
INSTITUTIONAL REVIEW BOARD

ANNUAL REPORT

2018-19 AY



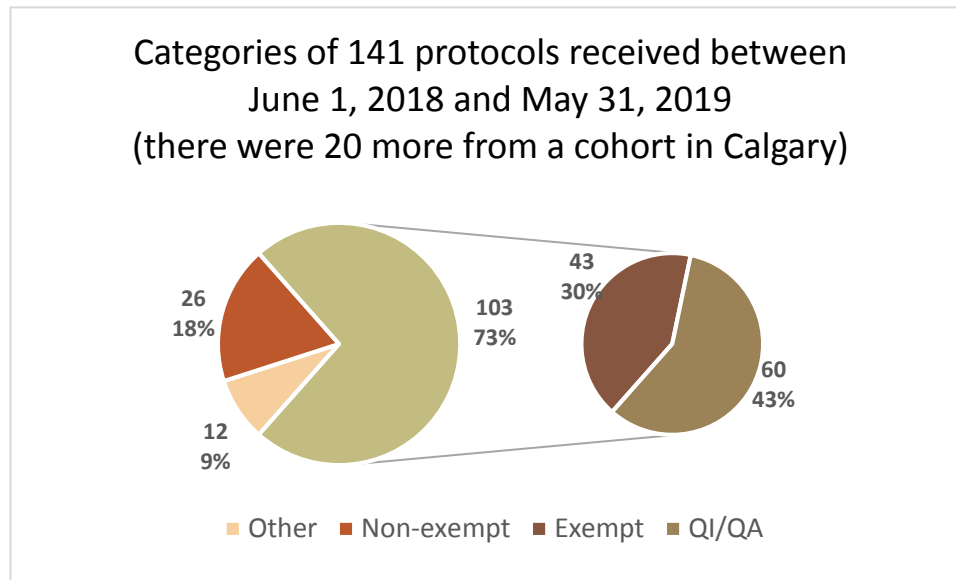
JULY 24, 2019

Dr. Elaine Radmer, Chair

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I. RESEARCH STUDY SUBMISSION NUMBERS



II. CHANGES IMPLEMENTED BETWEEN JUNE 1, 2018 AND MAY 31, 2019

Change #1: Sustaining reviews over the summer

- Piloted a compensation package for Non-exempt reviews (\$75 each) and Exempt reviews (\$25 each)
- Implemented a Chair-team to distribute Exempt reviews
- The total cost to the University for the completed summer protocols was close to \$2200

Change #2: Adjustments for the revised Common Rule

- A new exemption category – Benign Behavioral interventions (Category 3)
 - “Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection...
 - ...benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing”
- Revised Category 4 to include existing records originally collected for a non-research purpose
- Changed Exempt form and FAQ website
- Met with stakeholders to present and discuss revisions to the common rule regarding benign interventions

Change #3: Rolled out a University subscription to CITI (Collaborative Institutional Training Initiative)

- The Board reviewed the modules and determined appropriate assignments for our researcher population
- Paul Bracke worked with CITI for single sign-on
- We prepared instructions for Gonzaga personnel

Change #4: Continuing to clarify Quality Improvement/Quality Assurance (QI/QA) projects

- Created a separate QI/QA form
- Expanded the FAQ to address when and for whom IRB submissions are needed
- Added detail to the table distinguishing between research and QI/QA

Change #5: Continuing to collaborate with Kara Hughes for a SharePoint solution

- Automatic emails for Exempt and Non-exempt approvals
- Lots of troubleshooting as needed

Change #6: Additional adjustments related to privacy regulations

- Added statements about HIPAA and FERPA to Exempt forms
- Adjusted requirements for Exempt Amendments – a form need only be submitted if privacy, Data Use Agreements, or risk is likely affected.

Change #7: Planning for study closure

- We sent an email announcing that protocols approved prior to January 1, 2018 were closed.
- Exempt studies will now have a three-year expiration. Non-exempt studies will require a continuation form after one year.
- Some work is needed to enter dates in Sharepoint to support automatic emails.

Pilot Stage—Preparing a process for research with tribal communities

- Worked with Raymond Reyes and Wendy Thompson to prepare forms
- A two-step process is intended to encourage relationship building
- Forms to be piloted Fall 2019

III. NEXT STEPS

- Deleting records as per Gonzaga records retention policy
- Automatic reminders for expiring Exempt or end of year Non-exempt studies
- Distributing Exempt and QI/QA reviews during the school year
- Update Policies and Procedures as per revised Common Rule and additional changes; procedures for responding to reports of non-compliance need to be established
- Update Bylaws

IV. COMPLIANCE NEEDS

- Post-approval monitoring for non-exempt
- Records management
- Tracking NIH or CITI certificates
- Legal input for liability
- Responding to countries that have adopted the General Data Protection Regulation (GDPR) of the European Union and their additional data security requirements (with costly fines for failure to comply)

V. TABLED UNIVERSITY CONVERSATIONS

- University team met to discuss survey policy for GU students
- Will the Department Chair signature always be needed on the cover sheet?
- Determine how higher risk biomedical research will be processed – agreement with a for-profit IRB?
- As more medical studies are initiated, add Materials Transfer Agreement to forms where Data Use Agreements are mentioned

Gonzaga University's Institutional Review Board (IRB) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Gonzaga University.