

# The State of Research at UNC: The Office of Human Research Ethics Update

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Elizabeth Kipp Campbell, Ph.D., CIP  
Director



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# Topics of Discussion

1. Staffing and Reorganization of the OHRE Staff
2. IRB Committees: Refinement and Expansion
3. Educational Opportunities
4. Metrics of IRB Activity
5. New Initiatives
6. Coming Opportunities and Challenges



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# Current OHRE Staff

There are currently 20 staff members

These include: Director, 5 Management level staff, 4 Administrative staff, 1 Business services coordinator, 2 Senior IRB Analysts and 7 IRB Analysts.

There are currently 7 staff members who are certified as IRB Professionals (CIP).



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# Reorganization of the OHRE Staff

Due to increased volume, desire for better customer service and turnaround, and to attract and retain high quality staff and remain competitive with peers, a new staffing configuration was proposed and approved by the Vice Chancellor for Research in early fall of 2015.

This new configuration is almost fully implemented, but two key positions remain open: Reliance Compliance Manager and Assistant Director.



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# Refinement and Expansion: IRB Committees

1. Adding Vice-Chairs to all committees: succession planning
2. Developing training program for new Chairs and Vice-chairs
3. Adding expertise across all committees, including discussions with School of Medicine and Lineberger
4. Refining on-boarding process for new IRB members
5. Developing annual evaluation process for IRB Chairs and members



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# Educational Opportunities

Held 2-day PRIM&R special educational seminar in October 2015 for all members, chairs and staff

Sent 9 staff, IRB members, and chairs to the national Advancing Ethical Research (AER) Conference in 2015; 9 also attending in November 2016

Participated in numerous Webinars from OHRP, PRIM&R, and AAHRPP and others

Implemented first annual IRB Retreat in February 2016



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# OHRE IRB Metrics

- Total volume continues to increase, averaging about 6% per year over the past 4 years
- Reviewed over 5000 studies last year, and took over 10,000 actions this past year
- The largest portion of reviews is Expedited, followed by NHRS, Exempt, and then Full Board
- Anecdotally there appears to be an increase in the complexity of Full Board studies



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# New Initiatives

1. Faculty Advisory Committee
2. Implementation of IRB Pop-ups
3. QA/QI full program implementation



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# Faculty Advisory Committee (FAC)

- Composed of faculty from key colleges/schools across the university
- Goal to increase input from and satisfaction of researchers
- Provide advice and new ideas for customer service, education, collegiality and problem resolution
- Began in May 2016
- Meets quarterly



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# IRB Pop-Ups

- Individual, face-to-face assistance
- Overwhelmingly positive response
- Biomedical implemented February 2016
  - First and third Wednesday monthly in Burnett-Womack building
- Non-Biomedical implemented October 2016
  - Third Thursday monthly in Davie Hall



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# OHRE Quality Improvement and Quality Assurance Program

- Led by Diane Towle on the OHRE side and Val Buchholz on the Office of Clinical Trials side
- For-cause audits of researchers as directed by the IRB
- Routine auditing of a percentage of approved studies based on risk profile
- Education and auditing assistance as requested by researchers
- Auditing of our internal IRB reviews and processes



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# Coming Opportunities and Challenges

- Notice of Proposed Rule Making – Final Rule and implementation Dates???
- NIH Requirement for Single IRB of Record for Multi-center trials – begins May 2017
- AAHRPP re-accreditation submission (due December 15, 2016) and Site Visit (August 2017?)



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