

Enthusiasm for Clinical and Translational Research at Johns Hopkins

CTSA PROGRAM REACHES OUT TO THE COMMUNITY IN A VARIETY OF WAYS

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Most health professionals who enter biomedical research come to the field wanting to make a discovery that will improve the lives of their family, friends, and patients. However, understanding diseases and developing effective treatments and interventions is never easy and almost always takes longer than expected. At Johns Hopkins University in Baltimore, Maryland, there is a long tradition of discovery through clinical care and research. Trainees come to Johns Hopkins from every part of the United States and from around the world to begin their careers in research. As their research careers develop, they gradually narrow their focus on more specific questions or methodologies, making it easy to lose sight of the translational pathway. As the *CTS* editor recently discussed, there are a number of barriers to collaboration that are inherent in the structure of academic medical centers.¹ Even though most scientists acknowledge the value of translational teams, it is true that, in the current research environment, rewards come more easily to individual investigators who focus primarily on discrete questions.

Translational research is difficult because the pathway is long, and failures may occur at multiple points. Although creating comprehensive translational research teams may be a welcome challenge to some, others seem more comfortable with the approach of working with a smaller, more manageable research team. Translational research requires interaction with a complex regulatory environment and comfort with having less control of the entire process. Since its establishment in September 2007, our Center for Translational Sciences Awards (CTSA) program, The Johns Hopkins Institute for Clinical and Translational Research (ICTR), has strived to create an environment where research is engaging and rewarding and where investigators feel closely connected to a translational pathway. We will describe some of the ways we try to create an institutional environment that fosters a spirit of collaboration and translation among investigators and other members of the research community—to be, as we say in the ICTR motto, a place “where science and people connect.”

The Accelerated Translational Incubator Program

Feedback solicited from researchers and department chairs indicated to the leadership of the CTSA that access to flexible pilot funds would greatly enhance translational research at Johns Hopkins. In response, we created the Accelerated Translational Incubator Program (ATIP). The goal of this program is to provide up to \$100,000 for 1 year to allow research teams to quickly move their translational product to the next stage. Applicants are expected to describe the translational pathway they will take and the milestones they will use to judge their success. Ideally, these awards will result in the delivery of a preliminary product by the end of the funded year. Funds can be requested for a wide range of support,

including late animal testing, drug screening, research participant recruitment, development of computer algorithms, and pilot randomized clinical trials. Applications from new multidisciplinary teams or junior investigators are given extra consideration.

An additional service provided to each ATIP research team is the assignment of a research navigator as a partner for the duration of their grant. Each of our ICTR navigators has several years of experience as a high-level research coordinator at Johns Hopkins. They assist the ATIP research teams by developing detailed milestones for their project and identifying major barriers that should be addressed as soon as possible. The research navigators are also available to the larger Johns Hopkins research community as the first point of contact with ICTR. By making the navigators' broad research experience widely available, the ICTR can guide investigators to the information and resources that they need to move forward in their work. As the navigators document the guidance they provide, their interactions will be stored in a knowledge base that may eventually be transformed into a more rules-based electronic process.

While the ICTR includes many programs that support bringing new technologies and ideas directly to scientific investigation, we are also working to enhance the partnership between researchers and the public. The enthusiasm and participation of the community is essential for creating a high-quality translational research program, which is why additional emphasis in our ICTR is placed on community and volunteer outreach programs.

Given that study participant recruitment is one of the most daunting barriers to translation, we are attempting to address this multifaceted challenge from a number of perspectives. Part of creating a culture of translation *within* the Johns Hopkins research community is to recognize clinical trial participants *as part of* the research community. With this in mind, the ICTR is currently initiating and supporting a number of programs aimed at improving the image of clinical trial participation and emphasizing the importance of the contribution made by trial volunteers. Our hope is to create an environment in which study participation is recast in the same positive light as donating blood, signing up for organ donation, and other biomedical volunteer activities.

The ICTR's Office of Recruitment and Retention (ORR), which operates independently of the other ICTR cores, was established to support study coordinators and investigators as they develop and improve the recruitment process. In addition to consulting on various Institutional Review Board–approved recruitment strategies and developing better and more visible publicity initiatives, the ORR is developing a number of tools to monitor the success of both new and existing strategies. By applying evidence-based scientific techniques to recruitment activities, the ORR can point study staff

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DOI: 10.1111/j.1752-8062.2009.00080.x

to the most effective means of recruitment and help them avoid wasting time and money on ineffective approaches.

One current ORR project is the Research Participant Perception Study, a collaboration with other CTSA to create an instrument that will measure the experience of research participants in studies at Johns Hopkins. We hope that our efforts to improve the research participant experience will lead current volunteers to return for future studies and to encourage others to participate as well. Focus groups with research participants are ongoing, but we expect to assess whether or not the research participants perceived that the consent process was acceptable, the research team responsive, and the protocol completed safely. We also hope to assess whether the participants feel they contributed important medical knowledge to the study. This kind of systematic assessment will allow an institution to reward those teams that are doing an outstanding job and to retrain those research teams that have low ratings. We also believe that openly posting these ratings will increase the public's trust in the research conducted at Johns Hopkins and other participating institutions.

Research Subject Advocacy Program

Another ICTR-initiated program is the Research Subject Advocacy (RSA) program, a resource dedicated to the direct support and education of study volunteers. The RSA can serve as an independent witness to the consent process and will work on behalf of volunteers to explain the research process and clarify misunderstandings between the volunteer and the study team. The RSA's services are also available to clinical research units, investigators, and their staff who would like someone to review consent forms, protocols, and data and safety monitoring plans to assure high standards of human subject protection.

One recently launched and already highly successful program of the RSA is the Research Volunteer Appreciation Program, which provides free stickers and pins for research coordinators and other study personnel to distribute to study volunteers as tokens of thanks and acknowledgement. The colorful stickers, which say "I helped Johns Hopkins Medicine learn something today," are designed to be given to volunteers every time they come in for a study visit. Exceptional volunteers—for example, people who have participated in long-term, multiple, or vigorous studies—are recognized with die-cast pins shaped like the Johns Hopkins logo and printed with the words "Outstanding Research Volunteer." This low-budget, high-impact program is representative of the type of creativity and innovation that the ICTR will continue to encourage as we work to make clinical trial participation both easier and more appealing for everyone involved in the process.

Maximize Technology Use

Like many of our fellow CTSA recipients, the ICTR is also examining ways in which technology can be used to improve the trial participant registration process. For example, we recently launched a beta Web site called "Trials@Hopkins," a portal that draws on data from ClinicalTrials.gov (www.clinicaltrials.gov) to connect potential volunteers with projects at Johns Hopkins that are in need of participants. The site is intended not only to appeal to an external audience of interested potential volunteers but also to serve as a tool for the many Johns Hopkins employees (health care workers and

support staff) who are frequently asked about ongoing trials in the course of their interactions with patients and their families.

While leveraging the audience reach and data-processing abilities of the Internet will continue to serve as an important part of our recruitment tool kit, we are frequently reminded through feedback from our research coordinators that purely technical solutions often exclude potential participants with little or no computer access. In response, we also are working on event-based recruitment strategies that will allow us to invite members of the Baltimore community to visit our campus and interact directly with researchers and their teams. For example, in conjunction with the Hopkins Memory & Alzheimer's Treatment Center, the ICTR recently sponsored an Alzheimer's Research Participation Appreciation Forum where study participants were personally thanked and celebrated for their contribution to finding a cure for Alzheimer's. Along with other Baltimore-based health care organizations, we are also working with the nonprofit Center for Information and Study on Clinical Research Participation to stage a Clinical Research Education Day that will be free and open to the public.

Some of our research groups have done outstanding jobs working with their patient populations. They have created advisory boards, used patient groups to publicize studies, and enlisted patient volunteers to help with study recruitment. These relationships work particularly well with rarer diseases that have a significant impact on the patient and their families. Disease advocacy groups are less developed for prevention-based approaches or prevalent chronic diseases associated with few symptoms, such as hypertension. We have hired an experienced program manager who will work with a wide range of research teams to decide how a disease advocacy group might enhance their research programs.

For the first time at Johns Hopkins, we will be able to assess and track the efficiency of our research participant and recruitment efforts. As of July 1, 2008, all new studies are required to enroll their human research participants in the Clinical Research Management System (CRMS). The CRMS tracks potential research participants who decline to join a study or who do not complete a research study. We will be able to measure how often research teams are meeting their recruitment goals and from where research participants are being recruited. We can then assess research participants' zip codes to look for geographic (and thus indirectly socioeconomic) trends. The CRMS will allow us to systematically identify best practices for recruitment and retention.

The ICTR is now able to provide a wide range of services with the overarching mission of fostering an institution-wide culture of collaboration. Connecting research teams with the resources they need allows them to reconnect with the excitement of curiosity and the joy of discovery that initially led them to careers in science and health care. And by including patients, study volunteers, and other community members in our enthusiasm for the translational process, we can ensure that our discoveries stay connected with the people who inspired them in the first place. **CTS**

REFERENCE

1. Feldman AM. Does academic culture support translational research? *CTS*. 2008; 1:87–88.