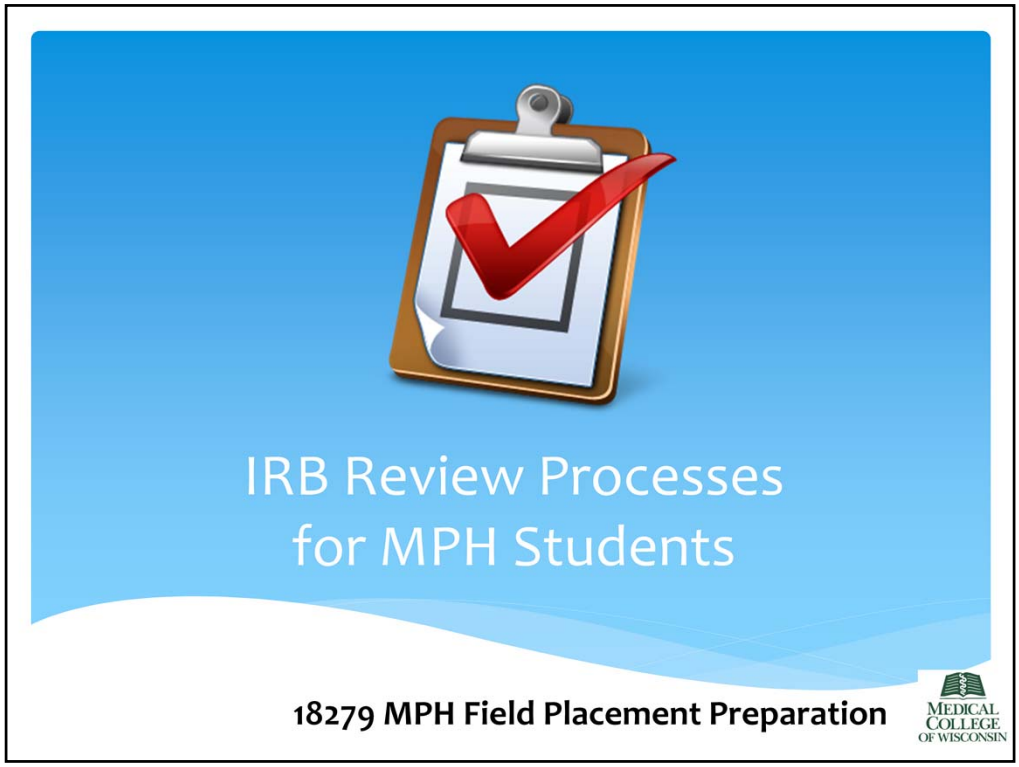
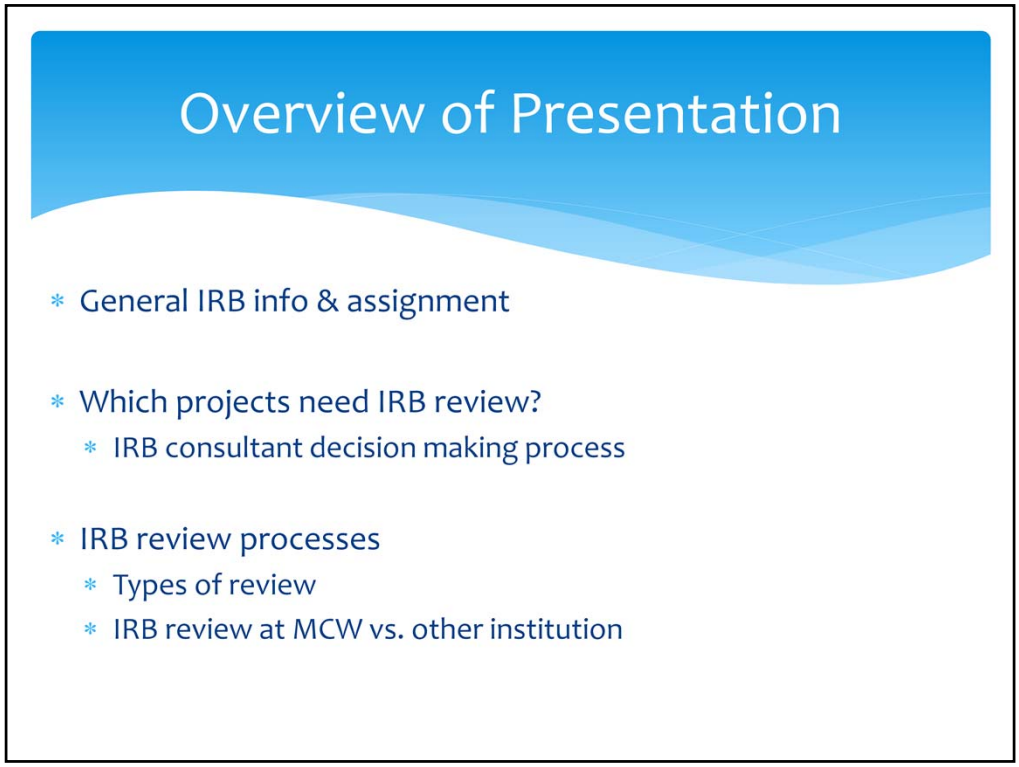


Welcome back. This presentation focuses on the logistics of the IRB review process as they pertain to you, an MPH student.



In this presentation, I will provide some general information about IRBs and the IRB consultant review of your field placement proposal, and I will help you figure out whether your project will need to go through a formal IRB review process. Finally, I will provide some general information about IRB review processes and explain a few procedures here at the Medical College as well as if you elect to go through a review at another institution.

Please keep in mind, whether your project involves human subject research and requires a formal IRB review process or not, the ethical principles of engaging in public health projects and community research still apply. If you have not yet done so, make sure you review Alan's lecture about public health ethics for more information.

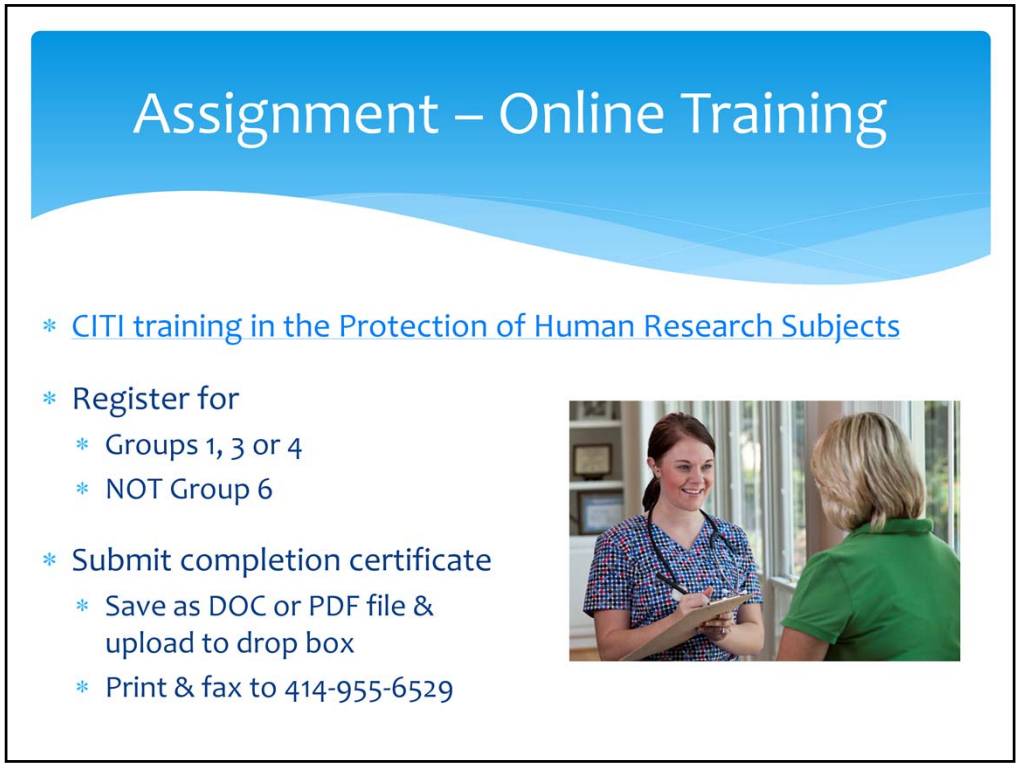
In the first section, I will explain the purpose of an IRB and how you, as an MPH student, will be involved. Additionally, I will explain the next assignment.

The Medical College of Wisconsin partners with Froedtert Hospital in many endeavors, including institutional review boards. The Human Research Protection Program of the Medical College oversees and supports the organizations' joint IRBs, and the program's primary mission is to protect the rights, welfare, and privacy of all individuals participating in research sponsored by the Medical College of Wisconsin and Froedtert Hospitals.

The IRBs review all research studies involving human subjects for safety, compliance with regulations, scientific quality, and ethical standards. Your MPH field placement is not likely to involve human subject research; however, it is very important for you to understand the work of our IRBs. If you were a faculty member at the Medical College, every project you worked on would have to go through a formal IRB review process. However, we have developed a preliminary process for our students.

Instead of every student's field placement and capstone project undergoing a formal IRB review process, members of the Medical College's Human Research Protection Program act as our IRB consultants and review each student's field placement proposal. If the project clearly does not involve human subject research, then the IRB consultants will approve it, and you will not need to go through a formal IRB review process. If, however, the project may involve human subject research, then the IRB consultants will ask for further information, and they may require you to participate in a formal IRB review process.

To help you learn more about human subject research and IRBs, you will complete an online training, which I will explain in the next slide. I have also provided further information about these topics in this presentation, and other details regarding proposal submission and approval will be provided in a later presentation.



Your next assignment is to complete an online CITI training in the Protection of Human Research Subjects. CITI stands for the Collaborative Institutional Training Initiative, and all researchers participating in federally funded research must be certified in this way. You are expected to maintain certification throughout your field placement and capstone project. To access the training, you should click on the link in this slide and visit the CITI program website. You will need to create a username and password if you do not already have one, and you should list the Medical College of Wisconsin as your organization.

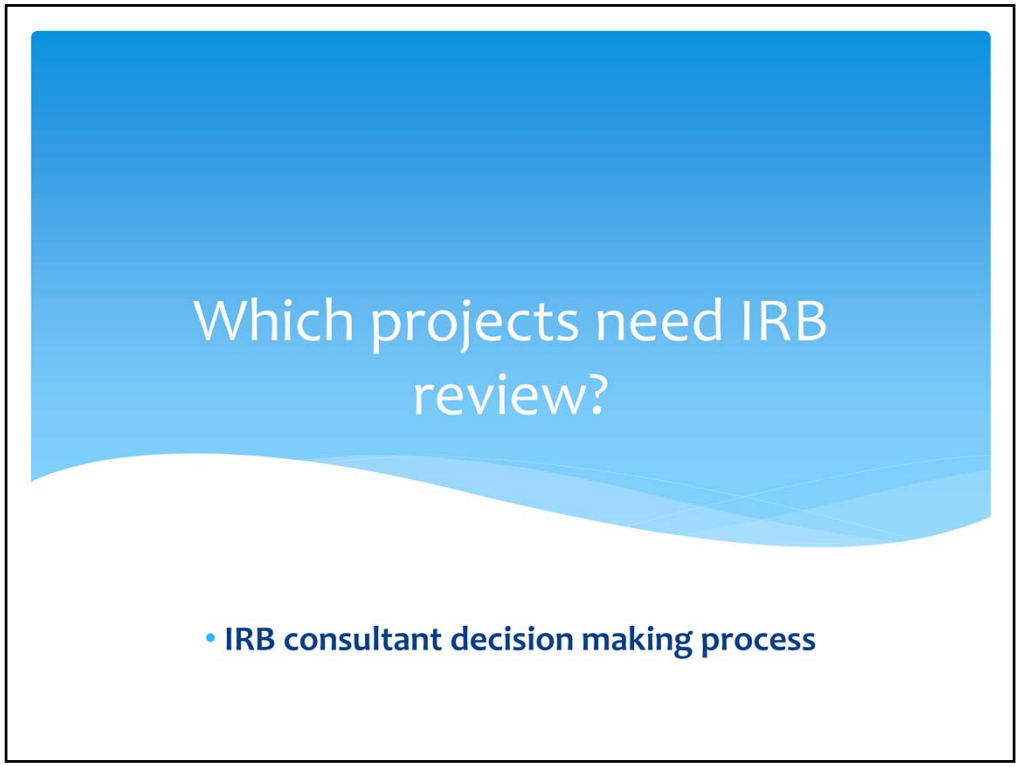
CITI Training: https://www.citiprogram.org/

When registering for the training, you must select a group to which you belong. The only groups you may select are one, three, or four. Group one is designed for biomedical investigators, co-investigators, and study coordinators. Group three is designed for all IRB members and everyone involved in biomedical and social/behavioral research. Group four is designed for social/behavioral research investigators, co-investigators, and study coordinators. Please note, you may not select group six. Even if you do not plan to conduct any human subject research for your field placement, you are not eligible for group six because you are neither a Healthier Wisconsin Partnership community organization nor a resident or fellow.

Students often ask me which group they should register for. It really depends on what you think your project will be. If you think it will be more biomedical in nature, I recommend group one. If you think it will be more social or behavioral in nature, then I recommend group four. Group three covers both types of research, but it is quite long and somewhat repetitive. Unless you are really unsure which group to choose or your proposed project clearly covers both fields, I would not really recommend that one. Any of the groups' training will take you a good amount of time to complete: usually a couple of hours. Since group three covers more material, it takes even longer.

To submit your completion certificate, you should save it as a Microsoft Word document or PDF and then upload it to the D2L drop box. If you are having trouble saving the document as one of those file types, you can print the certificate and fax it to me. If you do that, please address the fax to my attention.

If you have already completed CITI training as part of your job or other responsibility, you may just send me the certificate you have already received. There is no need for you to go through the training again unless your certification has expired. As always, if you have any questions, please let me know.



After hearing about our IRB review processes, the most common questions students ask are:

- Will I have to go through a formal IRB review process?
- How do I know whether my project will be considered human subject research?

In this section, I will walk you through the decision making process the IRB consultants will use in determining whether your project involves human subject research and, therefore, will need to go through a formal IRB review process. However, there are many nuances, so you are not expected to be able to figure it all out on your own. That is why you are developing your project and proposal as part of a team. Your faculty advisor and I can offer advice, and I can contact our IRB consultants if there are any questions we cannot answer.

To determine whether your project will need to go through a formal IRB review process, the IRB consultants will determine whether the project involves human subject research covered by 45 CFR part 46. 45 CFR part 46 refers to the code of federal regulations, title 45, which is public welfare, and part 46, which pertains to the protection of human subjects. IRBs must follow this federal regulation, so our IRB consultants will determine whether your project falls within its scope.

The first question the IRB consultants will ask themselves is whether your project is research. Does it involve a systematic investigation designed to develop or contribute to generalizable knowledge? This question refers to the purpose of your project. Are you trying to contribute to generalizable knowledge? Do you plan to publish or disseminate this information? If so, then the IRB consultants will move to the next step in the decision making process. Even if the purpose of your project is not to contribute to generalizable knowledge, the IRB consultants will still consider the other steps in the decision making process. They do this to make certain they are covering every aspect of your project and to ensure that their decision is applicable even if your purpose changes.

The next question the IRB consultants will ask is whether your project involves obtaining information about living individuals. If the information you are collecting pertains only to individuals who are deceased, then it would not be covered by 45 CFR part 46. However, most students engage in projects that collect information about individuals who are living.

Interaction & Individual Identification

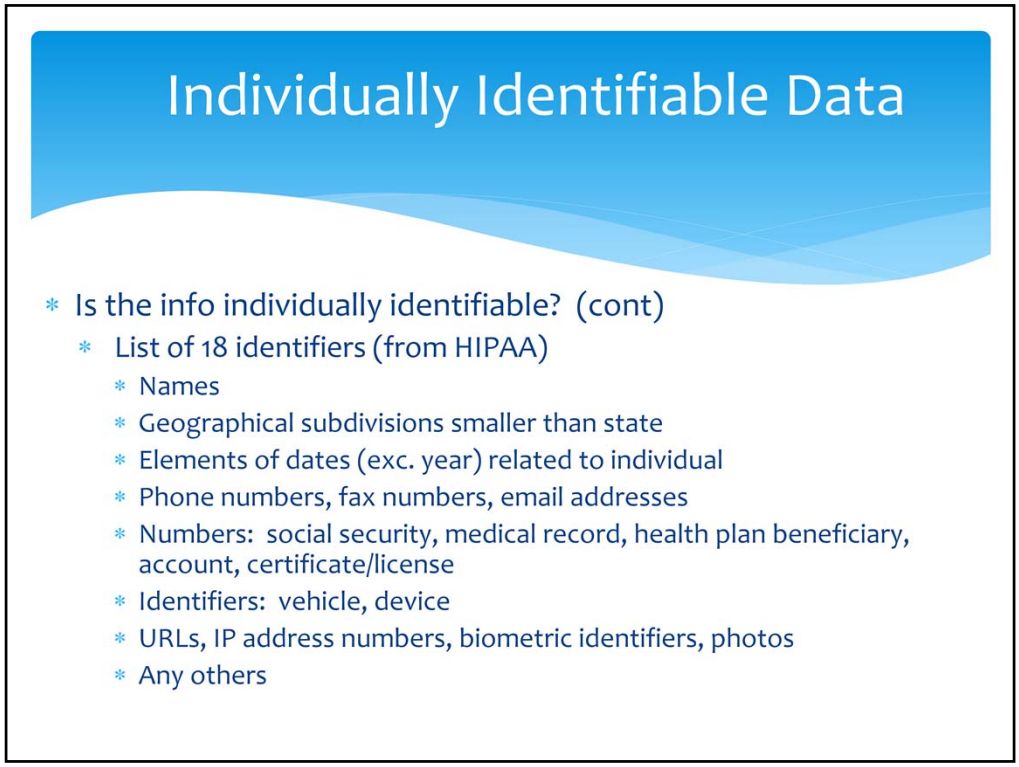
* Intervention/interaction with individuals?
  * Surveys = interaction
    * Even if you didn't conduct it
    * Not HSR if providing info about another population
* Is the info individually identifiable?
  * UCSF HRPP List of Identifiers

The next question the IRB consultants will ask is whether your project involves intervention or interaction with the individuals. This one can be a bit tricky because your interpretation of the terms *intervention* and *interaction* may not be the same as our IRB consultants'. For instance, if you are conducting a survey over the internet, you might not consider that to be interaction because you would never speak to the person. However, the IRB consultants consider it interaction because individuals are answering the questions you have developed.

Additionally, it is considered interaction if the information ever involved interaction with the individuals, so even if you were not the person who conducted the survey, the information that was collected is considered to be human subject research. However, if the information you are collecting is not about the individuals who are participating in the survey, then it may not be considered human subject research because the individuals are not speaking about themselves. This is the case when students interview health department employees or other experts about the populations they serve. As long as these individuals are speaking about the populations from their professional perspectives, meaning not their personal perspectives, then it would not be considered human subject research.

The next question the IRB consultants will ask is whether the information is individually identifiable. Could the identity of the subject be readily ascertained by the investigator or associated with the information? To determine this, the IRB consultants may consider the 18 identifiers outlined in HIPAA, the Health Insurance Portability and Accountability Act. A list of these identifiers and more information about them can be found on the University of California, San Francisco Human Research Protection Program webpage, which is linked on this slide. I will also provide more detail in the next slide.

UCSF Human Research Protection Program List of Identifiers:
http://www.research.ucsf.edu/chr/HIPAA/chrHIPAAphi.asp



Information that is considered to be an identifier by HIPAA includes:

•Names.

•All geographical subdivisions smaller than a state. That means street addresses, cities, counties, precincts, zip codes, and their equivalent geocodes are all considered identifiable. Therefore, any individual-level information from a city or county health department cannot be de-identified. Even if you remove the person's name and address, the geographical distribution is too small.

Another identifier encompasses:

•All elements of dates (except year) for dates related to an individual, such as their birth date, admission date, discharge date, and date of death.

Other identifiers include:

•Phone numbers.

•Fax numbers.

•Email addresses.

•Social security numbers.

•Medical record numbers.

•Health plan beneficiary numbers.

•Account numbers.

•Certificate / license numbers.

•Vehicle identifiers, such as license plate numbers.

•Device identifiers.

•URLs.

•IP address numbers.

•Biometric identifiers, including finger and voice prints.

•Full face photographic images.

•Any other unique identifying number, characteristic, or code.

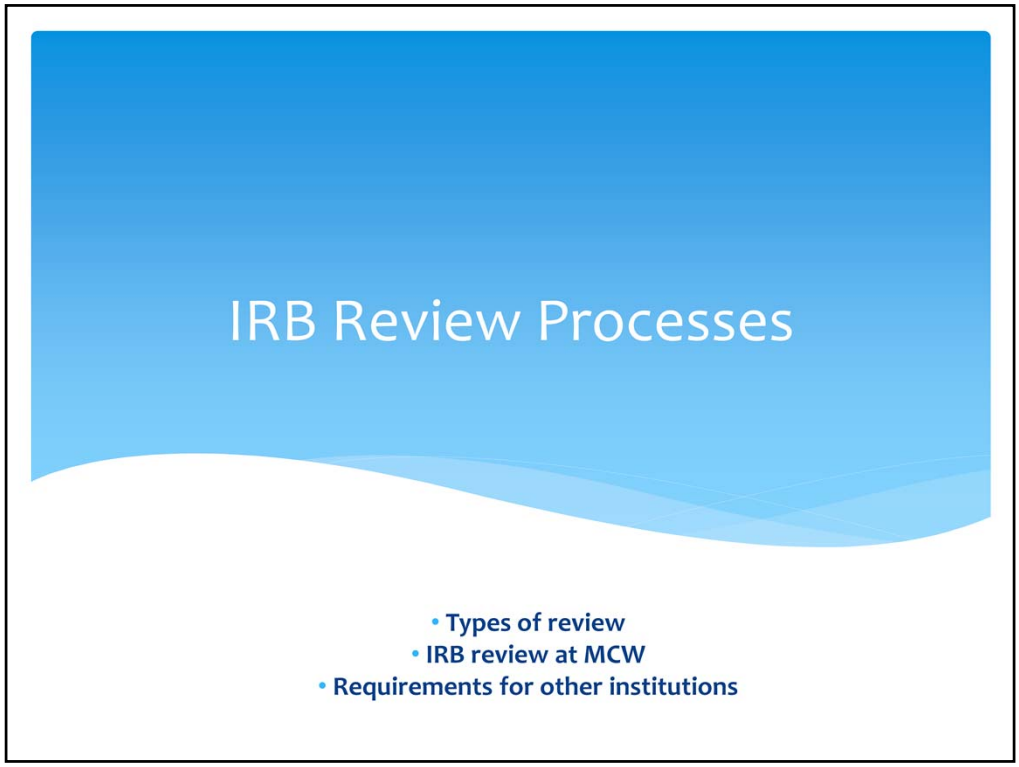
Individual Identification & Private Info

* Is the info individually identifiable? (cont)
  * To avoid – use aggregate data
* Is the info private?
  * Protected health info
* IRB review process needed
  * Private, individually identifiable info
  * Intervention / interaction with individuals
  * Systematic investigation

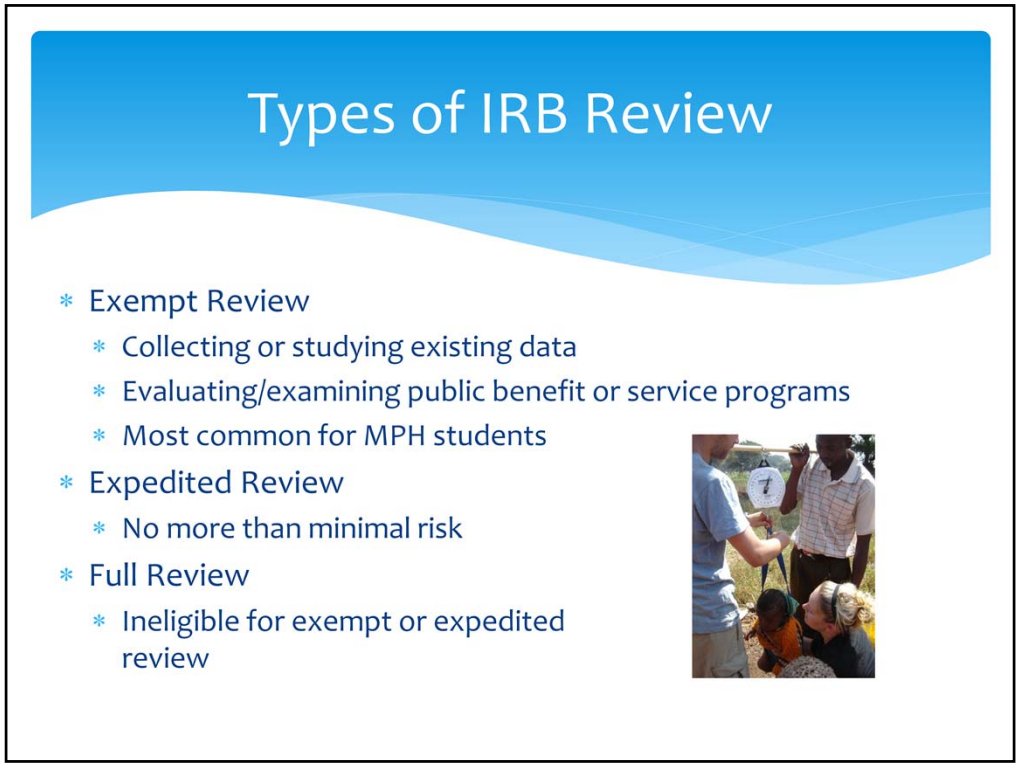
Given all of the information that is considered identifiable and given that many students work with organizations that function in a smaller geographical range than the state, they often ask me how they can work on a project. I explain, even though you cannot de-identify the data because of the geographic restriction, you can utilize data that are not individually identifiable if they are aggregate data. Aggregating data means to gather different data together. Therefore, instead of seeing one individual's health data or survey results, you would see the averages of 10 or 100 individuals. In this way, the information is not individually identifiable, so your project would not fall under 45 CFR part 46.

The next question the IRB consultants will ask is whether the information is private. Does the information pertain to a behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place? Has the information been provided for a specific purpose by an individual and which the individual can reasonably expect will not be made public? In your proposal, you will be asked whether you will be working with any private or protected health information. Protected health information is defined as any information in the medical record (or other designated record) that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service, such as diagnosis or treatment.

To conclude the explanation of this decision making process, let me summarize. If your project involves private, individually identifiable information for which you interacted with the individuals in a systematic investigation, then you will need to go through a formal IRB review process.



If the IRB consultants determine that your field placement project involves human subject research under 45 CFR part 46, they will let you know which type of review it should go through. You then have the option of going through the formal IRB review process at the Medical College or at another institution, such as a local one associated with your organization.



There are three types of formal IRB review processes. The first is exempt review. Certain research activities are exempt from the federal regulations, and these activities include:

•Research conducted in an established or commonly accepted educational setting, involving normal educational practices.

•Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior.

•Research involving collection or study of existing data, documents or records.

•Research studying, evaluating, or examining public benefit or service programs.

•Research involving taste and food quality evaluation or consumer acceptance studies.

If MPH students' projects need to go through a formal IRB review process, they are usually asked to go through an exempt review. It is important to remember that the IRB consultant review of your MPH proposal is not a formal IRB exempt review. The IRB consultant review is separate from the formal IRB review processes, so it does not hold the same weight.

The second type of formal IRB review is expedited review, which may involve just one member of the IRB committee, rather than the entire contingent. Certain research activities are specified by federal regulations as eligible for expedited review. These activities include research that presents no more than minimal risk to human subjects and research for which the identification of subjects would not put them at risk of criminal or civil liability nor be socially or economically damaging.

The third and final type of review, a full review, is required for projects that involve research activities that are not eligible for exempt or expedited review. The full review incorporates the entire IRB committee, rather than one or two individuals, and a majority of the committee members who are present must vote to approve the project in order for the process to move forward.

IRB Review at MCW

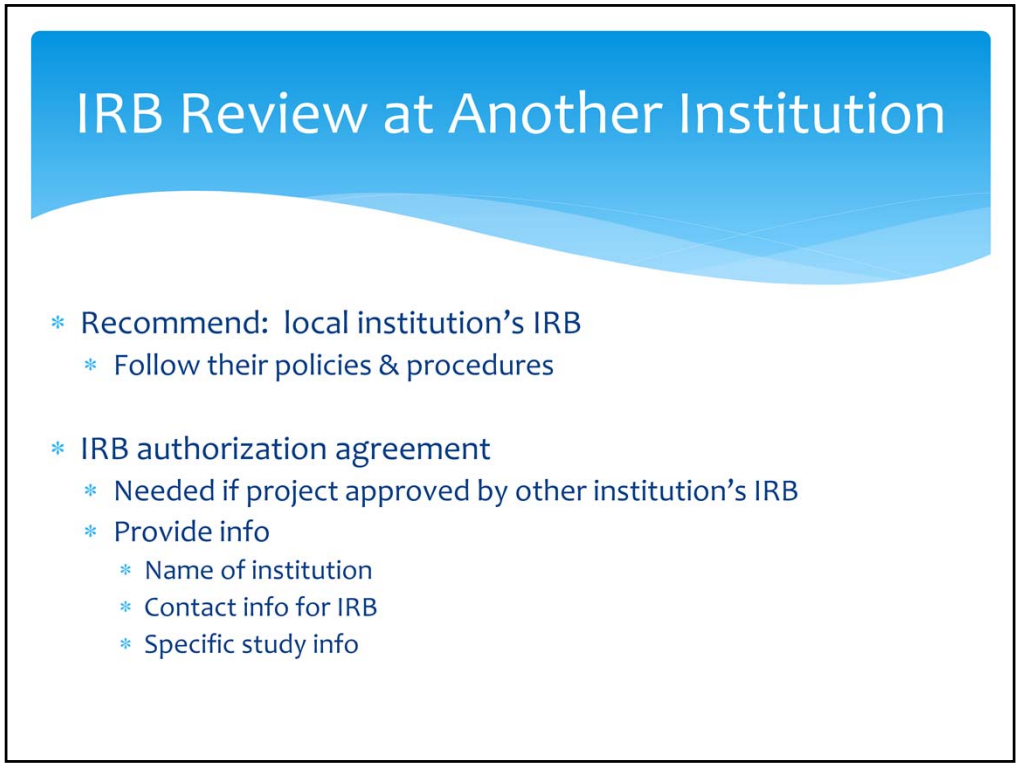
- Application needed
  - Different from FP Proposal
  - Submit via eBridge
- PI must be MCW faculty member
  - Should already be involved in project
- Lengthy process

If our IRB consultants determine that your project needs to go through a formal IRB review process, you will have to submit an IRB application. This application is separate from the MPH field placement proposal that you will develop and submit to me; however, much of the information in the two documents will be similar. At the Medical College, you would submit your IRB application through the online system, eBridge. For this system, you will need a login name and password, and I will help you get access to those.

Another requirement of the Medical College IRB is that the principal investigator, or PI, be an MCW faculty member. You, as a student, cannot act as the PI . . . which could create a challenging situation. If you are working on an existing project with a faculty member, then the faculty member likely already has IRB approval, and you would just need to make sure you are properly added to the team. If you are developing a new project with a faculty member, then the faculty member would likely be willing to act as the PI because he or she will be fully vested in the project.

The challenge comes in when you are developing a project with an organization, and there is not a MCW faculty member already involved. I will recruit a faculty advisor for your field placement project, but you cannot expect that faculty member to act as your PI. The PI role involves many responsibilities. This person will be the one who is legally and professionally liable for the study and all of your activities. For instance, the PI is charged with confidentially maintaining the data for the study for at least seven years if not the rest of their lifetime. If the faculty member is not going to be substantially involved in the project, then he or she is not likely to be willing to take on the role and responsibilities of acting as the PI.

The final consideration when going through a formal IRB review process at MCW is the time commitment. It is a lengthy process, usually taking 2-4 months, so if you know your project will involve a formal IRB review, you may want to start working on your project a semester ahead of time. If nothing else, you should keep in mind that you may be delayed by a few months when you are planning your schedule.



Another option is to go through a formal IRB review process at another institution. Sometimes the organizations you work with will require you to go through a formal IRB review process. Other times, it is our IRB consultants who indicate the need for a review. If you are working on a project with another institution, it makes sense to apply to the other institution's IRB because they will be more involved in the project. If you are working on a project with a community organization outside of southeastern Wisconsin, it might make more sense to utilize a local institution's IRB because they will have a better working knowledge of the organization.

When you apply to another institution's IRB, you will have to follow the processes and requirements of that organization. Specifics regarding IRB review processes vary from institution to institution, so you will have to learn the policies of the organization you are working with. For instance, you might be able to act as the PI in your application to another institution's IRB. Although here at the Medical College we only allow faculty members to act as PIs, that is not true of all IRBs.

If you go through a formal IRB review process at another institution, we will need to put an IRB authorization agreement in place. Additionally, if your field placement involves working on a project that has already been approved by another institution's IRB, we will need to get an IRB authorization agreement in place before you may begin working on your project.

The IRB authorization agreement allows the Medical College to name the other institution's IRB as the IRB of record. Then it can utilize the other institution's IRB's determination as our determination, too. Basically, it prevents you from having to go through a formal IRB review process at the other institution as well as at MCW. (Remember, the MCW IRB has to approve of your project because you are earning credit from us, meaning your activities reflect back on the College.)

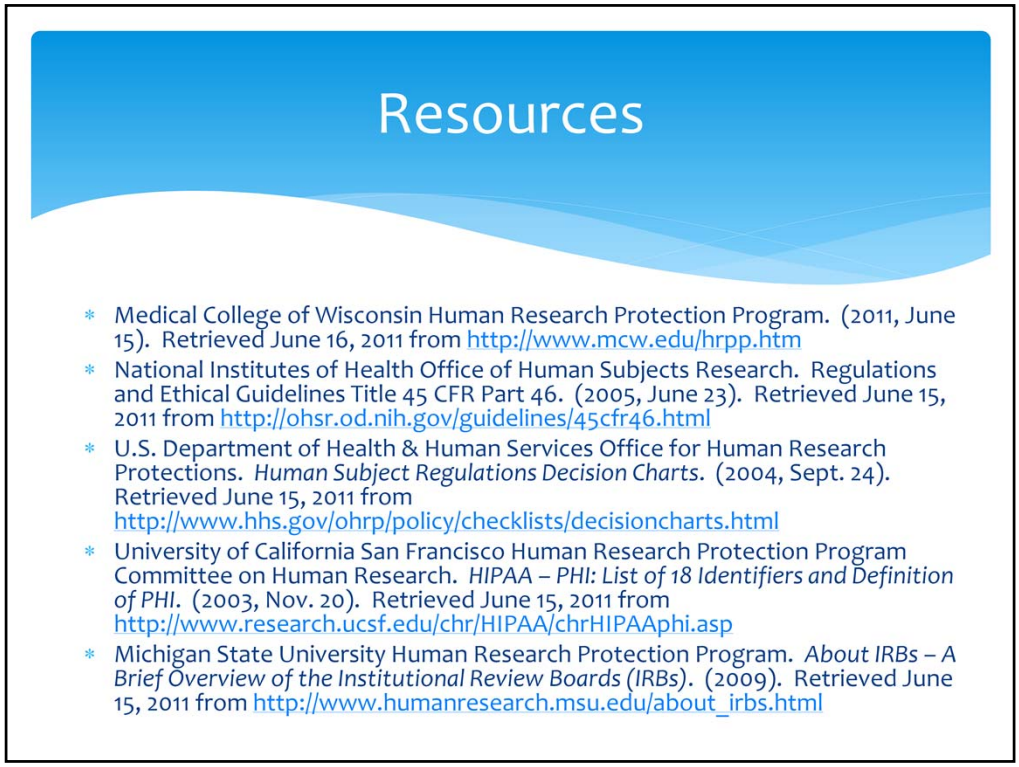
To get an IRB authorization agreement, I will need information about the other institution's IRB and your specific project. I will share this information with the MCW IRB so that they can facilitate the signing of the agreement. The information I will need includes:

•Name of institution whose IRB will review your project

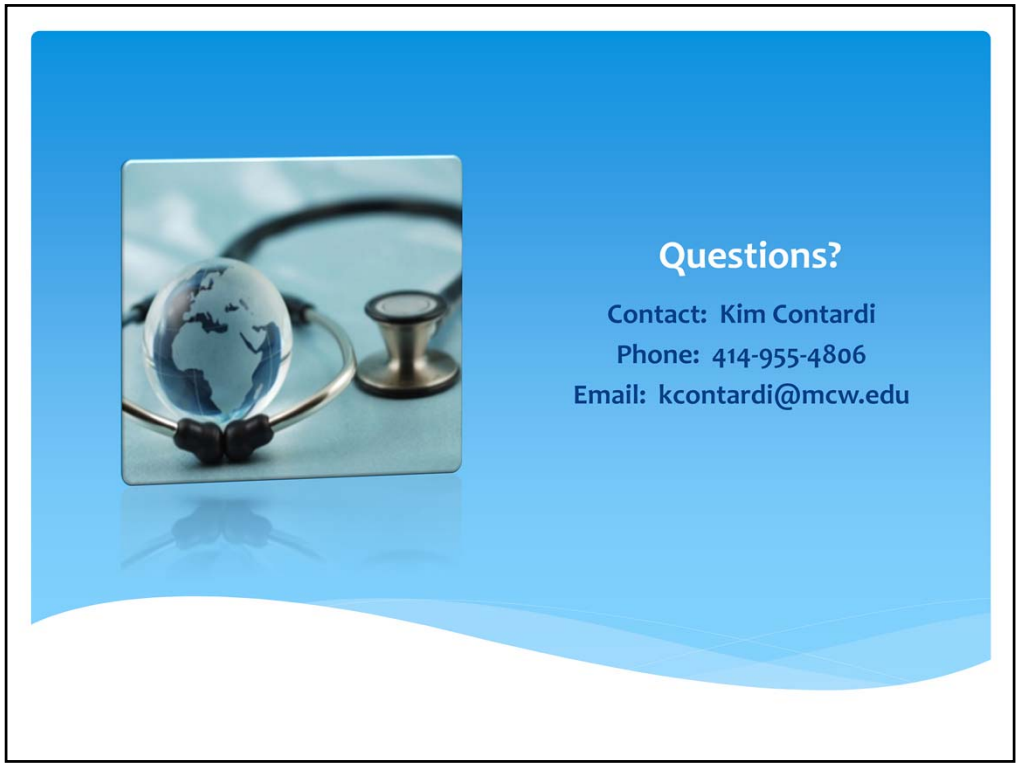
•Contact information for the IRB, including the contact person's name, credentials, phone number, and email address

•Specific study information, including the name of your project as listed on the IRB application; the study number, if one was given; the name of the PI; and the date the application was submitted or the study was approved

Once your project has been approved by the other institution's IRB and there is an IRB authorization agreement in place between the two institutions, then you may begin working on your project (assuming all of the other planning requirements have been met).



In the creation of this presentation, I utilized web resources from the Medical College's Human Research Protection Program, the National Institutes of Health Office of Human Subjects Research, the U.S. Department of Health and Human Services Office for Human Research Protections, the University of California San Francisco Human Research Protection Program, and the Michigan State University Human Research Protection Program.



As always, if you have any questions, do not hesitate to contact me. I know human subject research and IRBs confuse a lot of people, especially when they are not used to considering these topics, so please let me know if you have concerns about your project.