



# County of Monterey

Board of Supervisors  
Chambers  
168 W. Alisal St., 1st Floor  
Salinas, CA 93901

## Legislation Details (With Board Report)

<b>File #:</b>	17-1147	<b>Name:</b>	Natividad Medical Center Authorization for Local IRB Program
<b>Type:</b>	General Agenda Item	<b>Status:</b>	Passed
<b>File created:</b>	11/1/2017	<b>In control:</b>	Board of Supervisors
<b>On agenda:</b>	11/14/2017	<b>Final action:</b>	11/14/2017

**Title:** a. Authorize NMC to create a Local Institutional Review Board (IRB) to act as the local oversight for research projects approved by Central IRB partners with at least one member of the local IRB to have certification in Human Subjects Research.  
b. Authorize NMC to apply for a Federal-wide Assurance (FWA) registration for the Protection of Human Rights Subjects with US Department of Health and Human Services, which enables NMC to enter into agreements with Central Institutional Review Boards (IRBs) to pursue Human Subjects Research projects under Central IRB oversight.

### Sponsors:

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### Code sections:

**Attachments:** 1. Board Report, 2. IRB Requirements and Responsibilities.pdf, 3. Generic Central IRB-Reliant IRB requirements.pdf, 4. Presentation on IRB Program.pdf, 5. Completed Board Order

Date	Ver.	Action By	Action	Result
11/14/2017	1	Board of Supervisors		

a. Authorize NMC to create a Local Institutional Review Board (IRB) to act as the local oversight for research projects approved by Central IRB partners with at least one member of the local IRB to have certification in Human Subjects Research.  
b. Authorize NMC to apply for a Federal-wide Assurance (FWA) registration for the Protection of Human Rights Subjects with US Department of Health and Human Services, which enables NMC to enter into agreements with Central Institutional Review Boards (IRBs) to pursue Human Subjects Research projects under Central IRB oversight.

### **RECOMMENDATION:**

### **It is recommended the Board of Supervisors:**

a. Authorize NMC to create a Local Institutional Review Board (IRB) to act as the local oversight for research projects approved by Central IRB partners with at least one member of the local IRB to have certification in Human Subjects Research.  
b. Authorize NMC to apply for a Federal-wide Assurance (FWA) registration for the Protection of Human Rights Subjects with US Department of Health and Human Services, which enables NMC to enter into agreements with Central Institutional Review Boards (IRBs) to pursue Human Subjects Research projects under Central IRB oversight.

### **SUMMARY/DISCUSSION:**

Human Subject Research supports various quality improvement initiatives, academic programs and scholarly research publications and presentations. In order to be seen as an accomplished physician, nurse or other health professional in a particular field of medicine, publication in scholarly journals such as The New England Journal of Medicine or, presentations at academic meetings and societies is essential. Only formal research studies or case reviews with IRB oversight is accepted into such publications or presentations.

At this time, most County hospitals participate in some type of research activity. Salinas Valley Memorial Hospital and Community Hospital of Monterey Peninsula (CHOMP) have their own Institutional Review Boards (IRBs). Some hospitals act as Local IRB with

research approval and oversight from Central IRBs. Physicians and nurses from Natividad Medical Center believe that an official IRB process is needed for advancement of clinical professionalism and promotion of the NMC reputation as a current, up-to-date, world-class institution.

Instead of creating a stand-alone IRB, Natividad would like to establish agreements with various (parent) Central IRBs for research approvals and oversight. These agreements will be brought back to the Board for individual approval on the consent calendar. NMC will create a Local IRB committee (as required under most agreements with parent or Central IRBs), for local administration, local oversight and quality assurance related to such research and improvement projects. Since human subject research is new to NMC and since creating a stand-alone IRB is expensive, NMC would like to start as a local IRB under the guidance and oversight of various Central IRBs. Once NMC has a Local IRB established, they can then enter into agreements with various Central IRBs (agreements will be brought back to the Board for approval), as each Central IRB is typically devoted to certain areas of research. In doing so, NMC will also learn from each Central IRB about one day running their own stand-alone IRB. This model has been endorsed as a way to ensure safety, increase efficiency and consistency and reduce the administrative burden for researchers and institutions.

These Central IRBs would approve and track all research projects while providing oversight over that particular research. The Local IRB would be housed at NMC and be comprised of staff and community members, as per Federal and State laws related to Human Research. A Local IRB would require policies and procedures according to the US Government Health and Human Services Office of Human Research Protection requirements. The local IRB would be the first stop for staff that wish to request permission to conduct research. The local IRB at NMC would conduct regularly scheduled meetings, provide local oversight and report back to the Central IRB. They would assure researchers meet research educational requirements, and ensure that at local level, research was performed in compliance with all federal and state laws. NMC agrees to have at least one person on the Local IRB have a certification in Human Subject Research and all members of the committee agree to do a minimum of 12 credits of continuing education per year.

Ultimately, being able to pursue research will allow NMC staff to publish research articles and give scholarly presentations, both of which support career building and retention of staff because it allows them to develop expertise and move forward in their careers without having to leave Natividad. It also allows for cost-benefit analysis regarding certain treatments and interventions. The ultimate goal of scholarly work and research, enhanced and required by the IRB review process, is to improve patient outcomes and promote the health of the community. By partnering with Central (parent) IRBs, NMC is able to leverage state of the art IRB review and knowledge, with local controls.

NMC reached out to the Health Department (Health) to see if they would like to join NMC on the Local IRB board and Health declined citing a cost benefit imbalance for the Department, but stated Health may re-visit the issue in the future.

#### **OTHER AGENCY INVOLVEMENT:**

County Counsel has reviewed and approved this item including the Central IRB Institutional Review Board (“IRB”) Authorization Agreement template as attached. This item has also been reviewed and approved by NMC’s Board of Trustees on March 3, 2017. Monterey County Risk advised that NMC employees are covered for research conduct through BETA.

#### **FINANCING:**

There is no cost associated with obtaining an FWA registration number or completing IRB Central Authorization Agreement. Any central IRB expenses will be covered by grant monies and will therefore not have a cost (built into the grant funding). There may be costs associated with NMC staff time devoted to working on IRB issues, including administrative and contract needs. There is no impact to the General Fund.

#### **BOARD OF SUPERVISORS STRATEGIC INITIATIVES:**

The IRB Program meets the BOS Strategic Initiative to improve health and quality of life through the County by providing the opportunity for enhanced health research and quality improvement projects and opportunities at NMC. The IRB is essential for attracting and maintaining high quality health professionals along with supporting NMC health training programs for Monterey County health professional students and staff. These research and quality improvement projects, under the supervision of a NMC Local IRB, provide NMC with the additional support it needs to be able to provide innovative and best practice patient care which improves the health and quality of life for patients and their families.

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Approved by: Gary R. Gray, DO, Chief Executive Officer, 783-2504

Attachments:

IRB Requirements and Responsibilities

Generic Central IRB-Reliant IRB Requirements

Presentation on IRB Program

Attachments on file with the Clerk of the Board