Community Memorial Health System *Where Excellence Begins with Caring*	**IRB ANNUAL RESEARCH STATUS REPORT** **(For Chart Review Studies)**

Principal Investigators with studies determined to be under the categories of Expedited (45 CFR 46.110) or Exempt (45 CFR 46.101(b), as indicated in the initial research approval letter, are required to file an Annual Research Status Report with the IRB to ensure ongoing knowledge and oversight of active research when continuing review by the IRB itself is not required. **Failure to submit this form annually will result in the termination of approval and closure of your study.** **Incomplete reports will be returned to the PI.**

Please answer all questions.

Date: _____

Principal Investigator's Name: _____

Protocol Title: _____

CMHS IRB Number: _____

Current Approval Period: _____

Study Determined as: ☐ Expedited Category ☐ Exempt Category

Research Status	
1.	Estimated study completion date: _____
2.	Current status of research: ☐ Review of charts has not started. ☐ Review of charts is currently in progress. ☐ Chart review is complete, but analysis of data continued. ☐ Suspended or on hold. Explain: _____ _____ ☐ Other. Explain: _____
3.	How many charts was your study approved to review? _____ If approved for review of specific time-period, what is that period? _____ How many charts have been reviewed to date? _____ Do you wish to review additional charts or years than the study was originally approved to review?
☐	Yes. Please complete and submit a *Protocol Amendment for Approved Research Form* to request review of additional charts.
☐	No.
4.	Have there been any changes in funding for this study? ☐ No. ☐ Yes. Please complete and submit a *Protocol Amendment for Approved Research Form* explaining changes. ☐ Not applicable (unfunded/unsponsored study).

Note: Changes in funding must be reported to the IRB by using a *Protocol Amendment for Approved Research Form* before expending any of the new funding. Changes in funding sometimes trigger additional regulatory requirements that have to be addressed before moving forward with the research. Likewise, the loss or end of funding may remove requirements.

5. Are any changes in funding planned or anticipated in the next 12 months?

- ☐ No.
- ☐ Yes. Please complete and submit a *Protocol Amendment for Approved Research* explaining planned changes.
- ☐ Not applicable (unfunded/unsponsored study)

6. Have there been any changes to investigators or other research team members that have not yet been submitted to the IRB? **Please attach a current Research Team Roster.**

- ☐ No.
- ☐ Yes. Please complete and submit *a Protocol Amendment - Research Personnel Change Form* with this report.

7. Are there any proposed changes to the protocol (including plan to expand enrollment beyond number initially approved), consent forms, research materials, etc.?

- ☐ No.
- ☐ Yes. Please complete and submit a *Protocol Amendment for Approved Research Form* with this report outlining the changes made to the research and copies of the revised research materials.

8. Are there any interim reports (e.g., DSMB Report, sponsor or coordinating center report, audit or inspection reports, etc.) that have not been submitted to the IRB?

- ☐ No.
- ☐ Yes. Please submit copies of reports that have not been submitted to the IRB.

9. Is there any new information or literature that suggests a change in what was previously understood about the research by the IRB, or that may affect the rights, welfare, or willingness of subjects to continue in research, that has not been submitted to the IRB?

- ☐ No.
- ☐ Yes. Please submit copies of new information or literature that has not been submitted to the IRB.

10. Have there been any problems (e.g., unexpected/serious adverse events or protocol deviations) or complaints associated with the research that have not been reported to the IRB?

- ☐ No.
- ☐ Yes. On a separate attachment, please include a description of the event, deviation, and/or complaint that has not been submitted to the IRB along with corrective action plan and reason for delay in reporting.

11. Have there been any changes to a Conflict of Interest Status during the course of a study for Principal Investigators, Co-Investigators, Project Directors, Clinical Research Coordinators, and members of the research team identified as key personnel that have not been reported to the IRB?

- ☐ No.
- ☐ Yes. If yes, please explain in detail a separate page and attach. (The IRB may contact you for additional information.)

PRINCIPAL INVESTIGATOR'S ASSURANCE
By signing below, I certify that the information provided in this report is, to the best of my knowledge, accurate. _____ _____ Signature Date

LEAVE BLANK – FOR IRB USE ONLY:

Date received: _____

Date reviewed by CMHS IRB Chair: _____

☐ No significant changes/no action required. ☐ Action required: _____