REPORT/RECOMMENDATION TO THE BOARD OF SUPERVISORS OF SAN BERNARDINO COUNTY AND RECORD OF ACTION

March 12, 2024

FROM

WILLIAM L. GILBERT, Director, Arrowhead Regional Medical Center

SUBJECT

Non-Financial Data Use Agreement Template to Disclose a Limited Data Set for Research Purposes

RECOMMENDATION(S)

- 1. Approve non-financial Data Use Agreement Template to enable Arrowhead Regional Medical Center to disclose a Limited Data Set for research purposes.
- 2. Authorize the Director of Arrowhead Regional Medical Center to execute the Non-Financial Data Use Agreement Template with organizations conducting health related research, and make non-substantive changes to the template, on behalf of the County, subject to approval by County Counsel, for the term of March 12, 2024 through March 11, 2029.

(Presenter: William L. Gilbert, Director, 580-6150)

COUNTY AND CHIEF EXECUTIVE OFFICER GOALS & OBJECTIVES

Provide for the Safety, Health and Social Service Needs of County Residents.

FINANCIAL IMPACT

Approval of this item will not result in the use of Discretionary General Funding (Net County Cost) as this Data Use Agreement Template (Agreement) is non-financial in nature.

BACKGROUND INFORMATION

This Agreement will enable Arrowhead Regional Medical Center (ARMC) to provide a Limited Data Set to third-party researchers for the purpose of conducting health related research. It will allow ARMC physicians to perform multi-site studies with a larger database and better analysis and understanding of the problems, which may provide insight to identification and management of the county residents health and safety complications.

Under the Health Insurance Portability and Accountability Act (HIPAA), covered entities, such as hospitals, are generally required to obtain the written authorization of a patient prior to releasing protected health information about the patient, unless an exception applies. Under HIPAA, one such exception pertains to the disclosure of protected health information for research purposes. Specifically, under 45 Code of Federal Regulations (C.F.R.), Section 164.514(e), a covered entity may disclose a Limited Data Set to researchers to conduct health-related research without written authorization from patients if the covered entity and researcher enters into a Data Use Agreement with certain required elements. A Limited Data Set is protected health information that excludes certain identifiers relating to the patient as described in 45 C.F.R. Section 164.514(e)(2). The purpose of the Data Use Agreement is to ensure that research may be conducted to benefit the community while ensuring patient privacy is protected.

Non-Financial Data Use Agreement Template to Disclose a Limited Data Set for Research Purposes March 12, 2024

Approval of Recommendation No. 2 will authorize the Director of ARMC, to approve and execute the Agreement with organizations conducting health related research, and make with non-substantive changes, upon approval by County Counsel. This will expedite time and allow ARMC to participate in minimal risk studies and research with other institutions for more efficient patient care and safety. Previous research study opportunities have been missed due to inability to comply with full approval timelines.

ARMC recommends approval of this Agreement, because it will provide for the health and safety of county residents by allowing ARMC to participate in research by providing Limited Data Sets.

PROCUREMENT

Not applicable.

REVIEW BY OTHERS

This item has been reviewed by County Counsel (Charles Phan, Deputy County Counsel, 387-5455) on February 12, 2024; ARMC Finance (Chen Wu, Finance and Budget Officer, 580-3165) on February 16, 2024; Finance (Jenny Yang, Administrative Analyst, 387-4884) on February 21, 2024; and County Finance and Administration (Valerie Clay, Deputy Executive Officer, 387-5423) on February 23, 2024.

Non-Financial Data Use Agreement Template to Disclose a Limited Data Set for Research Purposes March 12, 2024

Record of Action of the Board of Supervisors San Bernardino County

APPROVED (CONSENT CALENDAR)

Moved: Joe Baca, Jr. Seconded: Jesse Armendarez

Ayes: Col. Paul Cook (Ret.), Jesse Armendarez, Dawn Rowe, Curt Hagman, Joe Baca, Jr.

Lynna Monell, CLERK OF THE BOARD

DATED: March 12, 2024

OF SUPERIOR OF SUP

cc: File - Medical Center w/attach

CCM 03/14/2024