Change and Progress at the IRB

Kenneth Tramposch
Associate Vice President for Research and
Institutional Official, UB's Human Research Protection Program

November 11, 2015

Goals of UB IRB in Executing Corrective Action Plan

- Train IRB and Investigators to improve compliance
- Institute Toolkit template to standardize submissions and review
- Create Research Regulatory Support Offices
  - Separate ***compliance*** from ***support***

Issues Faced when Implementing CAP

- Too much change too fast – Toolkit Implementation
- Inadequate resources
- Poor communications to investigators
- Training and guidance not tailored
- Poor quality of protocol submissions

- **Result: Unacceptable protocol backlog**

Too much change too fast: Huron Toolkit Implementation

- Hurried implementation of Toolkit put PI's and IRB on same compliance page, but
  - Paper version of Toolkit template was lengthy and redundant
  - "One-size fits all" resulted in confusion for many
- Ongoing effort to customize templates and guidance documents
  - Click Implemented – electronic submission and review

Inadequate resources

- Increased staff from 6 to 10 FTE
- Searching for HRPP Director
- Huron consultants on retainer

Poor Communications to Investigators

- Maintain comprehensive list serve - Automated with Click
  - Periodic mass emails
  - Publish program updates/FAQ
- Policy review
  - Clarify “gray areas” and provide specific guidance (FAQs)
    - ***Most importantly***, **include stakeholders in the process**

Training and guidance not tailored

- Huron training was generic
- Provide Customized training sessions
  - IRB committees, administrative staff
  - Investigators and study staff

Poor Quality of Protocol submissions

- Poor quality submissions slow overall review times for all investigators
  - Delays review of high quality protocols
- Create support offices to assist investigators in developing approvable protocols
- Implement scientific review process
  - Mandated by NIH as part of CTSA Award
  - IRB focus on ethics and subject protection

Protocol backlog unacceptable

	Days	
	National	UB
Convened IRB	45	78
Expedited	26	36
Exempt determination	19	21

- We **WILL** improve these metrics!

Protocol backlog unacceptable

- Merge 4 IRBs into one
  - Allows for weekly meetings
  - Working with IRB committee members on consistency
- Review of IRB meetings for efficiency
  - Prescriptive changes
  - PI on-call

Separate Regulatory *Compliance* from Regulatory *Support*

- Creation of a university-wide regulatory support offices – ***to assist faculty in conducting human subjects research***
  - Clinical Research Office
  - Office of Social and Behavioral Sciences Research Support
- Major UB investment of resources will impact quality of IRB submissions, contribute to improved approval times