

# TRANSFORMATION OF PENN STATE'S HRPP AND EMBRACING FLEXIBILITY

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Kathleen Hay, Director, Human Subjects Protections Office  
Sara Horn, Assistant Director, Office for Research Protections

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## HRPP Transformation

### 3 Part Transformation

- Process, Policies, and Procedures
- Organizational Structure Analysis and Re-Organization
- Implementation of New Electronic System



## HRPP Transformation Cont.

### Metrics Tracking

Metrics, such as staff response to change, staff performance, sprint performance, issue handling, earned value, and budget allocation were all tracked and managed at regular intervals

### Implementation

Decisions on implementing the Huron HRPP Toolkit, Click IRB software, timelines, and process were made by all governance bodies

- Governance Structure was key to success
  - Executive Committee
  - Advisory Committee
  - IRB Specific Advisory Committee



## Process, Policies and Procedures

### Huron HRPP Toolkit chosen

- Policies and Procedures (SOPs) define processes within IRB offices
- Checklists, worksheets and templates
- Integrated in Click IRB Product
- "Back to the regulations"
- Allows a more efficient accreditation submission process
- Provides a complete set of tools to meet regulatory and accreditation requirement



## “Back to the Regulations”

- Forced leadership and staff to take a step back and evaluate current institutional policies and procedures
- Trained/Re-trained staff regarding use of the HRPP Toolkit, interpretation of regulations
  - Used on-site consulting services during this process
- Developed new Protocol and Informed Consent templates to collect only necessary information
  - Rid ourselves of the “turbo tax” type of submission form to allow for flexibility in collaboration on the protocol and transparency of questions



## Built in Flexibility

HRPP Toolkit, as it stood, included areas of flexibility

- Confirmed that we have “unchecked the box” on our FWA
- Exempt Categories:
  - Exempt Category 2- No limitations on inclusion of children when research is not conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), or Environmental Protection Agency (EPA)
  - Exempt Category 4- For research conducted, funded, or otherwise subject to regulation by any federal agency “existing” means “existing at the time the research is proposed.” Otherwise, it means “existing at the time the research is proposed or v future for non-research purposes.”)



## Additional PSU Exempt Category

Implemented our own Exempt Category 7 many years prior and carried this over into HRPP Toolkit

- Social Science research in which participant interaction is limited to providing a response to a non-invasive stimulus. In addition, the following are exclusions: (Check if "Yes". If any are checked, research does not qualify for this category.)
  - Federal funding or federal training grants
  - Biomedical procedures
  - Sponsor or other contractual restrictions
  - Clinical interventions (including clinical behavioral interventions)
  - Prisoners as participants
  - Children as participants
  - The use of deception
  - Receipt of an NIH issued Certificate of Confidentiality identifiable research data



## Exemption Policy

- **NO Annual Review!**
  - Follow up after 5 years only to determine whether study is still active
- Do not accept modifications for things that would not change the exemption determination except (ORP Only for some):
  - Change to PI or Advisor of Study
  - Change to COI status
  - Change of Funding Source
- No review of ICF (ORP Only)



## Organizational Structure Changes

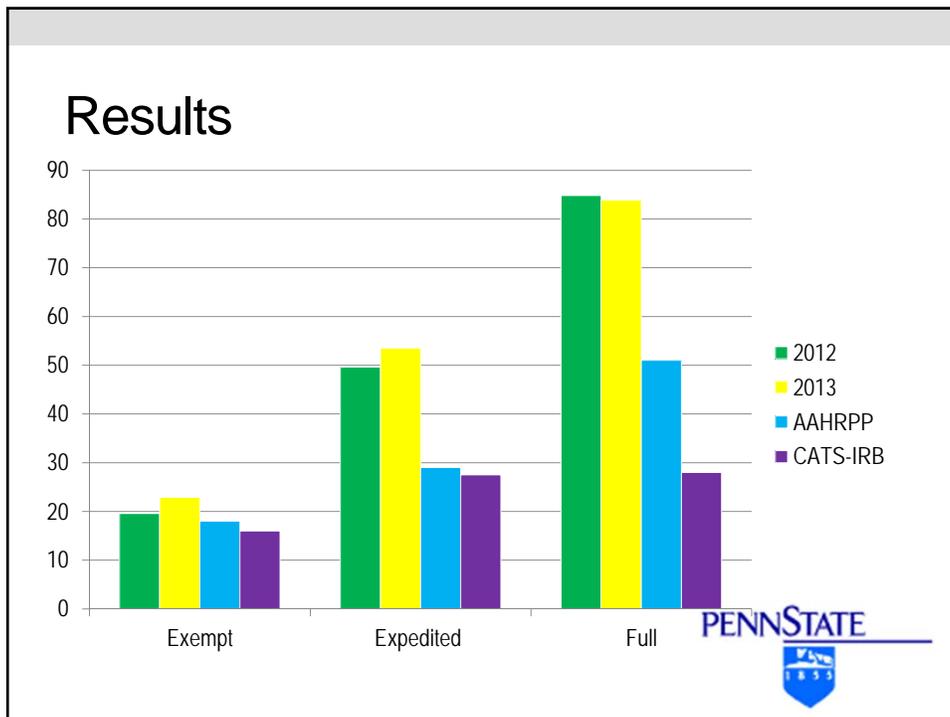
- Both offices – organized existing staff into teams
- Each team has a Team Leader (Senior Program Leader) and 2 IRB Analysts
- Submissions are assigned to teams based on the Principal Investigator's last name and stay with that team for life of the study
- Each team reviews all types of submissions – all team members conduct non-committee reviews
- Each team is assigned to a committee – responsible for the agenda, minutes and coordination of the meeting
- ORP – created a new position – Assistant Director, HRPP
  - Provides leadership to the IRB Program and reports to the Director of Research Compliance (also newly created position as of Nov 2014)



## New Electronic System

- Implemented a new electronic system
- HRPP Toolkit is integrated into the new electronic system
- New system has:
  - Electronic meeting management features
  - Electronic submission of all types of submissions
  - Electronic workflow routing and review
- Benefits:
  - Clarity in review process
  - Ability to directly comment in the system
  - Ease of submitting new studies
  - Elimination of the need for paper study files
- Biggest Challenge: Conversion of ongoing studies





## Results

- Significant improvement in review metrics
- Decreased use of office supplies, especially paper
- Decreased use of copiers
- Emptying of file cabinets and shelving – freed up space
  - More work stations
  - Conference room
- Improved clarity and transparency in review process
- Increased morale in IRB Offices
- Positive experience with new submissions for researchers

## Thank You!

### Kathleen Hay

Director, Human Subjects Protection Office

Penn State College of Medicine, Penn State Hershey Medical Center

[khay@hmc.psu.edu](mailto:khay@hmc.psu.edu)

### Sara Horn

Assistant Director, Office for Research Protections

Penn State University, University Park Campus

[sjh246@psu.edu](mailto:sjh246@psu.edu)

