

# Change and Progress at the IRB

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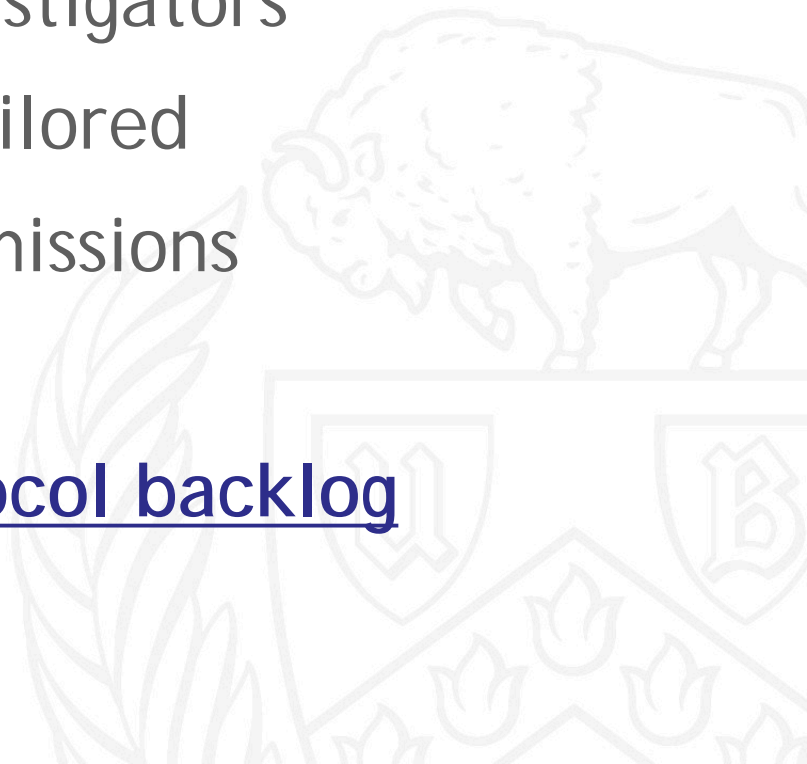


# Goals of UB IRB in Executing Corrective Action Plan

- 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
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# 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

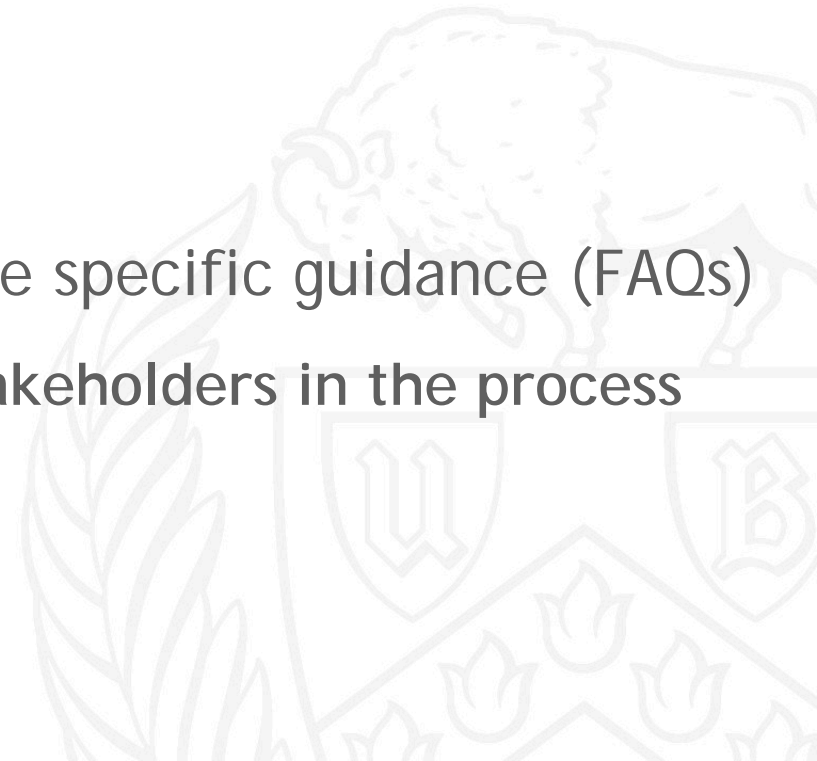
# Inadequate resources

- 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