Improving Community Engagement & Other Goals of UGA’s Human Research Protection Program

Kim Fowler, Director, Human Subjects Office
Jessica Lasebikan, Assistant Director, Human Subjects Office
Kim Fernandez, Compliance Professional II and PACT Lead, Human Subjects Office

Oct. 14, 2022
Our commitment: more information, more often

What?
• Portal changes
• Regulatory changes
• New guidance and policy
• New services

How?
• Research Insights
• Department or College level listservs
• Direct emails
• Research Live
• HRPP Website
Agenda for today

• Overview of HRPP enhancement goals and objectives
  o Quality improvement of HRPP compliance
  o HRPP quality, efficiency, and effectiveness
  o Improve outreach efforts to enhance understanding of human research by participants, prospective participants, or their communities
Why These Goals?

AAHRPP Recertification June, 2022
• Status Reports due November 2022 and April 2023

Our Mission and Values
• Ensure the UGA research community has practical, accessible resources and tools to ensure the ethical protection of human subjects in research.

It's the right thing to do
Quality Improvement of HRPP Compliance

Everyone is responsible

- HRPP Staff
  - Review audits
  - Performance metrics
- IRB Members
  - Minutes audits
  - Use of checklists during meetings
- Researchers
  - Post Approval Self-Assessment
  - Site visits and post-approval monitoring
  - Tracking expiration and Progress Report due dates
Audit Findings

- Missing consent review checklists
- Closure process – wrong determination
- Incorrect Expiration Date entered in approval
- Incorrect application of 2018 Common Rule
- Out of date IRB Member information
- Minutes are looking good
Performance Metrics

- Review times reflect total time
- Complete =
  - All submission questions are answered
  - Required materials attached
  - There is sufficient information to provide a determination or evaluate approval criteria
Reports of New Information (RNIs)

RNIs are:
- Adverse events and unanticipated problems
- Noncompliance (or allegations of)
- Unresolved participant complaints

- 43 in 2021
- 55 in 2022

This isn't bad news – monitoring helps to find issues *before* the bad things happen.

- Past due Progress Reports or expired approvals – 33%
- Recruitment material or process deviations
- External IRB – UGA updates
Improvement of HRPP Quality, Efficiency, Effectiveness

Focus on core services
Cross Train
Create Teams
Gather data from stakeholders
Goals

- Identify challenges
- Education
- Understanding
- Problem-Solve
Protocol Assistance and Compliance Team (PACT)
Core Services

- Outreach and Training
  - Class, events, organizations
  - Contact us [IRB@uga.edu](mailto:IRB@uga.edu)
    - Attn: PACT

- Education
  - Videos by topic

- Support Appointments
  - IRB related questions
  - General guidance
  - Protocol guidance
  - “Not Ready for Review”
Cross Training

- HSO Staff
  - Ongoing and regular educational training

- Reviews
  - Keep current
PEP Survey

We want to hear from you

Coming Soon: educational videos on topics you've chosen
Improve Community Outreach Efforts

- What the HRPP does now
  - Webpage info for potential participants
  - Webpage info related to GaCTSA
  - Webinar recordings, Guidance document for researchers doing CEnR/CBPR
Improve Community Outreach Efforts

• What could the future be?
  • Website to share research results
  • Centralized resources related to community projects
  • Community Advisory Boards
Improve Community Outreach Efforts

• **First Steps – Build a Taskforce**
  • New IRB application questions
  • Website improvements
  • Develop a Commitment Statement
Contact us

Human Subjects Office
2nd Floor, Tucker Hall
irb@uga.edu