Overview of the IRB Submission Process

<u>Please note:</u> This document is the text of an email sent to dental students who are working on their first research project. It is meant to provide general, overarching information on the process, but is not a definitive guide. The CWRU faculty member who will be the PI of the project (for students/residents/interns, this will be your faculty mentor) should be the primary point of contact for any questions regarding the IRB submission and the overall project.

Please feel free to contact me, Tricia Mehosky Ribeiro (<u>pam17@case.edu</u>), with any questions or comments about this document. While it is intended that this will house the most recent information, please consult primary sources to confirm the information here.

IRB (Institutional Review Board) Submission

Below are the steps needed to submit for IRB consideration. Everything is done through the SpartaIRB system and your faculty mentor will need to be listed as the IRB Responsible Investigator. You can be listed as part of the study team (Case policy requires that a faculty member be the Responsible Investigator). There is some general information entered into the SpartIRB system, but the bulk of the information is uploaded on Word templates. You will complete a protocol template for your study and attach any other documents needed, needed such as an informed consent, surveys, copies of flyers, etc.

The single most important piece of advice I can give is that you <u>include as much detail as possible</u> in the template. Answer all of the questions, using "N/A" or "Not Applicable" as appropriate. Don't leave anything blank. Be sure to think through the entire process of your project. Once the protocol is submitted and approved, that becomes set in stone. Any deviation from that process must be approved by the IRB before the change is put into practice.

To get started, you should determine if you have access to the SpartaIRB system. Please navigate to the site https://spartairb.case.edu/ and click on the login button under the CWRU logo. Use your case ID and password to log in. If you cannot access the system, you can request access by going to the SpartaIRB Info site (https://case.edu/research/faculty-staff/education-and-training/spartairb-info) and clicking on the "SpartaIRB New User Request" button on the right side of the page. Fill out the form and submit. The setup usually takes 24-48 to process. I'm fairly sure you will get an email saying that access has been granted, but you can also keep trying the site in a day or two and see if you can log in.

The type of project that you are planning to conduct will determine what forms need to be submitted to the IRB for review. All projects require a protocol document that explains everything about your project from beginning to end. The most up-to-date templates are housed in the SpartaIRB Library, which you can access once you have been added to the system (see previous paragraph)

There is a Protocol Submission Guide for SpartaIRB in the SpartaIRB Help Center. Once you have access, please take a look to get a more complete picture of the process. This is a step by step

guide that explains how to submit in the system. There are other guides in the SpartaIRB system under the Help Center tab in the IRB page that you can look at once you have access.

Another point to consider is from where your subject pool/data is coming. If you are using patients/data from the Case Dental Clinic, you will be submitting to the Case IRB. If you are using patients/data from UH, you must go through the UH IRB. The SpartaIRB system is the portal for submission to both the Case and UH IRBs, but using UH patients/data requires additional credentialing and clearances which take additional time and require some fees to be paid. Please get in touch with me if there is any chance you'll be using UH patients or data for your project and we can figure out what needs to be done.

Continuing Research Education Credit (CREC) program

Next, you will need to be trained in the protection of human subjects through Case's Continuing Research Education Credentialing (CREC) program. This is an online process that needs to be completed before the IRB approval can be issued. Details about the program and instructions on how to register and begin the training can be found at https://case.edu/research/faculty-staff/education-and-training/continuing-research-education-credit-crec.

Conflict of Interest (COI) Disclosure

Finally, you will need to submit a COI disclosure in order to conduct research on campus. The first thing that is needed is to create a profile in the Spiderweb system. Please go to https://research.case.edu/spiderweb/ and log in with your Case ID and password. The first screen that pops up will be a profile page. Please enter in the information for the required fields with the red asterisks. You can fill in anything else if you'd like, but it's not necessary. Once you have done that, please let me know and I can request that the COI team add you to their system. They will then send you an email with a link to the SpartaCOI system so you can submit your disclosure.