To faculty who plan to seek IRB approval for research projects,

Recently, the federal Office of Human Research Protection (HHS) implemented new and modified regulations relating to human research.  The new body of regulations is now referred to as the “Final Rule” or “Revised Common Rule.”  The good news is that these changes were made in order to better protect human subjects involved in research, while removing ambiguity and reducing the administrative burden.

Briefly, there are new definitions, explicit allowance for electronic signatures, additional criteria for exemptions, wider latitude for expedited review, more stringent language requirements for consent forms, and private information treated identically to biospecimens for all intents and purposes.

On behalf of the IRB and in order to make the IRB process at Centre operate as smoothly and efficiently as possible, I would like to make you aware of several things that will impact your applications.

1. Faculty must now approve the IRB application materials of their students.  The most challenging parts of writing IRB applications are defining the project and preparing consent forms or survey instruments.  The IRB chair and members are happy to answer questions along the way, but we cannot “help students fill out forms” or provide guidance on the content of their research projects.  We are working on updating the Qualtrics survey to spawn an email to the faculty member to obtain their approval of students’ submissions.  In the interim, this will be done manually – you’ll receive an email from me that contains the survey and attachments of your student’s application, and you will email me back to provide approval.  We strongly suggest that faculty advise students to fill out the sample IRB application that is posted on Centrenet, and use that as a pre-application review instrument.
2. We have new templates for consent forms, waivers of documentation of consent, and electronic surveys. These can be downloaded from the IRB Centrenet page: <https://centrenet.centre.edu/ICS/Academic/Academic_Affairs/Institutional_Review_Board/Forms_and_Documents.jnz?portlet=Free-form_Content>.  There is also an example that has been fully completed as for a ‘realistic’ project.
3. **Consent forms must contain all of the elements present on the new templates.  Old forms will not be reviewed.**
4. All projects involving humans must be assessed by the IRB, whether or not the project would have been treated as “human subjects research” in the past.  In some cases, we will simply register the project as journalism or oral history.  The majority will be approved by expedited review for one year, as “exempt” from continued IRB oversight.  Researchers should not make any determination of the disposition of their project as “human subjects research” or “not human subjects research.”  It is not always a straightforward determination, and intent to publish is only one of several criteria that determine HSR vs. NHSR.  Almost all of Centre’s projects will undergo expedited review by a single IRB member.
5. For class projects, all students acting as researchers must take the CITI online course on Human Subjects Research (HSR).  Registration directions are available at the “Forms and Documents” link above.

I am available as needed to provide guidance and help in advance – just call or email and we will figure it all out.  Many faculty have been reaching out ahead of their class projects to work out the best path to IRB approval, and we welcome this practice.  We also welcome your feedback!

Members of the IRB include: KatieAnn Skogsburg, Kiyona Brewster, Kaelyn Wiles, Mykol Hamilton, Aaron Godlaski, and Matt Kassner.