Community Memorial Health System

Where Excellence Begins with Caring

Institutional Review Board
Notice of Study Closure/Final Report

Please complete this closure form when:

1. All subjects have finished their final visits and follow-up.
2. The sponsor or the sponsor representative has indicated the study is closed at your site; and/or
3. All data at your site has been de-identified. Note that analysis of de-identified data can be either completed or ongoing, if the data has no identifiers or codes attached to it.
4. Do no leave any lines blank, if they do not apply please mark N/A. Incomplete reports will result in delay of review.

If this report is being submitted in lieu of a Continuing Review Report/Request, this report must be received prior to the expiration date of the IRB approval period.

Study Information	
1. Protocol Title:	
2. Protocol Number:	
3. Sponsor:	
4. Principal Investigator:	
5. Study Coordinator:	
Address:	
Phone:	
Fax:	
Principal Investigator e-mail:	
Study Coordinator e-mail:	

Summary

1. This study has been:
   - ☐ Completed per protocol
   - ☐ Project never started (please explain below)
   - ☐ Study terminated by sponsor (please explain below)
   - ☐ Other (please explain below)

2. Have you received an interim report on the study from an external monitoring board or committee, such as a Data Safety Monitoring Board (DSMB)?
   ☐ Yes (If yes, attach the most recent summary report.) ☐ No

3. Has this protocol been externally audited since it was last reviewed by the CMHS IRB?
   ☐ Yes (If yes, check all below that apply) ☐ No
   - ☐ FDA (attach a copy of the FDA 483 or FDA Audit Report)
   - ☐ Sponsor (attach a copy of the report)
   - ☐ Other (attach a copy of the report)

4. Please provide a brief summary of the study results. (Attach the Final Report if available.)

Retrospective Studies *(e.g. Retrospective Chart Review/Biological Specimen Studies, etc.)*	
1. Number of charts reviewed/specimens accessed to determine eligibility.	
2. Number of participant charts in retrospective chart review.	
3. Number of biological samples utilized for this study.	
Prospective Studies ***(e.g. Clinical Trials, Qualitative Studies, Registries, Prospective Chart Reviews, etc.)***	
1. Total number of **screen failures** (this number is <u>not</u> included in the total number of subjects enrolled):	
2. Date first subject enrolled:	
3. Date last subject completed:	
4. Total number of subjects enrolled (or charts/records reviewed): Of the total number of subjects enrolled, list the number that were: Implanted with device: _____ Control Group: _____	
5. Total number of subjects completed: _____ Of the total number of subjects that completed the study, list the number that were: Implanted with device: _____ Control Group: _____	
Withdrawal Prior to Completion of Study	
1. Total number of subjects who withdrew early due to an adverse event:	
2. Total number of subjects who withdrew early NOT due to an adverse event:	
Serious Adverse Events	
1. List below all unexpected or serious adverse events occurred at your site and date reported to the CMHS IRB. Attach separate sheet if needed.	
Protocol Deviations or Variances *A protocol deviation is any change to the IRB approved protocol without prior IRB notification and approval.*	
1. List below any protocol deviations/variances that have occurred since the last annual IRB review and date reported to the CMHS IRB. Attach separate sheet if needed.	
Protocol Documents	
1. Please list the version /date and date approved by the CMHS IRB of the last study documents utilized for the study.	
Publication/Dissemination of Results	
1. Have any articles been published or presentations been given using the results of the study? ☐ Yes ☐ No ☐ N/A If yes, please submit a copy of the abstract(s) or provide a list of references.	

If no or N/A, please provide brief explanation. Attached a separate sheet if need.

Record Retention and Destruction

Federal regulations require that study records be retained and accessible for review for a minimum of 3 years after the end of the study. This includes the approved application, amendments, continuing reviews and signed informed consents. This does not apply to de-identified data which can be retained indefinitely. In addition, other regulations (i.e., OHRP, HIPAA, FDA, VA) may apply and require retention of these records for a longer period of time. (See page 4-5.)

1. How will research information/data or specimens be protected and stored and at what location will they be kept?

2. Who is the individual responsible for retaining and destruction of these records? (Please list name and contact information.)

Note: It is the PI's responsibility to notify the IRB if there is a change in the responsible party.

Principal Investigator's Certification

I certify that all study activity involving participant contact, or use or access to individually identifiable information has ceased and the information provided in this report is complete and correct.

_____ _____

Principal Investigator's Signature Date

How Long Should I Retain my Research Data?

Regulations require each investigator to retain research data not only while the research is being conducted but also after the research is completed. How long do you have to keep the records after the completion of the research? Unfortunately, there are several different regulations each of which has different requirements.

Step 1: Determine which regulation applies to your research.

- It is important to determine which regulation applies to your research because different regulations have different timelines. It is also important to keep in mind that multiple regulations may apply to the research. If multiple regulations apply, the investigator should keep the data for the longest required amount of time.
- Below are examples of regulations that might apply to your research:
  - Office for Human Research Protections (OHRP) Regulations
  - The Health Insurance Portability and Accountability Act (HIPAA)
  - Food and Drug Administration (FDA) Regulations o Department of Veterans Affairs (VA) Regulations
- In addition to the above regulations, if your study is under a sponsored project (grant or contract) you must comply with any terms for record retention detailed in the award from the sponsor.

Step 2: After determining which regulation applies, determine the time requirement.

- To determine how long you should retain your research you should look to the specific language of the regulation. Some examples of record retention are the following:
  1. **Office for Human Research Protections (OHRP):** Research records must be retained for at least 3 years after the completion of the research. Research is completed when all research related interventions/interactions with human subjects have been completed and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished. http://answers.hhs.gov/ohrp/categories/1567
  2. **Health Insurance Portability and Accountability Act (HIPAA):** Any research that involves collecting identifiable health information is subject to HIPAA requirements. These records must be retained for at least 6 years after the personal health information was disclosed. http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/research.html
  3. **Food and Drug Administration (FDA):** Research records must be retained for 2 years after either (1) the date a marketing application is approved or (2) the investigation is discontinued and the FDA is notified. http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4
  4. **Department of Veterans Affairs (VA):** Research Records must be retained indefinitely per VA federal regulatory requirements. This could be subject to change if federal regulators establish a national policy setting a shorter period for retention. Please contact the VA Research for additional information. http://www.va.gov/ORO/Research_Information_Protection.asp
  5. **Sponsor Requirements – contract:** If your study is sponsored you must insure that you comply with any terms for record retention detailed in the contract with the sponsor. For example, a sponsor may require you to retain your research related documents for 20 years. Prior to agreeing to a contract that specifies how long records will be maintained you should insure you will receive adequate funding to pay for the storage.
- **Questions of Data Validity:** If there are questions or allegations about the validity of the data or appropriate conduct of the research, you must retain all of the original research data until such questions or allegations have been completely resolved.

Step 3: Determine what information to keep.

- To determine what information you should keep you should look to the specific language of the applicable regulation above. As a general rule you should keep the following:
  - Signed participant informed consent/assent documents
  - Signed parental/guardian informed consent documents
- Written research summary.

IN SUMMARY:

1. **Determine which regulation applies to your research.**
2. **Determine the time requirement (minimum of 3 years). Researchers must comply with the longest applicable standard as described above.**
3. **Determine what information to keep.**

Another good practice is to retain data until there is no reasonable possibility that you will be required to defend against an allegation of scientific misconduct.

8/27/15

Protocol Amendment for Research Personnel Change 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 applications will be returned to the PI.***

CMHS IRB Number: _____

Title of Protocol: _____

Principal Investigator: _____

☐ Protocol Amendment – Research Personnel Change Form, including:

- ☐ CV for New Research Team Member(s)
- ☐ Signed Conflict of Interest Statement for New Research Team Member(s)
- ☐ Certification of GCP (Good Clinical Practices) training for New Research Team Member(s)
- ☐ Signed Principal Investigator Assurance, if there is a change of PI for the study. (For GME studies only.)
- ☐ Signed Faculty Advisor Assurance, if there is a change of FA for the study. (For GME studies only.)

Please submit this checklist with your application.

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

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Protocol Amendment - **Research Personnel Change**	LEAVE BLANK – FOR IRB USE ONLY. DATE RECEIVED: Action: ☐ Approved via Expedited Review by Chair/Co-Chair. Date: _____ ☐ Approved by Full Board Review. Date: _____

Please list research personnel to be added to the protocol, removed from the protocol, or whose project role is changing.

Protocol/Study Name:

Name	CMHS Affiliation	Action: Add/Remove/ Change Role	Project Role (if role is changing please note new role - i.e., Co-PI, Consultant, Research Assistant, etc.)	Effective Date of Change	Required Documents for Adding New Personnel to the Study
7	☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ GME Faculty ☐ CMHS Employee ☐ Other: _____ _____	☐ Add ☐ Remove ☐ Change Role			☐ CV ☐ Signed Conflict of Interest Statement ☐ Current GCP Certification For GME Studies, if change is for PI or Faculty Advisor: ☐ PI Assurance ☐ Faculty Assurance
	☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ GME Faculty ☐ CMHS Employee ☐ Other: _____ _____	☐ Add ☐ Remove ☐ Change Role			☐ CV ☐ Signed Conflict of Interest Statement ☐ Current GCP Certification For GME Studies, if change is for PI or Faculty Advisor: ☐ PI Assurance ☐ Faculty Assurance
	☐ Active Medical Staff ☐ GME Resident ☐ GME Medical Student ☐ GME Faculty ☐ CMHS Employee ☐ Other: _____ _____	☐ Add ☐ Remove ☐ Change Role			☐ CV ☐ Signed Conflict of Interest Statement ☐ Current GCP Certification For GME Studies, if change is for PI or Faculty Advisor: ☐ PI Assurance ☐ Faculty Assurance

Principal Investigator Requesting Protocol Amendment:

_____ _____

Principal Investigator Name (print) Date

Community Memorial Health System

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CONFLICT OF INTEREST

Name: _____
(print)

Name of Study: _____

☐ **Principal Investigator** ☐ **Co-Principal Investigator** ☐ **Research Team Member**

In order to protect subjects from financial conflicts of interest or perceived conflicts of interest, the IRB requires that such potential conflicts be disclosed. If the IRB determines that a conflict exists that could influence the research or jeopardize the well being of subjects, the IRB may require additional information about the conflict or may require that the conflict be resolved before the research is approved.

If you or any member of your immediate family (spouse, children, parent, in-laws, and siblings) has a financial interest in either a public or private company whose drug, procedure, technique, device, or software is used or tested in any study, you will disclose the conflict as research protocols are reviewed. Examples of a conflict of interest include:

- I own equity in the company (stock ownership equal to or greater than 5%, Stock Options, Real Estate, or other ownership interest in any amount) whose drug, procedure, technique, device, or software I am testing.
  ☐ **Yes** ☐ **No**

- The company holds patent rights to inventions created by me or a member of my immediate family (spouse, children, parent, in-laws, and siblings) or by another faculty member or other employee of the institution.
  ☐ **Yes** ☐ **No**

- I or a member of my immediate family (spouse, children, parent, in-laws, and siblings) hold(s) a position of senior management officer or director of the company whose drug, procedure, technique, device, or software I am testing.
  ☐ **Yes** ☐ **No**

- I am a scientific advisor or consultant to the company and I receive honoraria exceeding $5,000 annually.
  ☐ **Yes** ☐ **No**

- If a drug, procedure, technique, device, or software involved in the research is marketed, I or a member of my immediate family (spouse, children, parent, in-laws, and siblings) will get royalty income or other income from the sale of the product.
  ☐ **Yes** ☐ **No**

I understand that any other financial interests that may appear to conflict with the protection of subjects should be disclosed to subjects in order to secure informed consent.

I understand that if there is a future conflict, it is my responsibility to submit a separate letter of explanation to the IRB for their review and consideration.

_____ _____
Signature Date

Rev: 6/10/15

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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: _____

Attachment

For your reference, outlined below are the PI Responsibilities defined in the CMHS Policy, Institutional Review Board - Research Review and Approval Process (HS-ADM106).

V. PROCEDURE, STANDARD OPERATING

B. Post IRB Approval

1. PI Responsibilities - Under FDA regulations, the PI in a clinical trial is responsible for the conduct of the study and for leading the team of individuals coordinating the study. Each PI must accept specific responsibilities that include the following:

   a. Conducting the study only according to the protocol approved by the IRB;
   b. Submitting any change(s) to the protocol and/or consent document(s) to the IRB for review and approval prior to the implementation of the change(s);
   c. Submitting any changes to research personnel, including those whose project role is changing, prior to the implementation of the change(s) by completing and submitting a *Protocol Amendment – Research Personnel Change Form.*
   d. Ensuring that only persons formally approved by the IRB enroll subjects;
   e. Reporting immediately to the IRB any severe adverse event or serious problem, whether anticipated or unanticipated;
   f. Reporting immediately to the IRB the death of a subject, regardless of cause;
   g. Reporting immediately to the IRB all protocol deviations/violations along with a statement as to the follow-up/corrective action plan taken for the incident;
   h. Reporting of non-compliance.
   i. Reporting promptly to the IRB any significant findings that become known in the course of research that might affect the willingness of subjects to participate in the study or, once enrolled, to continue to take part;
   j. Submitting a Progress Report at intervals designated by the IRB (but no less than once a year);
   k. Forwarding Sponsor, Cooperative Group Safety, and Data and Safety Monitoring Board (DSMB) reports;
   l. Ensure that a HIPAA Compliant Authorization has been signed by the research subject or the subject's authorized representative. This Authorization allows the research subject to authorize a covered entity to use and/or disclose his/her PHI (protected health information) for research purposes. This requirement is in addition to the Informed Consent to participate in research required under the HHS Protection of Human Subjects Regulations and other applicable Federal and State law;
   m. Ensure the sponsor's study is consistent with sound research design; and
   n. Notifying the IRB when the study has been completed/closed and to submit a final report.