Protecting Human Subjects and Institutional Review Boards: An Overview
February 23, 2017

Erin Farley: Good afternoon everyone, my name is Erin Farley and I am one of JRSA's associates, research associates. For those of you that are less familiar with JRSA, it stands for Justice Research and Statistics Association. We are a national non-profit organization dedicated to the use of research and analysis to inform criminal and juvenile justice decision making and we are compromised of a network of researchers and practitioners, which at the core include directors and staff from state statistical analysis centers.

Erin Farley: It is my pleasure today to welcome you to our webinar, Protecting Human Subjects and IRB's: An Overview. It will be presented by a number of individuals form the University of Southern Maine. I have my little cheat sheet here and that includes Ross Hickey, who is an Assistant Provost for the Research Integrity at the University of Southern Maine. Then we also have Casey Webster, who is the Research Compliance Administrator at the University and then we also have George Shaler, who is the Maine Statistical Analyst Center Director.

Erin Farley: So, welcome everybody and before I go any further, I want to thank our partners at the Bureau of Justice Statistics for helping to make this webinar possible. I would also like to cover a few logistical items. We will be recording today's session for future playback and the link to the recording will be posted on the JRSA website. It's usually done the following day, so if you're interested and have staff who would like to view this webinar, it should be available tomorrow.

Erin Farley: Today's webinar is being audio cast via both the speakers on your computer and teleconference and we recommend listening to the webinar using your computer speakers or headphones. To access the audio conference select audio from the top menu bar and then select audio conference. Once the audio conference window appears, you can view the teleconference call in information or join the audio conference via your computer. If you have any technical difficulties or get disconnected during the session, you can reconnect to the session using the same link you used to join. You can also email Jason Trask at jtrask@jrsa.org.

Erin Farley: Okay, we have everybody who is coming into this webinar. You guys are on mute and you are allowed to submit questions to the presenter. What we would like though is if you anything that is pressing, you are welcome to put that in the chat menu. We would like to reserve the answering for any questions until the very end of the webinar. However, if you do have a question, what we would like you to do is to submit the question to the host, the presenter, and the panelist. So, if you see on this slide right here, go all the way down and you can see host, presenter and panelists, or all participants. That way everybody can see the question.

Erin Farley: This session is supposed to go for about one hour and let's see ... Okay, so what we are doing now is we are trying to get a better count of all the people who are
watching our webinars. So, if you are viewing as a group, what we would love for you to do is to take a second to actually use that chat window and type in the name of the person that's registered and the total number of additional people in the room. This will really help us keep track of the number of people who attend our webinars. So, if you have a second to just do that, we will keep track of that.

Erin Farley: We also do, at the very end of the webinar, we do have a few polling questions that we would like you to answer. This again, helps us to plan and improve future webinars and it helps us meet our reporting requirements.

Erin Farley: With that, I'm going to pass it off to George. So, welcome George and colleagues and you should ... I just pulled that little magic ball to your name, so you should have control of the slides, so it's all up to you now.

George Shaler: Thank you Erin and we can see that. Hi folks, this is George Shaler. I'm the Maine Statistical Analyst Center Director. My SAC is based at a University, we're one of seven SAC's that are based at a University and I am on staff here at the University of Southern Maine, as well. I'm also, just to let you know, the Vice Chair of the USM IRB and that's one of the reasons why I've become very interested in this issue and I roped in my colleagues here, Ross Hickey and Casey Webster into this presentation. They're going to give you a far more detail about IRB issues than I can, but I'm going to turn it over, right now, to Ross who is, as Erin said, the Director of our office of Research Integrity and Outreach here at the University of Southern Maine. So, we'll get started.

Ross Hickey: Thanks George. So, we're going to break this into chunks. You're going to hear from all of us. Where I'm going to come in first is to give you the broad overview of some of the fundamental questions that we hopefully will answer in looking at Institutional Review Boards and human subjects. I'm going to walk you through what some of the basic definitions are that guide whether or not your project needs to go through an IRB.

Ross Hickey: For example, we'll look at the definitions of what is research under the federal regulations? What is a human subject? What is an IRB? What are the areas that are outside of the IRB's purview? Why these regulations were created in the first place?

Ross Hickey: The first slide I will take you to is the question of what is research? Now, this definition is not one that you're necessarily going to see aligning with your area or discipline, but it is the one that the Feds look at and the one that drives whether or not an Institutional Review Board, which we'll talk about in a little bit, what an IRB or Institutional Review Board is, whether or not it's going to look at your project. This definition has been the bane of many researchers existence because it uses terms that should be defined in and of themselves.
Feds sought not to do that, but there are three essential elements that you should keep in mind when looking at this definition.

Ross Hickey: The project involves a systematic investigation, that there is a design involved that tends to develop or contribute to generalizable knowledge. So, the three elements are systematic investigation, that there's a design or an intent to develop and finally, that there is generalizable knowledge that comes out of that research.

Ross Hickey: Systematic investigation is fairly straight forward. That you're comparing and contrasting between different areas of data or different information that you have. That there's an intentionality to create research is pretty straight forward. It's that final part that many people struggle with, which is it generalizable. What they mean by generalizability here is not necessarily the same as they would with statistical analysis. It is that you can draw broader conclusions from the specific area you're looking at. That whatever the data is that you've collected, that it's not unique to your specific area that you're looking at, but so that you can draw from that broader conclusions to other like or similar situated locations or populations. That's not an official definition, but that's just through experience, which most IRB's come to and that they probably will define in their policies.

Ross Hickey: Once you ask the question of whether or not the project involves research, the second fundamental definition that will drive whether or not it goes to an IRB, is whether or not it involves human subjects. Again, this is not a definition that is intuitive, it's created in federal regulations and that usually means that intuitive is not a word you'll be using. When you look at this definition, the key areas that you need to remember are, that it involves a living individual. There are some regulations such as HIPAA, that may involve deceased individuals data that can be protected, but for the purposes of the common rule which is the regulation that drives human subject research and IRB's, the subject needs to be living at the time that the information is collected.

Ross Hickey: It also needs to be about the person. So, if you ask an individual information about an industry their in or an institution or something that is not about them or personal information about them, then it probably is not human subject research. It could very well be research, but it's important that both of these definitions have to go together. So, you can have research, but if it doesn't involve human subject than it should not go to an Institutional Review Board.

Ross Hickey: If you have a living individual and you're collecting information about them, you can do that in two ways. You can gather that information through an intervention or an interaction, which means wither you're collecting samples from that individual or you're collecting information from them, say through a focus group or a interview or a survey. It can even be an online survey, it can even be an anonymous survey, but under the federal regulations, that would be
considered an interaction. So, you either have an intervention or an interaction that provides information about an individual.

Ross Hickey: The other way that you could involve human subjects is by collecting identifiable private information. So, to contrast that with A, you very well can collect information that you have never met that person, you never interact with them, there's no intervention, but if you have access to information about them that's private and that is identifiable, you have involved them in your research even though you've never meant them. An obvious example would be that if you're working with a healthcare provider and you had access to someone's medical records or for the field that many of you are working in, if there was a way that you could identify information about a person that was not publicly available, that is private. That you would feel that they would have an expectation that before that information would be used, they would provide their consent and we will talk about consent later on in the presentation.

Ross Hickey: There is, right now, a major conversation going on nationally about the regulations that are in place to protect human subjects. I refer to it as the Common Rule. The reason it's called the Common Rule is because multiple federal agencies have all voluntarily agreed to join and create standard uniform regulations in place to protect human subjects. The last time that these regulations were revised or updated was in 1990, so it has been a long time and there has been a considerable push to revise these regulations with all of the changes that have occurred with research in the United States.

Ross Hickey: There is currently a new, revised Common Rule that has been promulgated and adopted. The question now is whether it will stay on the books or whether it will be removed by the new administration? No one can really tell you that today. If there is a decision to keep this on the books and to keep the proposed changes that were adopted, literally I think with in the last day or two of the Obama administration, there will be fundamental changes to many of the definitions including human subject. I'm sharing with you very quickly that, that would change the definition I just shared with you in certain ways. Most particularly, even though it still involves a living individual and it's still about information about that person, the information that can be collected through a biospecimen is also now a way that a person can be considered a human subject. So, it broadens in that regard, the way that you can collect data even if you've never met that individual and have it fit under the definition of a human subject.

Ross Hickey: Let's go to what an IRB is. An IRB is, again, defined under the Common Rule. It is an independent committee that is reviewing the project that you're proposing to make sure that it protects the rights and welfare of the human subjects involved. It is making sure that they are treated under the basic standards that the Common Rule promulgates. Also, other additional foundational documents that drive this process, such as the Belmont Report, which you may hear about in a little bit. This is not an ethical review board. Something that often comes up
when looking at IRB's, that people say, well, this is the ethics committee. Not necessarily, the IRB has a very defined role under the federal regulations and as we've seen, if you are not involved in human subject research, your project is probably not going to go through an IRB.

Ross Hickey: When you look at what an IRB is composed of in general, it has certain requirements. It has to have at least five members. It has to have both a scientist and a non-scientist on board. For our University, which is an example, we need to have a member that is not otherwise affiliated with the University so that we have that community member who provides a perspective on what we're doing. When you look at an IRB, wherever you're at, if it is a federal registered IRB, meaning that it's an IRB that can review funded research, it has to have certain characteristics such as what you see on the screen and what I'm describing. Those things must be in place for you to get your federal wide IRB registration and obtain a federal wide assurance number, which allows you to do federally funded research. That's how institutions, even when they're at a local level, will come under these federal regulations because they want to obtain that federal funding.

Ross Hickey: There is a lot of flexibility in the way the Common Rule sets this up. You don't have to create your own institutional review board at your site, you can have another IRB located somewhere else review your project. You'll see that people do this through a variety of ways. They can have a for-profit IRB that they pay to review. They can also have, which is something that we have here, a collaborative IRB where multiple agencies come together and pool their resources and pool their researchers together to create a shared IRB, which is perfectly fine. If you have a multi-site study, that involves multiple places that will be working on a project, one IRB can be the IRB of record and review that project on behalf of other institutions. There are many ways that you can be in compliance with the Common Rule. There's a lot of flexibility under the regulations and even with the proposed changes, that will increase. In fact, it will be mandated that you'll see more one review by one IRB of record instead of multiple reviews by multiple IRB's. Again, there is flexibility here with the system.

Ross Hickey: If the project that you are working on is funded by a non-Common Rule agency or it might be industry sponsored research that does not involve a new drug or biologic or medical device, or it involves another country, doing research in another country and it doesn't involve funding through a Common Rule Agency, yo udo not necessarily have to go through an Institutional Review Board. There are things that are outside the purview of an IRB, unless, and this is very important, the institution you're at has created a policy that says, even if it's not funded by a Common Rule agency, we will require review. Now, with any type of biologic medical device or experimental drug you'll still have to go through FDA review. There's still that additional requirement.
Ross Hickey: You also will consider going through an IRB, even if strictly speaking, you're funding doesn't require it because it's a requirement of a journal that you want to publish in. You'll see that many times journals will require that before you're allowed to publish. What happens at many institutions and locations as you get into mission creep, you'll find that IRB's are given oversight over things that they're technically do not have overview over under the Common Rule. That's fine, as long as that's in the policy of your institution, but if it is not, you want to be careful because you do not want to dilute the important mission that your Institutional Review Board has. So, as I talked about earlier, it's fine for your IRB to also be an ethical review committee for your institution, but you want that to be very clearly delineated in your policies because when you start to do things that are beyond the Common Rule and beyond what the regulations say, the admission if it's an IRB, you're going to have push back from your researchers.

Ross Hickey: We have these IRB's for a variety of reasons. There are a lot of historical atrocities that occurred throughout time. Relatively recently though, the RBI and the Human Subject Protection laws came into place, but you will know form your own research and background that there are many places that cause the United States to create the protections we have, such as the Nazi doctors and the work that they did that was brought up in the Nuremberg trials. The Tuskegee Syphilis Study, the untreated syphilis study that occurred over multiple generations in this country. That was looking at what happens when Penicillin is not given to individuals that are suffering with syphilis. You will also see that, that had a major impact on our research and our regulations and you also would see for social behavioral, the Stanley Milgram study, Obedience to Authority that had a major impact on why we have these protections in place.

Erin Farley: We're just going to do a quick seat change.

Ross Hickey: And I'm turning it over to my colleague Casey Webster.

Casey Webster: Hi everyone, this is Casey here and Ross just talked about what an IRB is, why we have them and what they do, so I just want to go over how IRB's of what they do.

Casey Webster: IRB's, as Ross mentioned, have to review research involving human subjects for compliance with federal regulations and ethical codes. They also consider local issues within the review process. In order for research with human subjects to continue, IRB's have to approve that research. How do they do this?

Casey Webster: Well, in order to know whether they can approve a research protocol, the IRB has to know what the research actually is. So, they ask investigators to submit research protocols and what that is, is you outlining exactly how the research will go down. So, the IRB knows everything that will happen. They do this through an IRB submission process. No two IRB submissions are the same,
they'll vary even within institutions, but here are some of the typical submission requirements. I just want to go over them real quick for you.

Casey Webster: They pretty much all require investigator information and they call you, the researchers, principal investigators or research staff and they want to know what you’re training is in research and in the protection of human subjects in research and what your particular expertise are. The IRB’s also going to want to know your funding source. They're going to want to know if it's federally funded, for important reasons as Ross pointed out, but whether even IRB review is required or not. Also, some funders explicitly state certain review criteria. They want the actual research protocol, which pretty much should read like an instruction manual. The IRB should be able to pick up this research protocol and go through and perform the research. So, it includes your study design, your methodology, and any research procedures.

Casey Webster: The IRB’s going to want to look at participant information. So, they want to know who is a participant, who you’re recruiting, how you’re recruiting them and if you're compensating them in any way. The IRB’s going to want to know what the risks are to the research and what the potential benefits are. This is really important because an IRB cannot approve a research protocol if the risks so outweigh the benefits. The IRB will also want to know about privacy and confidentiality. Privacy applies to the person, your subjects, the way that your potential participants are identified and contact. Contact is the actual research setting where research will take place. Then, confidentiality applies to the data. So, in your line of work I know there’s a lot of confidential data that is involved, so, the IRB will want to know how you’re maintaining that data and how you're going to access it and if there are proper protections in place for that data.

Casey Webster: The IRB will also want to know what the consent process is like and this is the process for which the research study is explained to participants. This is also the process where participants can ask the researchers the questions. This is also when they agree to participate in the research or not. Like I said, it's a process, it's not a form that investigators have participants sign, it is ongoing talk or discussion with participants. The IRB will also want to know if there’s any conflicts of interest and they want to know that you as researchers are going to fulfill your obligations to protect the human subjects.

Casey Webster: Ross mentioned HIPAA earlier and I just want to talk about it a tiny bit, just to address it, and if you don't learn anything at all from this slide, I just want you to learn how to spell HIPAA, 'cause it's always spelled incorrectly, there's two A's. HIPAA applies to covered entities. What is a covered entity? Their health plans, healthcare clearing houses or healthcare providers that electronically transmit health information. HIPAA also only applies to protected health information and protected health information is individually identifiable health information.
Casey Webster: The HIPAA privacy rule established conditions under which PHI could be used for research purposes. In order to do that researchers have to either obtain individual authorization form the individuals whom they're taking data from. They need to be using the research information for preparatory research, so to prepare for research or they could have approval from an IRB or a privacy board to waive authorization. In this instance, the IRB would say that you as a researcher do not have to obtain permission from the individual to use their PHI for your research. Or there's this thing called a Limited Data Set, which is health information given to use as a researcher with certain identifiers removed so that it no longer technically meets the PHI definition.

Casey Webster: There's various IRB review categories and I'm just going to go over them real quickly. Student classroom projects really only have to do with educational institutions, not human subject research, so Ross took good time going over what the definition of research was and what the definition of human subjects was. However, some institutions don't allow their researchers to make that determinations themselves. They may require the IRB to make the determination or someone with the office, so sometimes there's a form for that. Another IRB review category is exemptions. This is a explicit category, there's actually seven of them, that were created under the Common Rule, and if your research falls into that category then the project is technically exempt form IRB review. That doesn't mean it doesn't get any review, it just means that it doesn't have to go to an IRB member for review.

Casey Webster: Expedited, again, is some categories that were listed in the Common Rule. If your project fits within one of those categories, it is reviewed by a single IRB member. Some institutions may choose to have it reviewed by more than one, but it doesn't need to be reviewed by the entire IRB. Ones that do have to be reviewed by the entire IRB are called Full Board reviews.

Casey Webster: I just want to talk about what IRB members are looking at when they're reviewing research protocols. They want to make sure that risks are minimized. They want to make sure that the procedures that are used are consistent with sound research design. They want to make sure that the procedures don't involve unnecessary risk and they also want to make sure that the risks to subjects are reasonable in relation to the benefits. So, there's that risk benefit ratio I mentioned earlier. They don't typically consider possible long range effects of applying knowledge gained in the research when it come to benefits, so that's something important to consider. They want to make sure there's an equitable selection of subjects. The IRB, in order to do this, takes into account the purpose of the research, the setting and any vulnerable populations.

Casey Webster: I mentioned the informed consent process earlier and the IRB will want to make sure the informed consent is obtained. So, this is actually documenting the informed consent process and IRB actually could approve a waiver of the consent process or a waiver of documentation of consent, in certain
circumstances. The IRB will also make sure that privacy and confidentiality is protected, we talked about those earlier and that there are additional safeguards in place for any vulnerable population.

Casey Webster: I want to touch on vulnerable populations 'cause a lot of you work or potentially do work with vulnerable populations. They're actually specified by the Common Rule that was mentioned earlier. So, these are the four populations that are specified by the Common Rule. Fetuses, pregnant women, prisoners and children. We can see why they are listed 'cause they all are likely to be vulnerable to coercion or undo influence. There's also vulnerable populations that aren't specified and those vary by institution about how the IRB handles research protocols involving those populations. For example, they could be students or employees, cognitively impaired persons, terminal ill subjects, or people with AIDS, HIV. The big question is the inclusion of the vulnerable population adequately justified and are there safeguards in place to minimize the risks.

George Shaler: Okay, this is George. I'm going to jump in here because Casey's explained the process by which a set of research protocols gets to an IRB, so I'm going to make the assumption here that an IRB protocol has been approved. There are some protocols that are not approved by an IRB, but you'll find across IRB's that IRB's are generally very willing to work with a researcher. There might be a back and forth process by which an IRB might suggest alterations to a research design because the risks have out weighed the benefits and so on and so forth, but for the moment I'm going to assume that a protocol has been approved and I'm going to take you through a couple of steps that a researcher will want to keep in mind once their protocol has been approved.

George Shaler: Some of these are pretty obvious, like the first one, that the study is done within the study period and you're not still doing the research after the study period has come to an end. If the study is for one year, the IRB is going to think, all right, at the end of a year, at the end of say, December, they're going to think, all right, this project's done and if they find out that you've been doing research beyond that period without seeking an extension, there's going to be some kind of consequence for that. So, you'll want to make sure that you're doing it within the study period or seeking some kind of extension.

George Shaler: You want to, obviously, do the research in a way that's spelled out in your protocols and stick to it. This third point is especially important, is to inform the IRB at once, if there's any adverse research event. Such as, for example, the computer that you have been storing your data on has been lost and you have some confidential information on that and in the wrong hands, maybe, that information could be used in a way that would injure, so to speak, the people who are being studied.
George Shaler: Here's some other things. If you want to do ... This happens to me fairly frequently in my research. I get halfway into it, say six months into a year long study, and the organization that I'm working with wants to do something a little different. That's fine as long as you submit some kind of revisions to your protocol. That's not a terribly onerous process, it just requires letting the IRB know and the IRB reviewing those changes and saying, yes, they meet our approval. If there are any conditions in your protocols regarding the protection of information, such as where data is stored, you want to definitely conform to that practice. For example, I have some projects that have been approved by this IRB where I have to store data on a password protected drive, computer drive, here at the University because they don't want all sorts of people having access to those data.

George Shaler: Moving onto item number six. What our IRB does a great job of is notifying me 60 days in advance of a project coming to an end. That your protocol is due to expire in 60 days, are you going to need to seek some kind of extension? Now, not all IRB's do that, so you'll definitely want to make sure that you're staying on top of that. One of the things that our IRB does and I think this is pretty standard across the industry, is that once a project comes to completion, you submit some kind of final report. Now, that's not necessarily a long report. Typically, the IRB here at the University of Southern Maine requires a page report and to be honest with you, what I often do is I'll take elements of, if I've done some kind of report that includes an executive summary, I'll take elements of that executive summary and put it into a final report and it just gives the IRB a record of what happened during that research.

George Shaler: I'm going to move on here to what happens in the event of a problem. As an IRB member and as a researcher, I have encountered both. I have had to be called into the IRB at one point because I committed a research violation. That happened to me actually not too long ago, full disclosure, This was not something that I had a direct hand in, but someone was submitting data to me and I had set up a protocol by which they submit those data to me on a protected server. They sent it to me via email and that had some information in it that should not have gone through email because that creates a trace that could conceivably be found by people who had more time on their hands then they need to. So, I had to immediately file what's called a breach and let the IRB know that there had been this breach.

George Shaler: Now, sometimes if the information that is breached and I'm referencing number three here on this slide, is that sometimes if there had been a breach with names included you would have to notify the study participants to let them know that the information that we thought was going to be kept in a confidential manner was released, so that they know about it and that you have to let them know that you're taking all sort of steps to ensure that any injury to them is being minimized.
George Shaler: Moving along here, here are some possible remedies to problems that sometimes come up with research protocols. One of the things that Casey outlined was that an IRB will want to know who’s included and excluded from the study. Sometimes unanticipated problems will require you to change those criteria. Maybe there are other steps that you have to take to monitor additional procedures for monitoring the people that you’re studying. In some cases, an IRB will suggest to you that you suspend enrollment of new subject. We don’t see a lot of that here at our University, but sometimes if were to work with an IRB that is at a medical institution that is testing some kind of new drug, they might say, well there are some unanticipated consequences of that new medication and so the IRB of record will say, we will no longer allow new subject to be enrolled. Here are some other possible remedies that can happen and sometimes we have to modify informed consent forms and we have request additional information about newly recognized risks to subjects.

George Shaler: In the last couple of slides here, one of the things I wanted to touch upon was what you should consider when choosing an IRB. One of the things that is really important, I think, and I’ve gone to IRB conferences. You might be thinking, why would you do that? But, they’re actually really interesting. You want an IRB that’s really responsive, so if I submit a protocol, I’ll pick on my colleague here Casey, I want to know that that’s going to be acted on fairly quickly because I want to get my research going. I don’t want to wait several weeks because often the work that I’m doing as a pretty short duration and so I don’t want to waste a lot of time just sitting around waiting for my set of protocols to get reviewed.

George Shaler: To me, one of the big issues is the timeliness as well and so if I submit something, I want to know within a few days if Casey’s going to get back to me with a response, whether it be to approve it or whether I need to make further modifications to my protocol or better explain some of my protocols. That’s, I think, one of the things that with our IRB that we’re looking to always minimize our turn around time so that researchers here at our University view us as an ally in this research process and not as a roadblock. So, definitely look at, if you’re shopping around for an IRB, ask them if they have a turn around time on IRB protocols.

George Shaler: Obviously cost is an important consideration. Different protocols are going to require a different cost. A full board review will cost more than an exempt review because a full board review will take more staff time and the time of the IRB itself. Reputation, like anything, is important. Expertise, if you are looking around for an IRB, especially in our field, you want to know if they have people on the IRB who are familiar with the justice field, whether it be a corrections population, law enforcement courts, definitely ask about that. Then finally, just generically, is it convenient or am I going to have to ... In terms on convenience, is the IRB near by. If it’s not, can they get information back to me in a prompt manner through email or through phone. So, definitely think about those things when you’re picking an IRB.
George Shaler: One of the things with the approval process is when you're submitting for IRB protocols, definitely follow the instructions. One of the things that we've noticed here at the University is that Casey and Ross have done a great job of spelling out what's needed. Casey had a slide earlier that said these are the things that you'll need for your protocol submission. Definitely follow though because that's one of the things, if there's guesswork on the part of the IRB, it's probably in the first round, not going to be approved. It'll go back for further questionings. So, if you do get questions, answer them completely and as ... I typically will get, on a number of my protocols, questions seeking clarification. It doesn't require a long discourse, it just requires a couple of concise sentences in responding to those questions.

George Shaler: Just some other things, our IRB asks for attachments including CV's, consent forms, surveys if you are doing a survey. Here at the University, we'll want to see the instrument itself, so that we want to get an idea of how the questions are being asked and just to see if they're asking ... If the information being asked is too personal, could you get by with questions that are not as probing and then again, responding to IRB questions promptly.

George Shaler: So, that's IRB 101 in a nutshell. We'd be happy, at this point, to take questions. I know that's been a whirlwind of information, but that gives you an overview.

George Shaler: Here's a question, who gives consent for a fetus?

George Shaler: So, who wants to take that one? Casey do you want to jump in?

Casey Webster: Yeah, so that actually depends on the risk level of the research. Either just the mother or both parents actually may be required to give consent. It's not really consent, it's permission. Does that answer the question I hope?

George Shaler: Yeah. Other questions?

Casey Webster: I can't read it sorry. Next question is, is most of the IRB communication taking place in writing or in person? Do you actually meet with the board?

George Shaler: Oh, that's a great question. So, the answer to that is both. I'll just take me as an example, when I submit protocols and I probably submit five or six protocols a year, the first communication I'll get is an acknowledgment that the protocols were received, which is really helpful because you want to know. We do an online submission for our research protocols, not all IRB's do that, but we do that here at the University. That allows us to manage the protocols a lot more efficiently. So, what will typically happen with my protocols is I'll have one person on our IRB who I do not know, even though they are my fellow IRB members, will review it and if they have any questions will submit questions to me electronically. That I will then go into our IRB software, if you will, and respond to them.
George Shaler: Now, sometimes the IRB will ask the researcher to come in and further explain their research protocols and we typically have tow or three of these a year, maybe. Where we'll say ... Maybe we've done that because we've got some concerns about the research methods and they haven't been able to sufficiently answer our initial questions, so we will invite them to our monthly IRB meetings. As I just kind of mentioned, our IRB meets as a full board once a month. Typically, we do more than just review protocols. We'll look at the protocols that have been approved across the University and we'll also engage in some continuing education, as well as looking at our response time on protocols.

George Shaler: So, here's another question. Did all agencies adopt sub part C and D that protect vulnerable populations? I don't think justice adopted these sub parts.

Casey Webster: Right, so that's a great point. Not all the agencies have adopted the sub parts. So, the Common Rule itself excludes those vulnerable populations that I mentioned. The fetuses, the pregnant women, the children, and the prisoners, so that's a great point. I believe you're right that the justice department did not adopt all of those. That being said, many IRB's will still consider those a vulnerable population. They may not require you to take certain actions, but they'll be considerate of that.

George Shaler: Next question, from Lisa Sampson here. Where do you look for the IRB? Is there an IRB clearing house? Do most Universities provide this information on their websites?

George Shaler: Many research Universities have an IRB, not all of them do. Right now here in Maine, we have seven campuses that make up the U Maine system. Of the seven, there are two campuses that have IRB's, the University of Maine at Orono, which is the largest of the seven campuses and the University of Southern Maine where Ross, Casey, and I are located. In terms of a clearing house-

Ross Hickey: There are different ways you could figure that out. I talked about earlier the federal wide assurance number that you would receive and also linked to that would be an IRB of record that would have to have its own registration. So, you can go on ... That's all publicly available information and you could see through the office of Human Research Protection at the federal level. They store all of that information so you could see who has the federal assurance and who has an IRB that is allowed to review federally funded project and that would be a good place to look. Not all institutions are going to do external reviews. Many of them don't want to do those reviews for anyone but their own institution. There are some that have chosen to allow that. For example, our University does do external reviews for other institutions or individual researchers and they don't have to be located in the state of Maine. There are other places that would say only project affiliated with our institution.
Ross Hickey: You'll also see that if you're going to have an institution review it for you, on your behalf, they likely are going to charge you some sort of money to either allow them to offset the expense or it's a for-profit, this is what they do, this is how they make their money. Those sites, if you do a Google search, you'll find very quickly.

George Shaler: Yeah, the other thing I'll just point out is that there are some liberal arts colleges or undergraduate institutions that do have IRB's. I think one of the things that I would caution folks about is that you want an IRB that has some expertise in the field of justice policy. Some colleges don't have that, where as a University is more likely to have that expertise.

George Shaler: Let's see, here's another question. We are not sure if we are able to be heard, we will see. I don't know what that means.

George Shaler: The other things is, I just want to pick up on something else that Ross said is that our IRB does do external reviews. We've actually done some reviews for the Ohio and Colorado SAC, so we do some other work outside our state and you'll see if you shop around for IRB's is that some universities will do that. They'll look outside their state. We did it for a couple of reasons here. One, is that we wanted to increase our capacity and we thought that was an exciting opportunity to get involved in reviewing research going on in other states.

George Shaler: So, here's another question. How do you know which is the "right" IRB? For example, if you have access to an IRB through both a major University and an institution, e.g. a state agency, is there a reason to believe that one is better than the other?

Ross Hickey: Yes, never underestimate, and George has already talked about this, word of mouth. Having the access to folks who've had the experience of using those institutions or those review boards is helpful. Also, looking at the research portfolio of that institution and seeing if they have significant research projects coming through that align with what you need reviewed. There's other things as well in the industry, looking at the support unit behind your IRB. So, being able to look at how robust or how many folks are in the support staff for the IRB and what are the credentials of those folks.

Ross Hickey: For example, in the field of human subject protection, there's what's called a CIP, or Certified IRB Professionals. If you have someone on the website who looks to be connected or is supporting that IRB who has that credential, that should give a good indication of a few things. One, their expertise, but also that institutions placing of importance on their human research protection program. Another thing you can look at and I am not connected to them in any way. I should say that I'm on the CIP council for [inaudible 00:52:54], so I will disclose that, but for AAHRPP, that an accredited agency. If you see AAHRPP accreditation they've gone through a very formal review process. That's another
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indicators that their significant resources dedicated to that program at that institution.

George Shaler: The other thing that I'll just jump in on with the reference to the state agency is that some... Being here in Maine, I work with a number of state agencies. We do a lot of work with our health department in Maine and that's referred to as the Maine Centers for Disease Control, they used to have an IRB. They weren't meeting enough. They were meeting every three or four months, because they didn't have a big research portfolio and a couple years ago they approached us to become the IRB of record for them.

George Shaler: So, one of the things, if you're looking at a state agency, is to see is it possible, if they have an IRB and if you're thinking about working with them, is do they meet frequently enough to help you.

George Shaler: We've got another question that's come in here. This one's a little-

Ross Hickey: While you guys are reading that I just want to add very quickly. George makes a really good point because what you'll tend to see out in the field is that if the IRB is not reviewing many projects, the tendency there is to over estimate risk, which means that they're going to elevate the review level that Casey talked about and it's going to be a longer turn around time. So, that's why you want to find people that are not overwhelmed and have capacity to review, but actually see frequently enough projects, so that they're pretty sharp on what the review requirements are.

George Shaler: All right, so this is a long question.

Casey Webster: I think this question is asking whether their project does research with human subjects or not?

George Shaler: So, should I read the question? I don't know if everyone has seen it.

George Shaler: If working with a community that requested assistance in reducing a criminal justice issue, the community stakeholders are engaging focus group interviews with the community to identify personal opinions or observations of the criminal justice issue in the community. Is an IRB approval necessary if you're using the community member's opinion to identify strategies to mitigate the criminal justice issue?

George Shaler: I would say, yes, on this one.

Ross Hickey: Well, the first two, if we go back to the definitions. You have an individual that you are in interaction, you're interacting with them through the focus groups or interviews. You're asking them information that is their personal opinion. A personal opinion isn't about themselves, it's not information that just simply
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factual, it is their personal opinion. So, you have the first prong in that you have human subjects. The question then is it research? Now, is it research, you have a systematic investigation which you talked about, but do you have it's designed in a way to produce information or share information, but is it generalizable. Is it information that can be extrapolated more broadly than that community and that's where you're going to run into, I think, the question of whether or not it is human subject research.

Ross Hickey: Is there a generalizable component of it and if there is, then you would want to err on the side of having an IRB look at it. Again, given the type of work that that is, it should not necessarily be a very high review level unless there's something we're missing in the question.

George Shaler: The other thing about that is even if it's not, one of the things that you want to make sure of is how that data is being collected and captured. For example, if you are recording that focus group and names are being used in transcripts that are being produced as a result of that recording, then that's possibly a higher risk 'cause maybe someone has given a personal opinion that is critical of someone and if that information was to be divulged, it might be injurious to that person.

George Shaler: For example, maybe you made a critical remark about the Department of Corrections Commissioner or their practices, or one of your focus group participants did and even though it's not generalizable as Ross was saying, you'll want to have some safeguards in your protocols to protect the individual.

Ross Hickey: This is where it can get very tricky in social behavior research because publication does not necessarily mean generalizability. I'm sure this information is going to be publicized, which means you ama need colleagues to look at it and help you with maintaining its confidentiality, as George said, and if you a have an office like ours, we're happy to look and give you advice. To go back to the importance, IRB's usually will want to be very careful that they are not claiming oversight over a projects that are not considered human subject research. The other thing is if you go to publish in a journal, I'll bring that up again, if they're telling you it's human subject research or the funding source tells you that it should go through an IRB, then that's not a hill to die on, you should probably go through an IRB. Even if there's an academic argument to why it shouldn't, you'll find that many times because they want that protection that George says, your funding source will say, we think it needs to go through an IRB. My advice to you is that you probably then want to do that.

George Shaler: I think just the final takeaway on that is that again, one of the things that when I was starting out as researcher so many years ago, the thought of submitting something to an IRB just made me cringe a little bit because I thought it would be a long and laborious process. I now know that it isn't that way, especially as the field has really become more professionalized and the turn around ... I now
know what I need to include in my protocols and I know, like our University, and I think other universities are similar this way, is that I can expect a prompt turnaround. So, just think about that and an IRB is not a four letter word.

George Shaler: It doesn’t look like we have any more question and we're past our hour. I don't know if anything else. Bailey or Jason, I'll turn it back to you. If you have any further questions about IRB's please email me gshaler@maine.edu. I'd be happy to get back with you on any of that. So, Bailey, I'll kick it back to you.

Stan: Hi, this is Stan Orchowsky, can anybody hear me?

George Shaler: Oh, Stan I'm sorry.

Stan: Thank you. Thank you, all of you. We really appreciate the information. As George said if you have questions for him, feel free to email him or JRSA, we'd be happy to forward those on. [inaudible 01:00:25]

George Shaler: Stan, we're kind of losing you a little bit here.

Stan: Okay. The number of people who ... If you didn't get a chance and you’re with a group, go to the chat window, tell us who registered and how many people were listening. The poll is up now, so if you could please take a few minutes to fill that out and look for upcoming webinars in the upcoming weeks and months. Thank you all.