# UNC's OHRE Future State

2019

THE UNIVERSITY
*of* NORTH CAROLINA
*at* CHAPEL HILL

# What is HRP

- HRP is a consulting group made up of approximately 15 consultations with each more than 10 years of HRPP-IRB experience.

- They are distinct from many as there consulting group does not market their other products (BRANY IRB, CITI, and Protocol Builder) as part of a consultation visit.

- Karen Christenson, RN, BSN, CCRP is UNC's assigned consultant from HRP
  - Associate Vice President of HRP
  - Over 30 years of experience (research nurse, IRB & Education Manager, AAHRPP Site Visitor, HRPP Director, Associate VP)

# Purpose

- Karen spent several weeks reviewing material prior to her on-site visit:
  - SOP's
  - Reviewer Checklists
  - Guidance's
  - Common Rule Revisions

- Karen spent several days on-site in February completing a review of the program and member education at the IRB retreat. The SOW included:
  - Common Rule Revision Check
  - IRB Member Retreat Training
  - Review of IND/IDE Checklists
  - Overall Evaluation

# Highlights

- Comprehensive program for the protection of human subjects with many strengths
  - Knowledgeable and dedicated professionals who are passionate
  - Highly customizable system compared to other off the shelf systems
  - Well-defined processes for Reliance agreements that are aligned with other similar size organizations
  - SWAG provides quick review of NSI's
  - Farther along with the Common Rule implementation than others.

# Observation and Recommendations

# Drivers for Change Identified by Board Members-Refrigerator

- Increased Board Volume
- Safety-NSI/Modification Timing Confusion
- Application vs. Protocol Issues
- Non-biomed are on a month delay and leads to expirations and rushes.

# #1 Observations-Consistency (Full Board/Expedited)

To support efficiency, submissions are assigned to the next available biomedical meeting rather than having protocols primarily managed by a single committee. IRB Analysts are also assigned to a single committee. From a process standpoint, while efficient, because the protocols “float”, no committee or Analyst has a strong working knowledge of individual protocols and the decisions that were made over time (nor the basis for the decisions). This lack of historical knowledge can result in review inconsistencies and in issues or trends being overlooked.

# #1 Recommendations

- Having a Senior Analyst (or the Deputy Director once on board) attend every IRB committee meeting.
  - Once both Senior Analyst are in office, one Senior Analyst will attend every full board meeting.
  - Managers and Director will each attend a minimum number of board meetings a year.
  - The Deputy Director once hired will attend a majority of the board meetings.

- As planned by the Director, having more than one team member assigned to each IRB committee meeting.
  - Continue to work towards all boards having two analysts.

- Having a Senior Analyst assign submissions in the "not full board bucket" rather than leaving it to everyone to go into the bucket and assign themselves. This not only will help with the perception of "fairness" in work volume but will also give the Senior Analyst the opportunity to identify and share any relevant historical information about the protocol with the Analyst and/or Committee. It is HRP's understanding that since HRP's visit, the OHRE Director has engaged the Managers in discussion regarding how to best implement this change as part of a larger initiative to reconfigure staff responsibilities and assignments based upon experience.
  - Kathy and Cat are working on bringing a plan forward to the June Manager's Meeting, this may need to be moved to July.

# #2 Safety

- The SWAG process provides great value, new safety information (NSI) is quickly reviewed, any additional needed information is gathered, corrective and preventative actions are drafted when appropriate, and the submission is triaged for either acknowledgment or IRB review.

- However, efficiencies are lost and IRB review of the very types of information most critical to the protection of human subjects can be delayed by having the IRB review conducted by the Safety IRB, which meets monthly, instead of at a weekly biomed or non-bio-med IRB committee meeting.

# #2 Recommendations

- UNC – Chapel Hill should consider disbanding the Safety IRB and having the biomed and non-biomed IRB committees pick up NSI reviews. Not only will IRB review be more timely, but the boards will have better insight into issues with research that should be informing their determinations (e.g., whether continuing review should be required for a study, whether review should be conducted more often than annually, whether the project requires verification from sources other than the investigator whether changes have occurred since the prior IRB review, etc.).
  - See next slide

- The SWAG process should continue as is and the Compliance Manager (Safety) and Analyst should continue to manage NSI reviews – initial and follow-up (including any resultant modifications) – so that NSI review doesn't impact the committee-assigned Analysts' workload.
  - Continue to explore processes in connection with recommendation #1 for the Compliance Program to manage NSI processes through NSI lifecycle

# Reporting Concern

- NSI's that meet the criteria of reporting are required to be prompt, and should be completed within 30 days. There is no "set" requirement for the process of reviewing these events, including by whom.

- This is not always occurring due to safety meeting once a month.
  - E.g., SWAG occurred on May 7 and identified the event as potentially reportable, 4 events that are potentially reportable will wait until June 13, and letters will likely not go out until the week after.
  - Negative subject impact
  - Modification and Notification issues due to multiple boards reviewing, e.g., modification may go to the biomed board and be responding independent of Safety.

# Other Issues

- Losing historical understanding of study in relation to review and approval.

- Boards are not able to learn from the events that are occurring, and are unable to utilize “trouble spots” in future reviews

# Additional OHRE Recommendations for Board Structure

- Run 6 biomedical/nonbiomedical boards a month that review safety events.
- Reduce delay of safety review and more compliance with reporting deadlines
- This would give the average board meeting 20 items, and with the removal of the industry sponsored, would eventually decrease by about 10% per year as new industry sponsored are not submitted and are closed. Could potentially get to as low as 15 submissions per meeting**.
  - Shorter Meetings
  - Smaller more manageable boards (rolling roster)
  - Meetings that provide more time for discussion.
  - Allow for more robust education
  - Makes room for additional NIH funded studies with Single IRB mandate.

**Aligns with board member input

# What does this mean for Safety and Non-Biomedical Board?

- We would like to take the members of Safety and Non-Biomedical and provide at least 1 Safety Member and Non-Biomedical Member to each of our Committees.
  - Volunteers?
  - Every Monday
- Board Members from biomedical, switch to safety/nonbiomedical boards.
  - Volunteers?
  - 2nd Tuesday of the Month and 2nd Thursday of the Month
- Transition Safety in August/September Timeframe
  - Provide 1-day intensive training to all chairs-HRP and Jeanne
  - Provide board members training in August and September
- Transition Non-Biomedical in January 2020 with rolling roster

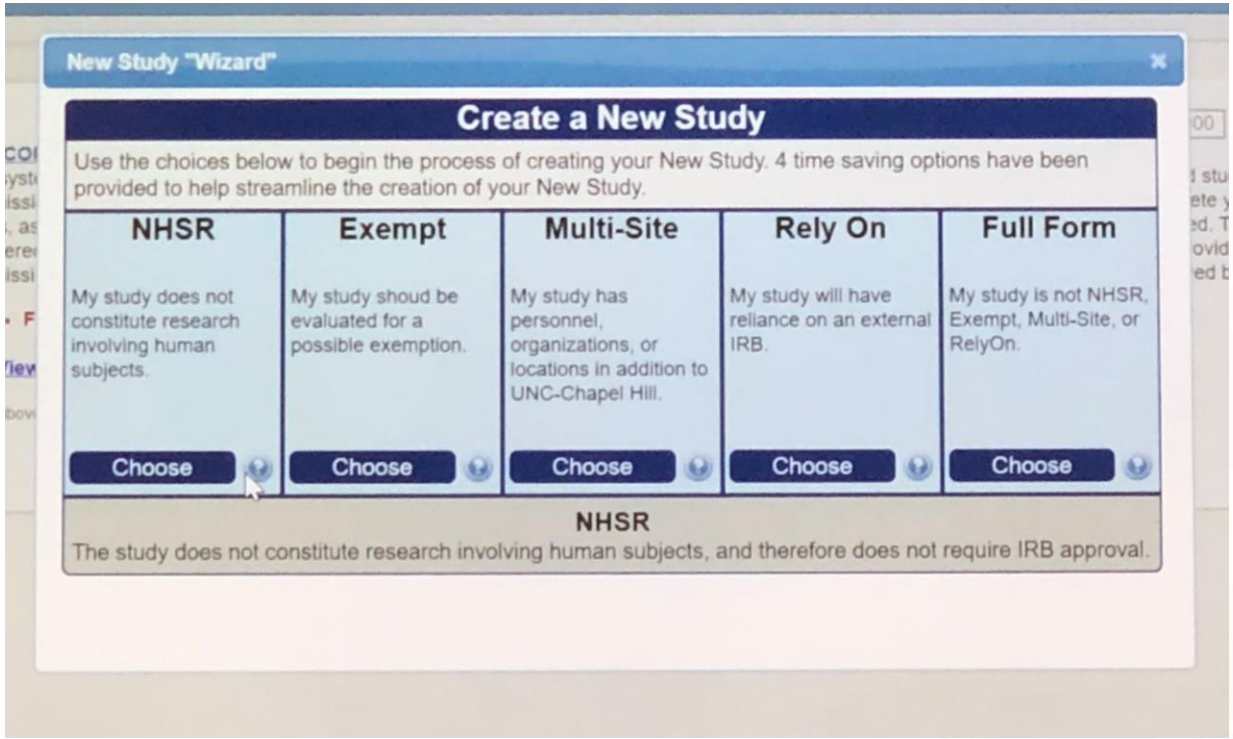
# Observations- Roles and Responsibilities of OHRE Staff

The roles and responsibilities of OHRE staff versus IRB committee reviewers are not clearly delineated and, based on interviews, seem inconsistent across staff/boards. On some committees the staff seem to take primarily responsibility for IRB review with simple sign-off by the Chair/members while on others the staff seem to take a more traditional pre-review role. This inconsistency increases the risk of issues being missed especially when staff are covering for someone who is out of office.

Next Steps:

Received approval from OVCR's office for next SOW and includes Reviewer Checklists and process review.

# IRBIS Updates- Protocol Vs. Application



# IRBIS Updates Continued

- Listening and Feedback Sessions for IRBIS
- Streamlined Commercial IRB Procedures
- Continuing Review Submission Types
- Personnel Only Modification
- Personnel Feed from Ramses
- New Drug and Device Sections

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