



Research Connections

News and Events in Shriners Hospitals for Children’s Research Department

January 2016

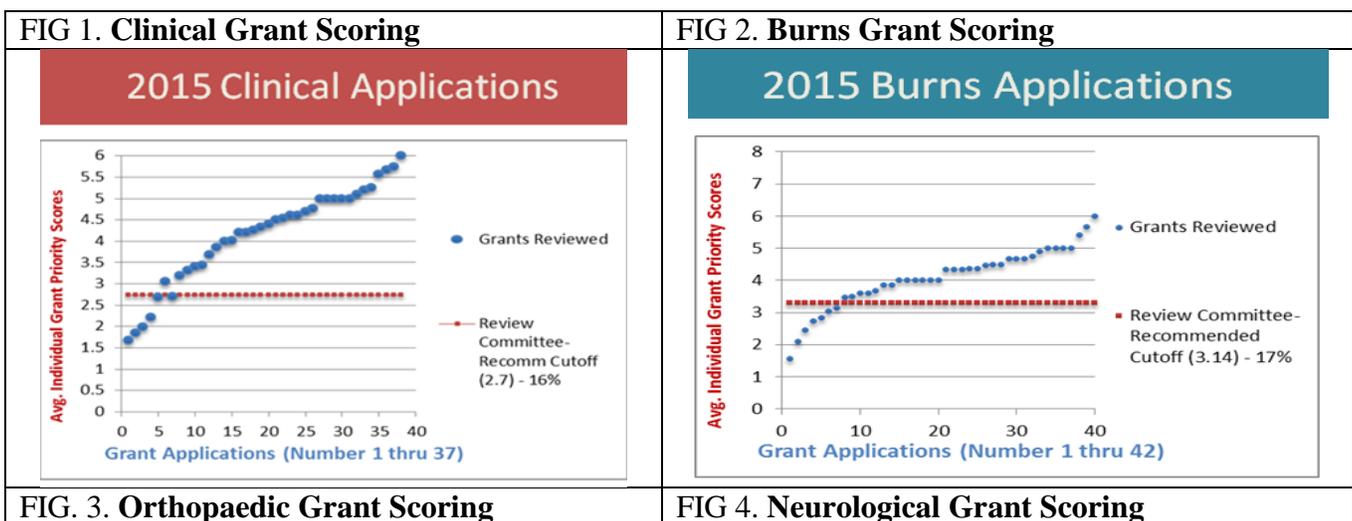
2016 Research Grant Funding

Research continues to be an important mission of Shriners Hospitals for Children (SHC). Accordingly, SHC funds both competitive clinical and bench science research projects, as well as competitive Special Shared Facilities which provide infrastructural support through specialized equipment and resources accessible to multiple investigators, thereby offering an efficiency of scale for dedicated activities.

As has been our tradition, the Medical Research Department is pleased to publish the 2016 overall research awards made to the individual SHC hospitals/Research Centers. These awards reflect the recommendations of the Research Advisory Board (RAB) following their annual August grant review meeting and have the approval of the Clinical and Basic Research Committee, as well as the Boards of Directors and Trustees.

For the 2016 grant year, a total of **131 new/renewal/revision** grant applications were electronically submitted via **proposalCENTRAL**: **37** Clinical Research, **92** Basic Research and **2** Special Shared Facilities. Applications were reviewed and scored by the RAB using a system which parallels that of the NIH study sections: 1-Exceptional, 2-Outstanding, 3-Excellent, 4-Very Good, 5-Good, 6-Satisfactory, 7-Fair, 8-Marginal, and 9-Poor. The RAB panels discussed the applications and voted their final funding scores.

Figures 1, 2, 3 and **4** below graphically depict the occurrence of defined “breaks” used to determine natural “cutoff scores.” The “cutoff” line refers to a set score used to identify the grants likely to be funded (i.e., below the cutoff line) and those which will likely not be funded (i.e., above the cutoff line). Although not exactly a precise science, in most cases a clearly discernible “break” is observed. Nevertheless, other factors may also play a role in the funding decision. Only one (50%) of the SSF applications was recommended for funding.



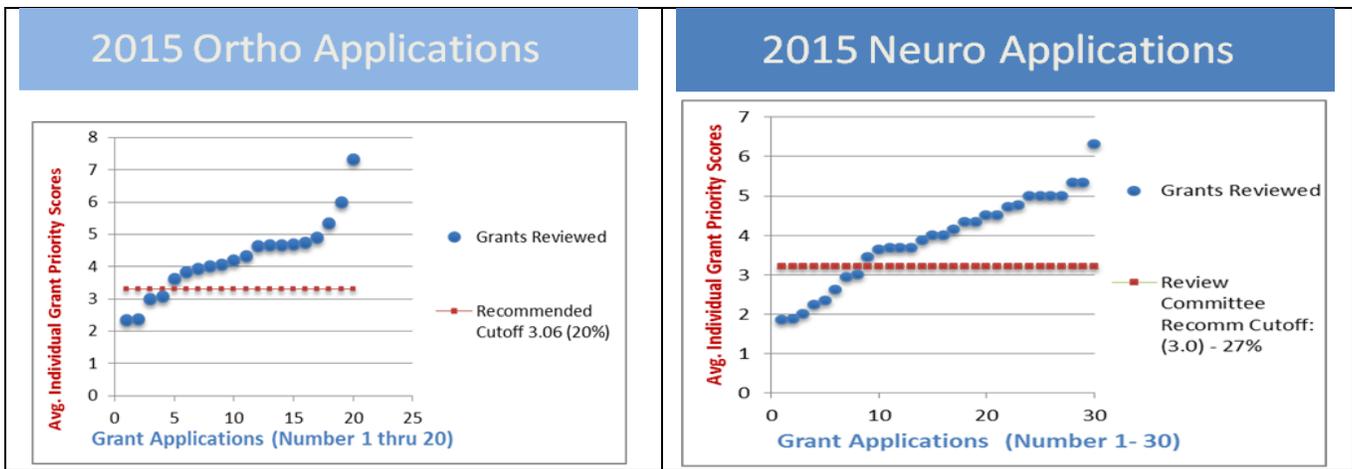
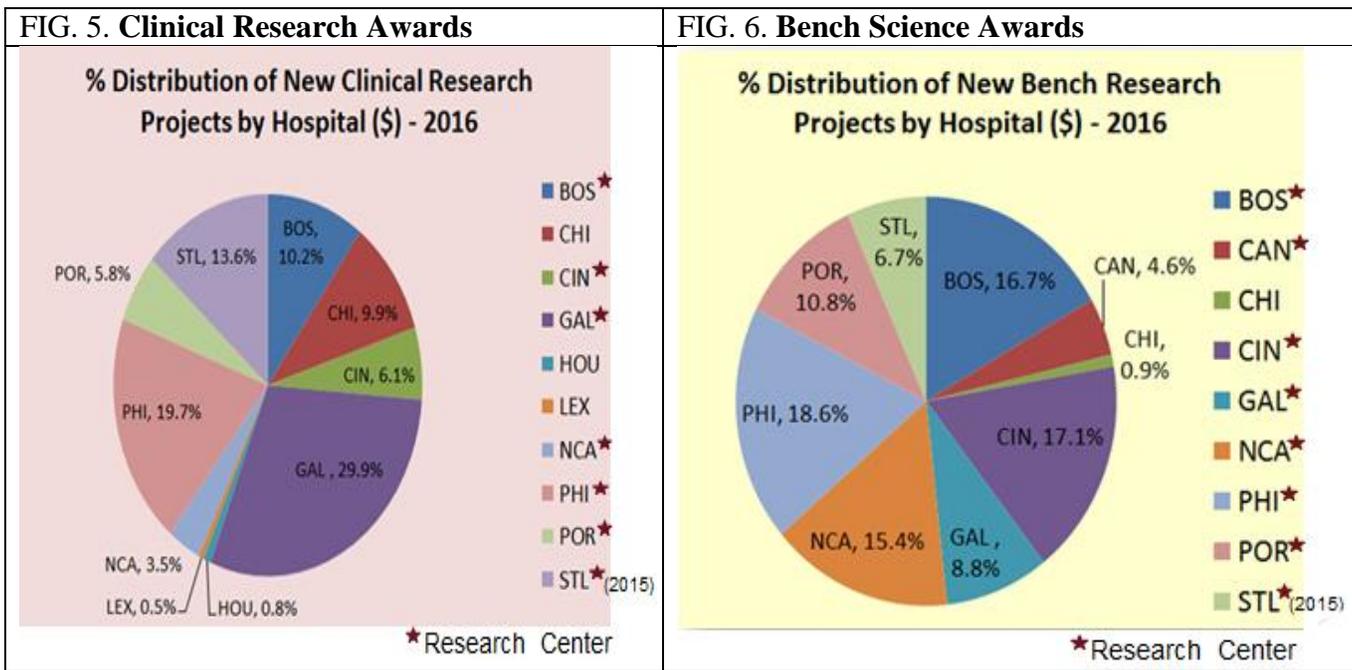


Figure 5 depicts the percentage distribution of dollars awarded to hospitals for the **newly funded** peer-reviewed Clinical Research projects and **Figure 6** shows the percentage distribution of dollars awarded to hospitals for the **newly funded** peer-reviewed bench science projects.



Overall, the 2016 research budget will support a total of **121** grants (new, renewal, revision and continuation): **67** bench science projects, **32** clinical research projects and **22** Special Shared Facilities. Eleven (11) of the SHC hospitals participate in one or more of the funded projects. In addition to research grants, support is also provided for Fellowships as a component of the education mission. The Division of Medical Research greatly appreciates all who have submitted grant applications dedicated towards research advancements to improve the care, treatment and quality of life of our SHC patients!

Applications now being accepted for new Research Fellowships beginning **July 1, 2016**. Applications may be submitted for review through the proposalCENTRAL SHC Fellowship Program.
Submission deadline is 11:59:59PM EDT on March 15, 2016

2017 Research Grant Cycle Begins

NEW THIS YEAR

Developmental (small grants) for both Basic and Clinical Projects must be submitted via the new "SHC Developmental Applications" module in *proposalCENTRAL*. The Developmental grant award is designed to support **novel research projects** of limited scope that can be conducted in a relatively short timeframe with limited resources and will yield seminal data. A project period of up to two years and a direct cost budget of up to \$60,000 per year may be requested. The submission **deadline** for **Developmental** grants is **Monday, May 2, 2016 at 11:59:59PM EDT**.

The regular submission **deadline** for **multi-year RO-1** type research grants for **Basic, Clinical** and **Research-Center-Only Special Shared Facilities** is **Monday, May 16, 2016 at 11:59:59PM EDT**.

Directors of Research submitting their own applications have until Wednesday, June 1, 2016 at 11:59:59PM EDT.

Centralized Institutional Review Board: Western IRB/Copernicus Group (WIRB)

An Institutional Review Board (IRB) is a panel composed of physicians, scientists and lay persons that is charged with reviewing and approving protocols and consents for clinical research studies involving human subjects. On January 1, 2016, Shriners Hospitals for Children entered into a contract with Western IRB (WIRB) for centralized IRB services, and a phase-in approach by site has successfully been initiated! We are excited to report the **average turnaround time** from HQ submission to WIRB approval for **new** and **transfer studies** is only **six (6) business days!**

While not all sites are required to use WIRB as their IRB at this time, the Board of Directors and Trustees has mandated that SHC-funded multi-site projects use WIRB. ***This mandate does not adversely impact any current relationship with the local IRB.*** For those few sites with an exclusivity clause in their contract, it does not prevent the site from using WIRB. The only requirement is for completion of one additional form (a written agreement for waiver of IRB oversight) as part of the application. Please contact our HQ Clinical Research Support Team (sterkowski@shrinenet.org or tmorse@shrinenet.org) for assistance with coordination of the waiver submission and for further information regarding WIRB.

Visit the Medical Research tab on the ShrineNet Intranet to review the WIRB FAQ sheet
And access updated submission forms

Carry-Forward / No Cost Extensions

Mechanism implemented in 2015 for FY2014 funded R01-type clinical and basic research projects. Requests are limited to no more than 15% of annual project award and no less than \$2,500.

FY2015 carry-forward/no-cost extension requests into 2016 are currently under review. Awards will be posted to **proposalCENTRAL** by **April 1, 2016**.

Project over-expenditures (negative balances) are **NOT** authorized and will automatically be charged against the following year's budget.

Intellectual Property / Royalties

Your research could provide the opportunity for intellectual property. The **SHC Intellectual Property Policy** and the **Intellectual Property Agreement** can be easily accessed via the Hospital Regulations & Staff Bylaws tab on the **ShrineNet Intranet** or contact HQ Medical Research (jsoucie@shrinenet.org).

Before you **publish** an abstract/poster **OR discuss** your idea with a colleague, ask yourself the following:

- New process or method; device; software; instrument; or article of manufacture?
- Novel molecules (e.g., biomarkers); animal models or cell line(s); or an improvement to something that already exists?

If “YES”, do not give up a patent opportunity that could benefit you, as well as the Shriners philanthropy. Contact your local Director of Research or the Vice President, Medical Research for direction regarding completion of a Record of Medical Invention form. The form must be submitted to the office of the Vice President, Medical Research in HQ (rnovak@shrinenet.org) for processing through the Legal Department.

A rapid, cost-effective assessment process is in place through HQ Medical Research/Legal.

SHC’s Relationship with Affiliated Institutions

SHC hospital sites and local academic medical centers (affiliated) must recognize that for research involving SHC patients, SHC is a legally separate entity. SHC should not be considered an extension, clinic or attached enrollment location/site of the affiliated institution. SHC regulations and policies regarding participant safety; clinical research design; data collection; data and sample storage; and access must be respected and followed by all SHC sites.

Royalties are available to investigators who file application through the Shriners or conjointly through the Shriners and affiliated organization (e.g. University). As defined in **Section 1.4 of the SHC Intellectual Property Policy**:

“§1.4 Income from Biomedical Research Intellectual Property. Any Annual Net Income received from Biomedical Inventions by Shriners Hospitals is presently allocated to the Shriners Hospitals Research Fund. Unless a different division of such Annual Net Income is determined appropriate by the Board of Directors and Boards of Trustees, either prospectively or retroactively, Shriners Hospitals’ creators of Biomedical Inventions collectively will receive, in the aggregate, 35% of the first \$100,000.00 and 20% of the excess over \$100,000.00 of such Annual Net Income or other payments as determined by the designee of the Committee, with the Committee’s approval. ... ”