Partnerships for discovery & application
ICTCR
Iowa Center for Translational and Clinical Research
Update

May-June, 2010

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In This Issue

About Us

The ICTCR facilitates patient-centered research through the combined strengths of its founders: Mercy Medical Center, and Des Moines University along with its partners Drake University College of Pharmacy and Health Sciences and Mercy College of Health Sciences and welcomes inquiries from interested clinicians and scientists.

For more information, please call (515) 247-4435.
www.iowatranslationalresearch.org

Catholic Health Initiatives Research Leaders Visit Mercy Medical Center

Senior research leaders from the Research and Development arm of Catholic Health Initiatives (CHI) were in Des Moines for a one day meeting to present information about the research vision and operations that exist in the hospitals of the system. CHI participants included Dr. Alan Armer, VP, Institute for Research and Innovation, John DiCola, Senior VP for Strategy and Business Development, and Ms. Deb Hood, National Oncology Service Line Director. While discussions focused in large measure on developing cancer research activities, all areas of medical research were covered by the CHI and Mercy attendees.

CHI outlined its organizational structure for research, embodied in its three centers: The Center for Clinical Trials, The Center for Healthcare Innovation and the Center for Translational Research. The potential relationship of each of these centers to physician researchers at Mercy and with their ICTCR partner, Des Moines University was showcased. One of the important topics was the role of CHI in helping its hospitals successfully compete for the NCCCP grants, of which Mercy Medical Center is one of the 30 recipients nation-wide. CHI was pleased that 5 of their hospitals were included among NCCCP recipients and will share their experience with this program to the team here at Mercy.

In addition to CHI providing information on its activities, an impressive array of Mercy physician-investigators described their research efforts in order to allow CHI to have a better understanding of the level of research and significance of the contribution of Mercy Des Moines to biomedical research. Among the research programs represented were cardiology, neonatology, obstetrics, family medicine, orthopedics, surgery, endocrinology and public health policy. The audience was informed that among all open clinical studies, whether sponsored or investigator initiated, there are currently 345 open studies approved for enrollment at Mercy Medical Center. Of these, 39% of those vetted by the Mercy IRB are investigator-initiated suggesting a robust climate of original research thinking.

Des Moines University Welcomes Cancer Researcher

Dr. Abigail Henderson joined the DMU Cancer Research Laboratory on June 29. Dr. Henderson has a background in immunology and was previously at the St. Jude's Children's Hospital where she was involved in cancer immunology studies before returning to Iowa. Because of ongoing collaboration between Mercy and the DMU laboratory related to the identification of biomarkers at various stages of solid tumors and at times after cytotoxic treatments, the addition of Dr. Henderson will enable additional new research projects that will expand the laboratory's scope beyond biomarkers into cancer immunology and other host-response investigations and will foster new clinical-basic science interactions between Mercy and DMU. The laboratory is currently directed by Dr. David Strom.

The Tenets of Responsible Conduct of Research Reviewed

The agencies that fund biomedical and fundamental research are increasingly interested in assuring that the integrity of research in America, and particularly the research that leads to new therapies and devices, is done without bias with utmost accuracy and that conflicts of interest do not have an effect on research outcomes, especially when these findings are able to impact the health or recovery from illness of Americans.

In this Issue of the "Update" we provide a brief reminder of some of the most critical elements that clinical investigators and scientists should always keep in mind. The entire topic of Responsible Conduct of Research is larger than might be portrayed here, but for the busy research a "quick-take, ten commandments version" of the concepts may prove useful to reinforce what is already known.

The reason for the ten statements below is based on the Federal requirement that training be given to federally-funded researchers in 10 categorical areas.

The Commandments:

- The ethical foundations for research is Honesty, Objectivity, Accuracy and Efficiency
- Human subjects research involves living persons about whom generalizable knowledge will be gained through interaction or intervention with the research subject or through that person's private information, and such research must be prospectively reviewed by a duly constituted Institutional Review Board unless the board grants a waiver or exemption
- Animal subjects contribute to medical knowledge when the research is necessary, scientifically valid and the principles of refinement of experiments, reduction in numbers of animals to minimum levels needed and replaced when possible with less sentient animals to reduce any pain and suffering, and, as with human subjects reserch, must be reviewed prospectively by an ethics board known as the Institutional Animal Care and Use Committee
- Research misconduct which includes falsification (altering the research record), fabrication (making up the findings) or plagiarism (copying other people's intellectual products without proper attribution) and may occur during the proposal, data gathering, or reporting stages of research
- Authors who are listed on a publication should have contributed meaningfully to the work
- Mentors and trainees have a mutual responsibility to each other and obligations in both directions should be understood and honored by both mentors and trainees alike to avoid abuse of the power of the mentor or lack of performance by the trainee
- Conflicts of interest, real or only perceived, undermine public trust in the research process and should be declared by the person with the conflict, managed by the investigator's institution, and public assurance of the lack or management of conflicts provided

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Additional Information on Responsible Conduct of Research:

The summary provided in the article to the right is a distillation of the concepts that are mandated and described in precise legal detail on the government website for the Office of Research Integrity (http://ori.dhhs.gov).

This website has resources that flesh out the concepts covered briefly at the right.

The Office of Research Integrity has research misconduct as one of its key focuses and, with respect to Federally funded research, has the ability to investigate alleged breaches that involved government sponsored research.

The latest news in the area of research integrity is a congressionally driven plan to strengthen rules on financial conflicts of interest and enforcement of reporting on the presence or absence of conflicts in industry-sponsored clinical trials.

For additional information on the proposed regulations related to financial conflict of interest, see the online version of the Chronicle of Higher Education (http://chronicle.com/article/NIH-Proposes-Tougher-Rules-on/65636/).

Individuals who are interested in having access to a more comprehensive overview of this topic should start with a free online book by Nicholas Stanek. This book is available on the ORI website and is downloadable or available for purchase in hard copy (http://ori.dhhs.gov/education/products/RCRintro/)

A wealth of other resources has become available through the ORI as medical schools, universities and hospitals have realized the need for responsible conduct. education.

Featured Researcher:

Dr. Jan Franko: Specializes in oncologic surgery, Surgical Affiliates, Mercy Medical Center

Investigators Please Note:

The ICTCR will be pleased to feature recently published articles, books, chapters or national / international presentations made by Mercy affiliated physicians, residents and staff. The increasingly robust research enterprise at Mercy Medical Center deserves the attention of medical and scientific colleagues within our community and throughout CHI. Please inform us of your research by email: blarsen@mercydesmoines.

- Collaboration is valuable in today's reserch environment, but requires exceptional communication and written understandings because one collaborator can undermine the whole research program
- Data must be gathered carefully, protected and not destroyed, corrected properly if errors are made and shared appropriately and is the property of the institution or sponsor in most cases, rather than the investigator who is the keeper of that data

-Bryan Larsen

Dr. Jan Franko Reports on Hyperthermic Intraperitoneal Chemoperfusion combined with cytoreductive surgery in the journal "Cancer"

In a study consisting of a look back at the survival of patients treated at the University of Pittsburgh Medical Center from 2001-2007, an effort was made to discover the impact of contemporary treatment options for colorectal carcinomatosis. They stratified 105 individuals into groups where cytoreductive surgery plus contemporary chemotherapy was compared to cytoreductive surgery, contemporary chemotherapy and hyperthermic intraperitoneal chemoperfusion. (see PMID: 20564081.)

As quoted from the published abstract: "The authors concluded that 1) contemporary chemotherapy is associated with prolonged survival among patients with carcinomatosis as compared with historical controls, and 2) addition of cytoreductive surgery combined with hyperthermic intraperitoneal chemoperfusion to modern chemotherapy regimens may significantly prolong survival. Cytoreductive surgery combined with hyperthermic intraperitoneal chemoperfusion and systemic chemotherapy are not competitive therapies, and they both have a role in a multidisciplinary approach to patients with carcinomatosis."

While individual characteristics mitigated against a successful outcome (liver metastasis), the finding of a significant effect of the intraperitoneal delivery of drug at elevated temperature is a welcome finding and Dr. Franko and his collaborators are to be congratulated for helping to advance the field through this research which is intrinsically difficult to conduct, but has important translational value to patients with certain types of cancer.

Statement of Purpose

The ICTCR is a research enterprise that facilitates productive research collaboration between its partners by sharing intellectual and infrastructure resources for the purpose of advancing patient-centered research that seeks better health for our communities and education and research opportunities for our faculty, staff, students and trainees. We believe the comprehensive training of medical students, residents and other health care professionals must be accompanied by a working knowledge of clinical research methods and best practices and that the best way to accomplish this is through active research endeavors. The ICTCR is dedicated to ethical and compassionate care for all individuals who participate in clinical research studies and actively supports the principles of autonomy, beneficence and justice in clinical research programs.