanticipated problems involving risks to subjects or others and adverse events will be submitted to the CMHS IRB according to its reporting guidelines.
- I will keep myself informed of current developments that may impact the research, and I will immediately notify the CMHS IRB if I become aware of any information that may materially alter the risk/benefit ratio.
- All required research records will be maintained and will be made available in accordance with applicable regulations and CMHS IRB policy.
- The CMHS IRB will be immediately informed of any violations of HHS regulations (45 CFR 46), FDA regulations (21 CFR 50.46), HIPAA regulations (45 CFR 164.530), state/local laws or CMHS IRB Policies and Procedures for the protection of human subjects.
- Per HIPAA Privacy Rule regulations, the minimum necessary data needed is being requested to achieve the goals of the research described in this application (if applicable to the study).
- If unable to direct this research personally, as when on leave or vacation, I will arrange for a co-investigator to accept responsibility in my absence and notify the CMHS IRB of temporary change by submitting a Research Personnel Change Form (Attachment HS-ADM101a).
- Upon completion of study, ensure all required research records will be retained and accessible for the required period mandated by FDA, HIPAA, OHRP, VA, etc. regulations.

I certify that I have read and agree to the foregoing statements and accept these conditions.

Signature: _____ Date: _____

Print Name: _____

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Faculty Advisor's Assurance
(For GME Studies Only)

The Faculty Advisor must agree to accept the responsibilities associated with that role, as described in the faculty advisor's assurance.

Faculty Advisor's Assurance:

By submitting this protocol for IRB review, I, as Faculty Advisor to a Resident/Student Principal Investigator (PI), accept responsibility to monitor and verify that the Resident/Student PI complies with the following:

- The information provided in this application represents an accurate description of the study.
- All project personnel will conduct the study in compliance with all applicable federal, state, and local regulations and CMHS IRB and health system requirements and policies. All project personnel will be properly trained in their respective responsibilities, licensed as required, and have requisite hospital privileges.
- Only the current CMHS IRB approved informed consent documents and recruitment scripts will be used.
- No changes will be made to the protocol without prior CMHS IRB approval except when necessary to eliminate immediate hazards to the subject, in which case the CMHS IRB will be notified as soon as possible.
- Valid informed consent/assent will be obtained and documented from all research subjects or their legally authorized representatives unless these requirements have been waived by the CMHS IRB.
- Timely written reports of unanticipated problems involving risks to subjects or others and adverse events will be submitted to the CMHS IRB according to reporting guidelines.
- All required research records will be maintained and will be made available in accordance with applicable regulations and CMHS IRB policy.
- The CMHS IRB will be immediately informed of any violations of HHS regulations (45 CFR 46), FDA regulations (21 CFR 50, 56), FERPA regulations (34 CFR 99), PPRA regulations (34 CFR 98), HIPAA regulations (45 CFR 164.530), state/local laws, or CMHS IRB Policies and Procedures for the protection of human subjects.
- Per HIPAA Privacy Rule regulations (if applicable to the study), only the minimum necessary data to achieve the goals of the research described in this application is being sought.
- Upon completion of study, ensure all required research records will be retained and accessible for the required period mandated by FDA, HIPAA, OHRP, VA, etc. regulations.

In addition, I, as Faculty Advisor, will:

- If unable to supervise this research personally, as when on leave or vacation, I will arrange for another faculty member to accept responsibility in my absence and notify the CMHS IRB of temporary change by submitting a Research Personnel Change Form (Attachment HS-ADM101a).
- I will keep myself informed of current developments that may impact the research, and I will immediately notify the CMHS IRB if I become aware of any information that may materially alter the risk/benefit ratio.
- I will meet with the resident/student on a regular basis to monitor study progress.

I certify that I have read and agree to the foregoing statements and accept these conditions.

Signature: _____ Date: _____

Print Name: _____