

Progress report:

WCGF Receives \$100,000 Grant from Robert Wood Johnson Foundation To Support Expanded Access Project for Desperately Ill Patients

WCG Foundation (WCGF) has received \$100,000 from the Robert Wood Johnson Foundation (RWJF) to support WCGF's new Expanded Access Project. The grant targets physicians and institutional review boards (IRBs), who play key roles in helping desperately ill patients gain access to experimental medicines.

Launched in July, the Expanded Access Project seeks to streamline the process for those seeking Food and Drug Administration (FDA) approval to try investigational drugs and devices. The goal is to make the process less burdensome and more equitable and transparent.

The FDA offers an expanded access (compassionate use) program for patients who have exhausted all options for treatment and clinical trials. With sponsor approval, these patients can apply to the FDA to try investigational drugs and devices. Applications typically are filed by the patient's physician and must be reviewed and approved by an IRB. This process can be confusing and cumbersome for patients, physicians, and IRBs.

"The Robert Wood Johnson Foundation grant will help WCGF transform the IRB review system for those who are desperately ill," WCGF Executive Director Marjorie Speers says. "The result will be a system that improves the quality and accessibility of IRB review, decreases the IRB approval time for those seeking access to experimental medicines and, ultimately, maximizes the chances for a positive outcome."

The RWJF grant will also support efforts to provide guidance to IRBs on how to review expanded access requests and help physicians understand their roles and responsibilities in the FDA's expanded access program.

Specifically, WCGF's Expanded Access Project will improve the review system by:

- Arranging for a core group of experienced IRBs to help expanded access patients who cannot pay for the cost of IRB review.
- Streamlining and standardizing the IRB application and review process.
- Disseminating information to IRBs and physicians on best practices for expanded access review.

"Thanks in large measure to RWJF's support, the IRB process will be more efficient, unnecessary barriers will be removed, physicians will be better prepared, and patients will be able to more easily access potentially life-saving treatments," Speers says.