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2009 Necessary Elements in the Fundamentals of Human Subjects Research: Investigator Initiated Studies for the Study Coordinator

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2009

Necessary elements: Investigator initiated studies for the clinical coordinator

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Recommended Citation
Fowler-Dixon, Sarah, "Necessary elements: Investigator initiated studies for the clinical coordinator" (2009). *2009 Necessary Elements in the Fundamentals of Human Subjects Research: Investigator Initiated Studies for the Study Coordinator*. Paper 3 Human Research Protection Office.
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Necessary Elements: Investigator Initiated Studies for the Study Coordinator

May 15, 2009

Farrell Teaching and Learning Center
Sarah Fowler-Dixon, PhD

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Thanks to the Planning Committee

- Debi Delano
- Sandy Dolan
- Michelle Jenkerson
- Heather Robertson
- Patty Suntrup
- Sarah Fowler-Dixon

With assistance from

Sara Baalman, Chris Bear & Mary Louise Seiff

The Plan for Today

- We hope to lay a foundation and touch on areas important to know about when planning and conducting investigator initiated studies.

- We hope that with this knowledge, you will be able to assist the PI by asking questions about areas that should be considered when developing these protocols.

Future Presentations

- We will touch on many topics today. Since we will not have the time to elaborate on all topics today, we hope to expand on some of these topics touched on today in future Brown Bag Sessions.

- Our request is that you list the topics of most interest to you on your evaluation form to help us prioritize future presentations.

Our Speakers

Evan D. Kharasch, MD, PhD
Professor of Anesthesiology

- Russell D. and Mary B. Sheldon Professor of Anesthesiology and Director, Division of Clinical and Translational Research.
- Dr. Kharasch has written many investigator initiated protocols and has developed a NIH template useful in putting these together.
- Dr. Kharasch will present: "How to Write a Protocol Outline"

Craig Coopersmith, MD

Associate Professor, Surgery and Anesthesiology

- Director, General Surgery Resident Research and Co-Director Surgical ICU
- Dr. Coopersmith has written and been awarded a number of grants. He has presented on the process of writing a grant through protocol development many times.
- Dr. Coopersmith will present: "Study Protocol"

Sarah Fowler-Dixon, PhD
HRPO Education Specialist

- Dr. Fowler-Dixon has worked with the WU IRB for 8 years. During that time, she has assisted study coordinators and investigators with various aspects of IRB submissions, study conduct, audit findings, policies and regulations.

- Dr. Fowler-Dixon will present: "Protocol Issues that Warrant Special Attention."

Michelle Jenkerson, BS, RN, RRT, CCRC
Research Participant Advocate

- Ms. Jenkerson has been the Research Participant Advocate for a number of years. Currently with the Center for Applied Research Sciences, she previously worked under the GCRC grant. In her role, Ms. Jenkerson has assisted and trained a number of study coordinators in the conduct of research in addition to auditing studies.

- Ms. Jenkerson will present, "After the IRB approval: Now..What do I do with all this paper."

Sandra Dolan, RN, CCRC
HSR QA/QI Program Analyst

- Currently an auditor with the Human Subject Research Quality Assurance/Quality Improvement Program, Ms. Dolan previously worked as a study coordinator for investigator initiated studies.

- Ms. Dolan will present, "After the IRB approval: Case Studies in Writing Protocols."

Who can I contact for further assistance?

James M. DuBois, PhD, DSc
Director, Center for Clinical Research Ethics, Institute of Clinical and Translational Sciences.
Hubert Mäder Chair of Health Care Ethics
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Other information that may be useful

University Policies & Procedures

- Review and certify to the University Code of Conduct.

  http://codeofconduct.wustl.edu/

- Bookmark and Review Research Roles & Responsibilities Document

  http://roles.wustl.edu/

- Review WU Roles & Responsibilities document.

  http://roles.wustl.edu/

- Review WU Research Policy websites

  http://research.wustl.edu/

Human Subject Protections

- Complete Human Subject Research Education web-based training
  http://aisinfo.wustl.edu/ra.htm
- Obtain password and complete HIPAA web-based training
  http://hipaa.wustl.edu/
- Bookmark and Review Human Research Protection Office (HRPO) website
  https://hrpo.wustl.edu/HRPO/
- Attend HRPO New Submitters Orientation: Offered bi-monthly
- Attend HRPO Q & A Sessions: Offered quarterly

Financial Management

- Review Financial Management Resource Guide under Education at http://spa.wustl.edu

- Attend Financial Management Series classes sponsored by Research Administration and Sponsored Project Accounting. (Offered 2-3 times per year – listed on Research Education Calendar)

- Complete effort reporting training. http://researched.wustl.edu/Effort%20Reporting/EffortReportingMain.htm

Billing Matrix

- Attend orientation to Billing Matrix/Compliance Tracking

  Offered weekly on Wednesday at 1 p.m. CCS Conference Room

  Contact shornickm@wusm.wustl.edu for more information.

- Coverage Analysis & creation of the Billing Matrix for all studies is done at the time the budget and IRB submission are prepared. Please send a copy of the protocol, consent, & budget to CCSCoverageAnalysis@wusm.wustl.edu.

- Billing compliance for the university and hospital is initiated by the Billing Matrix. This system requires a review of the matrix by the PI/coordinator, and patient enrollment in a timely fashion. To attend training, please reserve your spot by sending an e-mail to ccsbillingmatrix@msnotes.wustl.edu.

- Do you have any questions about these processes? Please call or e-mail Kathy Hoertel (747-7667) or Phyllis Klein (747-4289).

Clinical and Laboratory Safety

- Complete OSHA specimen handling & shipping training. Check training schedule at http://www.ehs.wustl.edu/

- Complete Environmental Health and Safety (EHS) Clinical Safety Training

- Complete EHS Annual Laboratory Safety Training (if applicable).

Project Management

- Review Research Resource Forms Library at: http://hsrqa.wustl.edu/default_files/Page514.htm
- Review record retention policies at http://fishelp.wustl.edu/spweb.nsf/
- Become familiar with electronic systems related to participant records (Clindesk, Touchworks/Allscripts, IDX) as required. Attend training if offered.

Research Ethics and Research Integrity

- Bookmark and Review websites pertaining to clinical research regulation & policy

- Office of Human Research Protections

  http://www.hhs.gov/ohrp/

- Office of Research Integrity

  http://ori.dhhs.gov/

Professional Development

- Subscribe to Research News for education, policy and development updates.

  http://researchnews.wustl.edu/

- Attend Research Coordinator Brown Bag Meetings Offered Monthly

- Attend Necessary Elements in Fundamentals of Human Subject Research: 3 day course offered two times per year

  http://hrpohome.wustl.edu/study_team/education/necessary_elements.aspx

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