West Virginia University

Fall 2014

Office of Research Integrity & Compliance

Newsline

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General News

Please Welcome Our New Hires!

The ORIC staff would like to announce and welcome our new assistant director for the Office of Research Integrity and Compliance, Ms. Deyanira Santiago, MBA, RLATg.

Ms. Santiago has a background of over 20 years in research and compliance. She has just arrived here from the Philadelphia area and has been involved at the National and local levels of the AALAS organization and other animal research/welfare organizations. She is also still very involved in her alma mater, Rutgers University and their alumni association.

We would also like to officially welcome Afton Wagner to our full time staff. She will work with the IRB staff to bolster our services and oversight ability. Afton graduated from WVU in December 2013 with a Bachelor's degree in Biology. She has worked in our office part time for the past 2 years, coming onboard full time in October. She enjoys traveling and Mountaineer sports.

Position Open

Please be aware that an administrative assistant senior position with the IRB is currently vacant. We are working diligently to fill the position and continue to look forward to assisting the research community during that process. Currently, all inquiries should be directed to 304-293-7073 or you can apply online at http://employmentservices.hr.wvu.edu/wvu_jobs/classified_positions/administrative-assistant-senior-80.

General ORIC Contacts

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Tracye Tennant Administrative Secretary (304) 293-7073	

Human Subjects Research & the IRB

Quarter Three (July thru September) Activity Report

For the months of July, August, and September, the IRB staff received 35 new not human subject research (NHSR) submissions, 123 exemptions, 92 expedited submissions, and 35 full board submissions. This brings the total number of active protocols in the KC submission system to 1,477 as of September 30th, 2014 (note that this excludes any protocols still active in the BRAAN2 system). Another 105 submissions in the KC system were still routing to the IRB staff or being revised by their respective research teams.

Overall, the type of review that accounted for the largest percentage of submissions in Quarter 3 was exempt review. Exempt reviews accounted for 43 percent of the total while expedited reviews accounted for 32 percent of the total. Full board reviews accounted for 12 percent of the total, which is higher than the standard 5 percent rate.

The median approval time in calendar days for exemptions and expedited protocols were 11 days and 21 days, respectively. Nationally, exempt authorizations took about 17 calendar days and expedited approvals took 30 calendar days. The review type that normally requires the most review time was full board, which stood at 24 days from receipt of application to approval notification during the third quarter. Once again, this was significantly faster than the average national review time of 45 calendar days for full board review.

Q3: Number of Submissions by Type
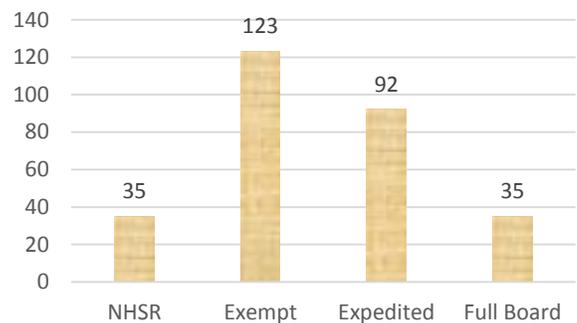
Q3: Percentage of Submissions by Type
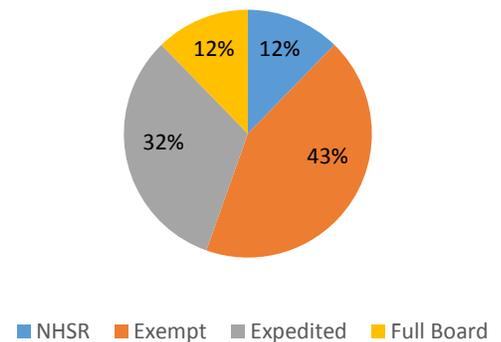
ITS HelpDesk and KC

Please note that all questions regarding technical problems with the KC IRB submission system should be directed to the ITS HelpDesk at 304-293-4444 or ITSHelp@mail.wvu.edu after Friday November 14th, 2014.

Any and all questions about regulatory issues or questions about information required to fill out the online protocol should continue to be directed to the IRB staff in the Office of Research Integrity & Compliance.

Q3: Median Time (Calendar Days) from Receipt to Approval

BRAAN2 System Phasing Out

Please be aware that you must migrate your protocol from BRAAN to the new system, KC by January 1st, 2015. If you need assistance in doing so, please refer to the migration instructions or call 304-293-1119 for assistance.

Change in Deviation Policy

Please note that the deviation policy – located in section 9.3 of the IRB standard operation procedures (SOPs) – has been updated. Any major deviations should be reported within 5 calendar days of the investigator becoming aware of the occurrence. However, any minor deviations may be summarily reported with the renewal for that particular protocol. The definitions of what constitutes a major or minor deviation can be found in section 9.3 of the SOPs.

CITI Single-Sign-On (SSO)

Effective immediately, WVU researchers and their staff should begin using MyID usernames and passwords when accessing services offered by the Collaborative Institutional Training Initiative (CITI Program) at the University of Miami.

CITI provides training modules that help researchers nationwide learn to comply with federal standards as they conduct their work. Federal agencies that fund research often require this training, and WVU's Office of Research Integrity and Compliance (ORIC) also requires certification through some CITI training modules.

Until now, WVU research teams have signed in to CITI using various email accounts and credentials. That means the training sessions were not automatically linked to the same user. Now, researchers can use their MyID usernames and passwords to ensure that all training sessions are linked to the same account.

Users who know that they have used multiple accounts in the past or who know they have never used MyID credentials must follow the instructions in this link to merge those accounts: http://citiprogram.desk.com/customer/portal/articles/163321-i-currently-have-two-learner-accounts-can-i-merge-them-into-one-citi-program-account. Any technical issues with the CITI SSO should be reported to the ITS HelpDesk at 304-293-4444 or via email at ITSHelp@mail.wvu.edu.
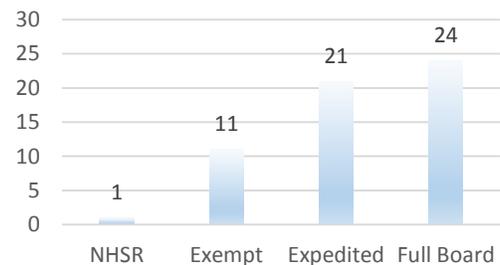
Clinical Trials through Chesapeake IRB

The IRB staff would like to announce that an agreement has been reached whereby all non-investigator-initiated clinical trials that are phase II, III, or IV studies may opt to go through the Chesapeake IRB – a central, external IRB – for approval. The approval must still be reported to the WVU IRB for reporting and oversight purposes. Please be aware that the WVU IRB must still give initial approval on all investigator-initiated clinical trials and all Phase I clinical trials whether they are investigator-initiated or not. For more information, please visit our Chesapeake IRB Portal.

New Changes to the WVU+kc System on Monday December 15th

In October, the WVU+kc Steering Committee requested feedback from the WVU research community on the enhancements it would like to see implemented in the WVU+kc (Kuali Coeus) research administration system. Information Technology Services appreciates the feedback. Based on the customer-satisfaction survey results, we have already made some improvements to WVU+kc.

This weekend, we will be addressing additional priority items for the IRB Protocol module to include:

- The amendment/continuing renewal form Microsoft Word attachments will be replaced with new sections that will populate on the Questionnaire page.
- All sections of a protocol will be editable by default when an amendment/renewal is created.
- A validation error will populate if a closure form is not attached when submitting a request to close.
- Email notifications will automatically be sent when a protocol has been assigned to a board for review.
- The protocol type will be displayed in the header.

While 48 percent of the 122 survey respondents were satisfied or very satisfied with the product, 52 percent indicated a need to improve. The WVU+kc team is listening: The primary purpose of the survey was to help identify and prioritize improvements in both the IRB Protocol and the Award Initiation module.

With this upcoming implementation, we will have completed five of the top 13 items identified in the survey. For the complete survey results visit the WVU+kc website. We plan to continue to request feedback from the WVU research community to identify future enhancements.

The WVU+kc Steering Committee also recognizes the need to improve search functions or create a better interface that will display all research activity associated with the logged-in user. This will be one of the team's priorities moving forward.

Any questions or comments can be directed to researchIT@mail.wvu.edu.

Human Research & IRB Contacts

Lilo Ast, MA	Barbara White

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Jonathan C. Young, PhD, CIP HRPP Administrator (304) 293-1119	Afton Wagner IRB Asst. Coordinator (304) 293-5923

Animal Research & the IACUC

Searching for Alternatives to Painful and/or Distressful Procedures

As per USDA/APHIS Animal Care Policy #12: "The Animal Welfare Act (AWA) regulations require principal investigators to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements."

The PI is required to document that they have searched the literature to determine if there are alternatives to any of their procedures in the protocol that may cause pain and or distress to the animals. If alternatives are available, the PI should demonstrate why they cannot be used for their study.

Searching for alternatives to painful/distressful procedures is one of the most difficult aspects of completing an animal care and use protocol. We have provided some guidance and helpful tips below to help accomplish this requirement.

Things to consider before beginning a search:

1. Consider other possible animal or non-animal models (e.g., tissue culture, cell culture, fish, rats, etc.).
2. Consider the objectives and endpoints.
3. Note any drugs or compounds used in procedures (e.g., anesthetics, analgesics, test compounds, etc.).
4. Note methods and procedures using animals, paying particular attention to those procedures that may cause pain or distress to the animal.
5. List any potential alternatives of which you are aware (e.g., alternate methods, modified techniques, housing modifications, modified restraint, in vitro methods, computer simulations, etc.).
6. Develop a conceptual search strategy using the keywords and concepts that were noted above. A search strategy is necessarily flexible, dependent both on the topic and on the database selected. If too many records are retrieved, additional relevant terms may make the results fewer and more useful; if too little is retrieved, fewer terms and a more conceptual approach may identify the relevant material. Use these terms and concepts as needed when searching.

7. Database selection: Choose those that are appropriate for the area of study, keeping in mind the type of protocol (research, teaching, or testing protocol).

Other important points to keep in mind:

1. A separate search will be required for each potentially painful/distressful procedure.
2. It is important to conduct a literature search on a case by case basis. It is impossible to search for an alternative to a painful/distressful procedure outside of the context of an experiment (e.g., looking for alternatives to something as general as thoracotomies in dogs). More questions need to be addressed such as: 1) Why is the procedure being performed. 2) What is the expected outcome? 3) Is the procedure terminal?
3. It is important to remember that the search for alternatives to painful/distressful procedures should be specific to the study being proposed. Therefore, it is important to include a search term or keyword regarding the outcome that is of interest, not just the procedure itself for which you are looking for an alternative.

Documenting an Alternative Search

1. The names of the databases (at least two) searched must be listed. It is important to use appropriate databases based on the protocol topic. Here is a link to a guide to bibliographic databases for alternatives searching http://www.lib.ucdavis.edu/dept/animalalternatives/databaseapproach.php.
2. The date the search was performed must be listed.
3. The period covered by the search must be listed.
4. The keywords and/or the search strategy used must be listed.
5. Once the search has been performed, the PI must provide the number of hits obtained from the search and describe the search results. In other words, how did the results of the search lead the PI to conclude that there is no alternative to further reduce, replace or refine this potentially painful/distressful procedure, and if there are, why the PI cannot use them for their particular study?

In addition to these tips, PIs can go to the UCDavis Center for Animal Alternatives http://www.lib.ucdavis.edu/dept/animalalternatives/worksheet.php for additional help. They provide a very useful worksheet for a step-by-step approach to alternatives search http://www.lib.ucdavis.edu/dept/animalalternatives/worksheet-info.php.

Animal Research & IACUC Contacts

Melinda Hollander, MS, CPIA Animal Care and Use Officer (304) 293-9368	

Conflict of Interest in Research

WVU Joins the Association of American Medical Colleges (AAMC) Forum on Conflicts of Interest (FOCI) Academe!

The Association of American Medical Colleges (AAMC) developed the Forum on Conflicts of Interest (FOCI) Academe to provide a forum for the leadership in the biomedical arena who oversee and manage conflicts of interest to promote the highest ethical and professional standards in the conduct of their institutions as they carry out their missions of patient care, research, education, business, and service.   There are over 400 members from over 95 institutions.

Aside from providing us with incredible resources and feedback The FOCI Academe spearheaded the COI Metrics Project. In 2011, 73 institutions registered to participate in the Metrics project, designed to collect information readily available to participating AAMC member medical schools and teaching hospitals to measure the impact, cost, and outputs of implementing and administering the NIH Rule. It has proven to be a unique opportunity to gain perspective on the effect and effectiveness of the rule using annual aggregate data regarding conflict of interest programs and review processes, disclosures made by investigators to institutions, and financial conflicts of interest identified and reported to federal funding agencies. The information has also been provided to the NIH for their own retrospective review of the effect and regulatory burden of the new rule.

The findings have been pretty fascinating thus far. The results from the first surveys can be found at the following link:
https://www.aamc.org/download/363236/data/firstresults.pdf

Federal Demonstration Partnership (FDP) Institutional Clearinghouse

We are excited to announce that WVU is now a participating institution in the FDP Institutional Clearinghouse. This site provides a central location for educational institutions and other entities to document that they are in compliance with the PHS Financial Conflict of Interest (FCOI) rules and regulations. It is highly recommended that institutions join the clearing house as a step toward a standardized locale for institutions to find assurance that sub-recipient institutions follow the new PHS standards. For more information and to see a list of participating institutions, visit http://sites.nationalacademies.org/PGA/fdp/PGA_070596.

WVU Electronic Disclosure of Interest in Research Form

Each member of the WVU research community must submit a Disclosure of Interest in Research (DOIR) Form annually to the Office of Research Integrity and Compliance (ORIC). This requirement must be fulfilled before your protocol can be processed through the IRB and before funds will be released by the Office of Sponsored Programs.

Please use the following link to access our new electronic DOIR
form: http://oric.research.wvu.edu/conint/disclosure-of-interest-in-research

For any questions or suggestions concerning conflict of interest in research please visit our website at:
http://oric.research.wvu.edu/conint or contact Joy Edwards.

Conflict of Interest in Research Contacts

Joy Edwards COIR Officer (304) 293-5475	

Responsible Conduct of Research

Policy Reminder

Please remember that all applicable students, fellows, and trainees on applicable protocols must adhere to the WVU Responsible Conduct of Research (RCR) policies and guidelines. The ORIC encourages all faculty and staff to educate their students on the RCR core areas and principles. Education and training is available for faculty, staff, and students to facilitate adherence to these very important policies and guidelines, both in-person and online.

Responsible Conduct of Research Contacts

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