Rise, Teach, Learn - Season 3 Episode 4

Ethical Considerations for Research

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We acknowledge and are mindful that CSU Chico stands on lands that were originally occupied by the first people of this area, the Mechoopda, and we recognize their distinctive spiritual relationship with this land and the waters that run through campus. We are humbled that our campus resides upon sacred lands that once sustained the Mechoopda people for centuries.

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Welcome to the Rise, Teach, Learn Podcast. I am Dr. Chiara Ferrari, Director of Faculty Development at Chico State, and we are happy to make this resource available to our campus community and beyond. The podcast is hosted by Dr. Jamie Linn Gunderson and she will engage in timely conversations with faculty, staff, and students and give you a taste of the Chico experience. Subscribe to our podcast and explore the many resources available on our website. Thank you for listening.

00:58
Hello, and welcome to Rise Teach Learn. I'm your host, Jamie Gunderson. In this episode, we expand on our previous conversation centered on supporting faculty research, and explore ethical considerations for designing and conducting research with Dr. Patrick Johnson, an associate professor in the Psychology Department and chair of the Institutional Review Board. Patrick, thank you so much for chatting with us today and sharing your knowledge.

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Thank you so much for having me, Jamie.

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So I understand that research can really come in many forms. And today we're highlighting human subjects research. In future seasons, I hope that we can explore other areas of research. But I want to start by reflecting back on our previous episode, wherein we discussed opportunities for faculty to receive funding to advance the research and or scholarship of teaching and learning. Before we jump into the procedures for moving research forward, Patrick, I was hoping we could discuss what's really important for faculty to know and understand before they start on their research journey.

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Sure, I think that's a really good starting point. So when we're talking about the Ethical Treatment of human subjects, probably a natural starting point in this country is the Belmont Report, which was agreed to by several different agencies in the federal government at the end of the 1970s. And this was really in response to a number of atrocities that occurred in or I should say, under the guise of human subjects research. In short, the Belmont Report spells out three important guiding principles of human subjects research as, it's going to be conducted from that point forward. And those are respect for persons, beneficence and the principle of justice. And so those three principles, I guess, if I could step

into each of those respect for persons, really says that individuals need to be treated as voluntary agents, their autonomy needs to be respected, that those individuals that for some reason, are maybe lacking that autonomy, they need to have special protections afforded to them. So for instance, individuals that are in prison, or individuals that are cognitively impaired in some way, the idea of respect for persons is that we recognize that these individuals should be able to make their own choices, without fear of coercion, retribution, or any undue influence. And that those individuals that are not in a position to make choices on their own, are afforded these accommodations that can allow them to participate in human subjects research safely, in a way that respects their well-being their health and their safety. And that plays into, of course, beneficence and beneficence is the idea that we should do no harm, and that if there are risks that they need to be outweighed by the benefits of the research. So that's not to say that we can't do human subjects research that involves some element of risk. But what it does mean is that if there is risk associated with the research, that there needs to be a reason why there is this risk that's going to be undertaken, again, voluntarily, by human subjects. And so with beneficence, we want to make sure that our again guiding principle is that we are treating our human subjects with compassion, that if for instance, we're working with a population
that could benefit in some way from the research that they're participating in, that they have access to the results of that particular trial. So let's say it's a, a drug trial. If that experimental drug appears to be efficacious, then those participants should have access to it as should participants who receive, let's say, a placebo.

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And that plays into this third principle of justice, which is related to equity, and ensuring that participants are recruited in an equitable manner, which means that we shouldn't target specific groups, unless there's a very important reason why we would do that we want to make sure that everyone has an opportunity to participate. And again, that the benefits are shared with participants in an equitable manner, so that the benefits are not withheld from some individuals on the basis of race, gender, disability, those those sorts of things. So again, I think this was a pretty sort of watershed moment in human subjects research in this country. From there, we moved into what we call the Common Rule, which is a set of federal regulations that specifically lays out how institutional review boards should function, their scope, and what some of the procedural elements in terms of maintaining a program of ethical human subjects research at, for instance, a university or or other institution might look like. And so the common rule has been that guiding set of regulations. And in 2018, the common rule was revised and sort of updated for modern times, to include things like for instance, how we should conduct survey research or online research, that sort of thing. That's the set of regulations that we abide by, as an IRB. And so we are beholden to those regulations, we have an assurance with the federal government, that Chico State will abide by the Revised Common Rule. And so in that sense, really, we are, of course, based at Chico State, but our priorities to human subjects and these federal guidelines.

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So Patrick, that's really helpful information for faculty to know, I am reflecting on my role as coordinator of the class program. And in that capacity, I support students who are doing research, and I'm also part of the team, the class grant, where we're collecting data on the students and doing our own research. So kind of a two-pronged role, if you will. In that role, I mentor my student researchers to go through

training to make sure that they're up on all of this information. Can you tell us a little bit about that training that's required through IRB,

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The ethics training requirement is relatively new at Chico State, and faculty, staff and students can complete the ethics training requirement through the city program, which is regarded as really the gold standard at other institutions conducting human subjects research. So at Chico State, we have a subscription, this is accessible, even if you're not doing human subjects research. So for example, if instructors want to use the city training as a component of a research methods class where maybe the students aren't doing research necessarily, but you want them to be cognizant of the history of human subjects research, and, again, these principles and sort of foundational concepts that help us to figure out the best way to conduct human subjects research. Those students could do the city training just as well. Most of the time when individuals on campus contact the city training, it's because they need it for IRB review and approval. And so this is something that we instituted this past year. The city training is important not just because it ensures that the researchers are aware of what it is that they're going to be doing and the importance of these guiding principles. It also serves to educate further faculty, staff and students who might be doing human subjects research on sort of unique situations they might encounter, populations that they might not necessarily work with immediately, but work with in the future. So the city training that is required for most everybody on campus, I would say 99% of us on campus would need to do the social and behavioral basic course, it does take a bit of time. So I think two to three hours realistically to sit down and go through these different modules. And researchers will learn about, for instance, the importance of obtaining informed consent, considerations when it comes to recruitment of and participation of minors in their research. And that might be something that for instance, in in the School of Ed might be really important information for students to consider, and sort of what, again, unique situations they might encounter and how they might navigate those ethical questions. Because there might not necessarily be a right answer to these issues that that come up. But again, the IRB is really striving towards what is the best possible balance of risk and benefit, protecting participants, but also allowing researchers to ask the questions that they want to ask.

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I think the IRB in some ways has a bad reputation. Because as a researcher myself, I want to start doing my research, I want to get my study up and running. And yet, I have to go through this process. And so it delays things further. And, you know, time is of the essence. And also, you know, the IRB comments on the procedures that you're proposing to implement, or other details of the research that you think as a researcher are critical. And the IRB members might not necessarily be experts in your area. And so the way that I think about the IRB is rather than the IRB telling faculty, staff and students what to do. Instead, my hope is that we can engage them in a conversation about what is the best possible arrangement that we can come up with. And so I think that the city training allows researchers to approach that kind of conversation with more of an appreciation for what it is that the IRB is going to be asking for or looking for. And so in that sense, I think the city ethics training has actually helped it's gone a long way towards educating faculty, staff and students with respect to how to prepare an IRB application so that it can receive minimal revisions. And, you know, not necessarily in the way that would, you know, avoid the scrutiny of the IRB. But one that truly shows again, those principles from the Belmont Report, the respect for persons, the beneficence and the Justice components. And to the

extent that the IRB sees that the researcher is taking those into consideration. Typically, we have few concerns. And so our turnaround could always be faster. Depending on the level of review that your application requires. It could be anywhere from a week, to a month or two, again, depending on how risky the research is.

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So once faculty, staff and students have armed themselves with the knowledge gained through this city certification on ethical considerations for human subjects research, what would be the next step four, a faculty staff or student who wanted to move forward with the IRB process? I know that as coordinator of class in helping my students, they are using the Cayuse platform, and I was really excited to learn that their city certification like automatically updates in the system. So as soon as they've completed their certification, the way that you all have it set up, it automatically shows up and is available for the IRB committee to review. But what are next steps next considerations for faculty staff and students looking to move forward with the process.

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Cayuse is relatively new again, we we transitioned over to Cayuse around the same time that we were transitioning into the city ethics training requirement. And so a lot of things happened at the same time. And Cayuse what it allows us to do is to centralize all of the IRB applications. So we no longer have paper copies on campus. Everything is digital, which is amazing. And what I also like about Cayuse is that if you modify your application, if you want to close it out, or let's say there's an incident that occurs, all of that is then attached to the same file, which is to say, your initial submission is not the beginning and the end, it's sort of an ongoing, evolving application. And prior to using Cayuse, we would have to file all these things in paper. And it was it was really cumbersome. So Cayuse is a really wonderful resource because it allows myself as the IRB chair, to log in review applications that are submitted, give feedback, return to investigators, and really make this process more efficient. Prior to this, it was a lot of email correspondence. And so with Cayuse, all the feedback is again, in the system, it's attached to the application. And not only in terms of the review process, but the documentation of approval. If research, for instance, involves vulnerable populations, if it involves more than minimal risk, which by the way we define as risk that is above or beyond the level likely to be experienced in an everyday situation.

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If those things are being proposed, then one's application is likely to undergo a full board review. But the full board review process, it now through Cayuse allows all of our IRB members to have access to that application to leave comments in a way that's more interactive. And, again, I think it really has optimized the IRB process. So getting on to Cayuse. First off every faculty member on campus, is automatically in the Cayuse system, staff and students because those roles tend to change more frequently, those individuals need to, if they don't already have a Cayuse profile, they need to be added to the Cayuse system. And they can do this by going to our IRB website. And there's a button off to the side that says Request to be added to Cayuse. And so once we add you to the system, you can log in, and you can initiate a new application. When you do that, you'll see that there are about 12 to 13 sections that need to be completed for the application. And things start off relatively simply who's on the study team, who's the principal investigator, but then we start getting into things like well, what is some relevant background with respect to this research, and this is where we're really hoping to give

researchers the opportunity to tell us why it is that they're doing the research that they're doing. So in other words, what does the literature suggest with respect to this area, what gaps are present? And again, for students, this is a really wonderful opportunity for them to get experience, thinking about how all these pieces fit together. It also allows us as the IRB to assess the degree to which the researchers are aware of what's happening in the literature, and you know, how their study fits in whether their hypotheses are well founded. A lot of the work that we see is exploratory. So it's not necessarily hypothesis driven. And that's perfectly fine. But we also want to know things like, what are the outcomes that you might anticipate from doing this research? From there we get into who are the participants likely to be? So for instance, where are they going to be recruited from? So what populations do you intend to sample? How many participants do you intend to enroll? What is your sample size? In other words, and what are the ages of your participants and this goes all the way from fetus to 18 plus. And then also in this section, I think probably one of the most important sections in the whole application is with respect to vulnerable populations. Federally, there are just a few vulnerable populations that must be protected. And those are fetuses, pregnant women, minors who cannot consent for themselves and prisoners. In our Cayuse application, we have added other vulnerable populations, that in the course of doing these reviews, we as the IRB have the authority to be more conservative with certain groups. And so what we really tried to do is pay close attention to who is being asked to participate in the research? And do we need to apply special considerations? Do we need to afford these individuals greater protection than what might otherwise be afforded? Moving a little bit further through the application? We of course want to know things like recruitment, how is it that participants are going to find the study? How much will they be compensated if they are going to be compensated at all? We also need to know things for instance, like what are your inclusion exclusion criteria? Who can be in the study? Who cannot?

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We also need to get information on the informed consent process. So how is it that the participants or prospective participants will learn about the research that's going to be conducted? How is it that they're going to be told about their rights to choose whether or not to be a part of the study to withdraw their participation, their consent at any point in time. And this is a really important document because it communicates these really foundational concepts to the participant. And we also want to recognize that participating in research is something that doesn't normally happen, this will be an unusual situation for your participants. And so they might not be aware of the fact that they have these rights to for instance, not be penalized if they decide to withdraw their participation, or if they're being interviewed and video recorded, that they have the right to withdraw, access to that identifiable information, even after it's recorded. So although informed consent is seen as a point in time, I think the better way to describe it is it is a right that the participant has that they confer in the process of joining a study. And they can again, withdraw that consent at any point in time. So it's, it's really an evolving process. So that's Yeah, with respect to the the Cayuse application, want to make sure that we have all those elements in place. We want to also see the study materials, we want to see the questionnaires that are going to be asked or provided to participants, we want to see the interview script, or at least a nearly finalized version of what that might look like. Anything that the participants might interact with, or be asked to do. We want to make sure that we have that in the Cayuse application. And of course, as you mentioned earlier, having the city ethics training completed. That's really critical. It doesn't necessarily, I sort of like to half joke about this, it doesn't make you magically ethical doing the city ethics training. But I do think it, it

goes a long way to helping you to understand why the IRB is asking these questions on the Cayuse application. So it is a lot of work. But I think having that information is so critical for the IRB to determine what level of review is appropriate for one's research.

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So let's talk about those levels. I understand there are three levels exempt, expedited, and full board review. Can you give a little insight as to the differences between those reviews?

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I think maybe the best place to start is with exempt. Most of the research that comes through the IRB here at Chico State is going to fall into the exempt category. Now, importantly, I think It's worth really underscoring this. Exempt does not mean that the IRB doesn't need to look at it. Exempt means that it is exempt from a full board review. So a full board review is one in which the IRB members, myself included, review the application have an opportunity to discuss it, meet with the study team, and go over some of these riskier elements. Or, for instance, how vulnerable populations will be treated and cared for as they participate in the study. Expedited applications. Again, I think this is another misnomer, go no faster than exempt research applications or full board applications. The reason why they are expedited is because they are usually expedited relative to the time it takes to approve a full board application. So an expedited research study might involve something like conducting interviews with minors who can't consent for themselves. Because this is a vulnerable population, we want to make sure that if the researcher is involved with doing those interviews, and this is outside the scope of let's say, normal educational practices, that extra care is taken. And so a study like that would not qualify for exempt status. Instead, it would be expedited. And so with respect to expedited research, it is more involved. It's usually somewhat riskier than exempt research.

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That's really helpful to understand the different levels. Patrick, my last question really would be: where can faculty go to get more information about how to effectively move through the research process?

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So yes, there's many ways that researchers, faculty, staff or students can contact the IRB or get information about how to navigate this often confusing process. And not only can it be confusing, but it can also be intimidating. And so I think one of the most important parts of my job as the chair is to make sure that researchers feel comfortable reaching out to someone like myself or other IRB members to get some help, get some advice and to become comfortable with the ethical review process. My hope is that faculty, staff and students feel comfortable collaborating with the IRB to conduct their research. And so the IRB plays a really integral role in making sure that the research happens in a way that protects participants, but also protects the study team and protects the university as well.

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And there you have it, folks. Today we explored ethical considerations and procedures for conducting research at Chico State. I'd like to thank our guest, Dr. Patrick Johnson for his contributions to this episode. You can access previous episodes of Rise, Teach, Learn as well as all of the resources

associated with this and other episodes through our FDEV podcast web page. A big thank you to you for listening and until next time, we got this Wildcats!