Medical School Pilot: Streamlining Industry Sponsored Clinical Trial Contracting

UMMS Office of Research & ORSP Partnership

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## Working Group Participants

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Issues Identified

• Lack of standard work throughout entire process
• Significant work occurs via email and outside of an IT system, which prevents tracking performance metrics
• Lack of transparency regarding progress through the process
  o Leads to repetitive effort of calling and sending emails
  o Sense of “black box”
• No deadlines for industry-sponsored clinical trials; fall to the bottom of the pile during NIH deadlines
• Process takes too long, effecting our competitiveness
Issues Identified

• Sentiment that most departments’ infrastructure is insufficient to support industry-sponsored clinical trials well
• Much of the work is sequential
• Lack of centralized resources and sharing of best practices
• Variable experience levels and training of team members
• DRDA staff level is insufficient to handle their work volume
• Signature authority for negotiated contracts resides with Financial Operations, adding another 2+ weeks
Improvements to Address the Issues

• Enhanced eResearch Proposal Management (eRPM)
  o Submit Non-Disclosure Agreements (NDAs)
  o Medical School NDA template with School signing authority
  o Clinical Trial Routing Form (preliminary PAF) to route draft contract to ORSP to start negotiations in parallel to other work
  o Introduced deadline fields to help prioritize work
  o Capture process performance metrics

• Launched the MICHR Clinical Trial Office
  [www.michr.umich.edu/services/cto](http://www.michr.umich.edu/services/cto)

• Eliminated central “internal budget” review for industry-sponsored clinical trials

• Hired two ORSP Clinical Trial Specialists
Business Process Changes

**NOTE: Applies to All Industry Sponsored Clinical Trials (Investigator or Industry Initiated)**

- Pilot involves *all* UMMS departments for next 6 months
- All new NDAs should be submitted in eRPM effective January 19, 2012.
- Use Clinical Trial Routing Form (CTRF) to get contract to ORSP while you work on budget and IRB application.
  - CTRF converts to full PAF
  - Full PAF cannot revert to CTRF (If you have started PAF, finish.)
- Correspond in the system; use Posted Correspondence.
- Use the deadlines judiciously; change/update if circumstances change (don’t cry wolf!)
We focus on you, so you can focus on great science.
Questions

Contact: UMMSResearch@umich.edu