## Human Subjects Research Protocol Submission EMU Digital Commons

(This is author journal-submission software. Periodically if the language doesn't make sense in relation to a research submission for human subjects – please ignore... The software was purchased by Halle Library for multiple applications – the price was right for our purposes.)

While we know this process may at first seem cumbersome, this allows you to: directly upload documents rather than sending them through email, track the review process, and get automatic emails. It allows the University Human Subjects Review Committee (UHSRC) to be notified of your submission, to assign reviewers, for reviewers to go to the site and review your materials and return to us the reviewer form. It allows the administrators to see the reviews and process a decision with email communication back to you for approval or to expedite needed changes.

Yes, please use this process for all research – exempt, expedited, and full board...

Site will be used for all FACULTY, STAFF, and DOCTORAL DISSERTATION research.

## You are ready to submit when you have available for posting the:

- Completed UHSRC application form (modification or study completion forms)
- Study summary
- Data collection materials (e.g., survey forms, sample interview questions)
- Informed consent documents and assent documents for obtaining agreement to participate from for example children
- Permission to conduct research @ a particular site (e.g., school superintendent or IRB approval from a hospital)
- Recruitment materials/fliers
- Adverse event procedures should an event occur

## **Submission Process**

- Go to <a href="http://commons.emich.edu/human\_subjects/">http://commons.emich.edu/human\_subjects/</a>
- In left margin under Author Corner, click on Submit Research.
- On the far right side, **Create a new account click sign up.** Required fields are marked with red asterisk. Use an email address you will check or one that rolls into your my.emich account. Click the **Sign up** button when done.
  - When you later return to the site, you would just login with your email address and digital commons password this will be the address to which UHRSC messages will be sent.
  - A confirmation email will immediately be sent to you. You must go into email and click to confirm before you can proceed with application submission.
- After confirming by email, return to <a href="http://commons.emich.edu/human subjects/">http://commons.emich.edu/human subjects/</a> log in and click on Submit Research in left margin.
  - This takes you to the Submissions Instruction site. Please read the information and click box that you **Agree to the Terms**, click **Continue**.

- You should now be on the **application form**. Complete all sections of the form noted as required.
  - Upload UHSRC application form (or modification or study completion form).
  - o For **additional items to submit** (e.g., study summary, informed consent, permission to conduct the research @ x school or hospital), click box, then click the **submit** button at the bottom of the page. This takes you to the next page where you can one-by-one upload all your additional items. It allows you to post a **description of each item**. Please be generic (e.g., study summary, family consent, teacher consent, student assent, letter of support, survey instrument, focus group questionnaire, etc.). Keep adding until all documents have been uploaded.
  - When done, click save file, and click continue.
- You will receive a message on your screen and an email indicating your submission was successful.
- · You will see buttons to revise your submission or add more content.
  - O If you revise your submission, it takes you back to your completed online application form so you can make changes. It will appear as though your uploads are gone, but they aren't. You may add additional files or amended files using the above- mentioned "additional items to submit" process. Please make the new description read "revised informed consent" or "updated application form", etc. so we can see there has been a change. ALWAYS USE BOLD OR HIGHLIGHTING TO NOTE THE CHANGE ON THE DOCUMENT.
  - Add more content, should ONLY be used if you are making a formal modification. This button takes you to a BLANK application form. Fill it out as if you are starting from scratch except to click minor modification as your submission type.
- You can click on the MY ACCOUNT button top right tab to check status of your submission and see that all your uploads are recorded. You can return to Digital Commons and again check status through this tab.
- Be sure to log-out of Digital Commons. Click on the **My Account** tab. On the My Account page, the **log-out** button is in the upper right hand corner.
- Per federal guidelines, WE NEED TO KEEP A SIGNED PAPER COPY OF YOUR UHSRC APPLICATION FORM, STUDY SUMMARY, CONSENT FORMS, SURVEY INSTRUMENTS, RECRUITMENT MATERIAL, ETC. PLEASE FORWARD ALL DOCUMENTS TO 200 BOONE HALL.

## **Future submissions**

- Return to Digital Commons.
- Repeat above process for a new application, a minor modification, or to post a study completion form.
- If you are referencing a previously approved protocol, please add to the end of the study TITLE the reference number noted on your approval letter (e.,g., 090205)