

Research Support in the County of Los Angeles Department of Health Services

The County of Los Angeles Department of Health Services (DHS) has a rich research history. Growth hormone, automated interpretation of EKGs, and a myriad of drugs, devices, and surgical and medical techniques were all developed because of research performed in a DHS facility. Thousands of scholarly articles published in the most prestigious journals have been authored by DHS employees.

The university relationships have allowed DHS to recruit and retain better clinicians than would be possible as a traditional non-research/non-teaching employer. In addition, the combined income of the 501(c)(3) research corporations exceeds one hundred million dollars, much of which has supported the DHS mission.

However, there has also been an unspoken, but very real tension, between the County mission of service delivery and the research agenda of discovery. Each region in the DHS system developed their own Institutional Review Board (IRB) and Fiscal Intermediary; each has their own approach to incorporating research into clinical operations. Heretofore, there has been a lack of system-wide clarity in the rules for research support, resulting in opaque accounting of research effort.

The perception that one has to “hide” their research activities is counter to the value research can bring to DHS. The purpose of this document is to clarify and articulate the role of research in DHS. We will develop a transparent and clear framework of what research may be directly supported by County resources, which projects benefit from the infrastructure of DHS, but require their own funding, and which are best done in other venues.

The landscape of research support on a national scale is changing. While there will always be a need for research on drug (molecule) discovery and the efficacy of specific treatments, it is clear that implementation science and effectiveness research are playing a more prominent role. Time and time again, we are reminded that it takes more than a decade for proven interventions to become part of usual care; it is one of DHS’s goals to become a leader in interventions that reduce the scale from years to months.

These principles and framework should not be interpreted as what you cannot do in DHS. Rather, it provides guidelines on what you can do, and what research projects can openly receive direct County support; something that heretofore was not viewed as a realistic expectation of DHS. While there are some additional steps in the research approval process, the process should have minimal, if any time delay for projects.

This is a new process, and as such, the Research Oversight Board, comprised of DHS and facility leadership, want to receive constructive feedback for improving the processes, which will ensure research is well supported and aligned with DHS strategic priorities.

- The guiding principles of the DHS Research Oversight Board are shown below in Table 1.
- The process flow for DHS approval of research projects is conceptualized below in Figure 1.
- The framework for the level of DHS support is shown below in Table 2. Each project must have a researcher-facility designated category. The level of permissible DHS support is defined by this categorization.

Table 1. Guiding Principles of the DHS Research Oversight Board

<p>Support meaningful, proportionate, and impactful healthcare research that aims to achieve the DHS mission</p>	<p>Streamline and facilitate research approvals</p>	<p>Enhance accuracy, availability, and management of data for research</p>	<p>Set-out a framework to guide oversight and the decision making process</p>	<p>Promote institutional capacity and external collaboration for research</p>
<p>1. That is, support effectiveness research, which directly impacts the DHS patient population</p> <p>2. That is, support efficiencies that align project review, approval, and oversight processes</p>	<p>1. Streamline the IRB process with other regulatory and DHS oversight approvals</p> <p>2. Harmonize IRB and compliance processes across the network of Los Angeles County institutions</p>	<p>1. Subsume the rules for access and use of research data under the DHS Business Intelligence governance model</p>	<p>1. A guidance for resource and research planning (refer to Table 2)</p> <p>2. Discussions the framework will generate are understood to be complex and the Research Oversight Board is empowered to establish precedence</p>	<p>1. Facilitate changes to DHS operational practices from within the office of the Chief Medical Officer and from the Research Oversight Board</p> <p>2. Facilitate a meaningful and effective mentorship model for opportunity creation</p> <p>3. Facilitate partnerships with regional and national networks</p>

RESEARCH REQUEST AND PROCESS FLOW

Figure 1

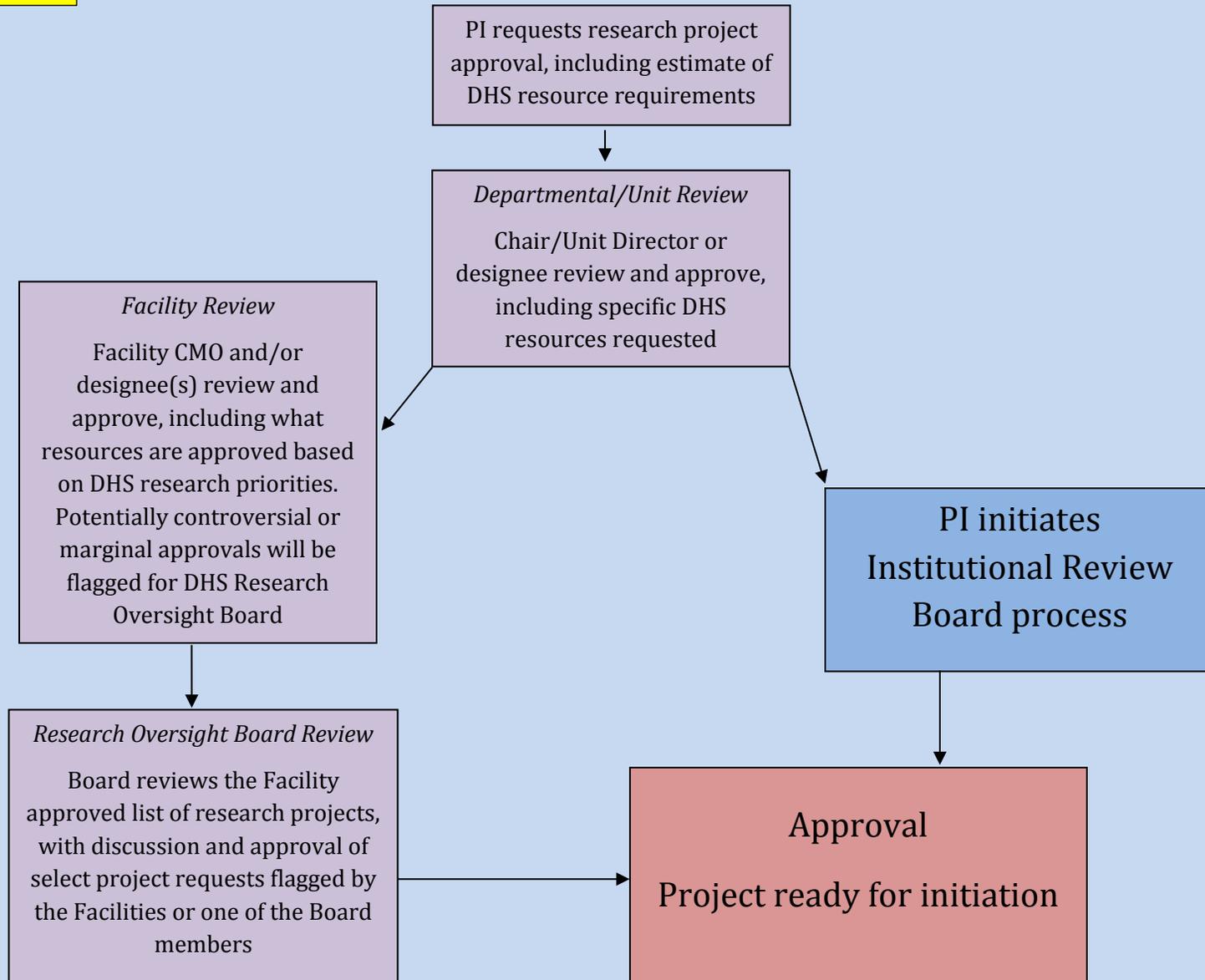


Table 2. Framework for research project categorization and DHS resource support	DHS Services or Supplies (a)	DHS Staff time and effort (b)	Access to Patients for study recruitment (study performed at another institution)
<p>Category 1:</p> <p>Research performed at DHS sites and well aligned with DHS business needs and strategic priorities. It is anticipated that the results of the research will have significant direct impact on clinical operations for a significant number of DHS patients. Direct DHS resources can be used to fully support projects in this category; however, researchers should make every effort to obtain extramural funding.</p>	DHS supports fully or partially	DHS supports fully or partially	DHS supports fully or partially
<p>Category 2:</p> <p>Research performed at DHS sites and well aligned with DHS business needs and strategic priorities. The research results are expected to affect care of the population served by DHS. Some external funding support is required to accomplish the research objectives</p>	DHS supports partially or none	DHS supports partially or none	<p>DHS supports partially or none for group recruitment.</p> <p>Individual patient referral to an appropriate study is always allowed</p>
<p>Category 3:</p> <p>Research performed at DHS sites with potential benefit to DHS patients in the future. DHS will allow access to resources, but the study must cover the cost of these resources.</p>	<p>DHS supports</p> <p>Study must fully fund at least variable costs (c)</p>	<p>DHS supports</p> <p>Study must fully fund at least variable costs (c)</p>	<p>DHS allows access, but study must cover cost of any negative operational impact of recruitment</p> <p>Individual patient referral to an appropriate study is always allowed</p>
<p>Category 4:</p> <p>Research intended to support the development of new drugs, medical devices, or procedures that, although having the potential of improving the care of patients in the future, does not address a key component of DHS's service priorities or needs that disproportionately affect DHS's patient population.</p> <p>These projects have potential positive impact for the DHS population (e.g. drug discovery)</p>	Full compensation of at least variable costs (c)	Full compensation of at least variable costs (c)	<p>DHS allows access, but study must cover cost of any negative operational impact of recruitment</p> <p>Individual patient referral to an appropriate study is always allowed</p>
<p>Category 5:</p> <p>Research that has no benefit to DHS or its partners and should not be conducted on a DHS campus</p>	No	No	No

(a) Services and supplies includes clinical services and supplies. This excludes outpatient pharmaceuticals (340b). Subject to the facility CEO's approval, drugs may be issued from the inpatient pharmacy inventory at average wholesale prices.

- (b) DHS staff time and effort includes administrative and clinical staff. DHS staff time will be based upon actual hourly salary, plus variable employee benefits. Space and related space support (utilities) is subject to availability and approval by the facility's Chief Executive Officer. Space and related space support will be billed based upon County CEO Real Estate's fair market value rental rate per square foot and facility's utilities cost per square foot, absent other research master space lease agreement provisions.
- (c) For purposes of determining variable costs, the following rate structure is applicable. Rates billed will be based upon date of service.
- Inpatient services: Medi-Cal daily per diem rate.
 - Outpatient services: Medicare fee schedule + 20%.
 - Ancillary services: Medicare fee schedule +20%.
 - Information Technology services: Hours multiplied by programmer's actual hourly rate, plus variable employee benefits.