Episode 59: Katie Linder

# KL: Katie Linder KL: You’re listening to “Research in Action”: episode fifty-nine.

# [intro music]

# Segment 1:

# KL: Welcome to “Research in Action,” a weekly podcast where you can hear about topics and issues related to research in higher education from experts across a range of disciplines. I’m your host, Dr. Katie Linder, director of research at Oregon State University Ecampus. Along with every episode, we post show notes with links to resources mentioned in the episode, full transcript, and an instructor guide for incorporating the episode into your courses. Check out the shows website at ecampus.oregonstate.edu/podcast to find all of these resources.

On this episode, I’m flying solo and I’m going to talk a little bit about the Institutional Review Board or the IRB. This is a common topic that researchers often discuss and it has been requested for the show, and so I thought I would spend some time in Segment 1, talking a little bit about IRB basics, in Segment 2, talking a little bit about typical components of the IRB application, and then in Segment 3, offering some tips for success with working with an IRB committee. Now we have talked about the IRB a couple of times on Research in Action already, you can find out a little bit more about it. In Episode 43 with Adriane Brown where she talks about IRB logistics for online research and you can also hear about it in episode 27 with Lydia Newton on survey design and recruitment, and she talks specifically about it in segment 2. In this episode, I want to offer a couple disclaimers before I start. One is, the IRB looks a little bit different on every campus. So I have been on an IRB committee for several years on a different campus than I am now, I have also gone through the IRB process several times at multiple different institutions, so I’m going to offer some generalizable things based on that experience and also based on generally what I know about the IRB process from the regulations. But you should always check your campus to make sure that what I’m saying matches up with their practice. Because the IRB is different at every institution, it’s really important to go to the IRB professionals on your campus if you have specific questions that are institutionally specific to you. The other disclaimer I want to offer is that the IRB regulations are currently undergoing changes, so it’s entirely possible that I am going to say something in this episode that is going to change. In terms of the levels of review that I’m going to talk about or what it means for a project to be exempt, I know those are things that are absolutely on the table right now in terms of some changing regulations. So again, this is a place where I would definitely encourage you to talk with the IRB officials on your campus.

So, let’s dive into some IRB basics. One of the first things to know about the IRB is that they’re based on federal regulations that are really about the protection of human subjects, and that they’re very concerned about the level of risk for the populations that you’re working with for your research. In part, this is because in the past, there had been some abuses of human subjects and in particular, some abuses of what is considered to be vulnerable populations. And so these federal regulations are really meant to make sure that you’re not putting the subjects of your research through any undue risk, and for that reason, alone, I think IRB is actually really important. Also we can sometimes get frustrated I think with the different kinds of components, the timelines, the logistics of working through IRB, the core purpose of IRB is to protect our human subjects, so that’s kind of an important thing to know from the very beginning. A lot of the IRB is based on the Belmont Report, which summarizes ethical principles and guidelines for human subject research. And if you ever need to go and do human subjects research, and you will know if you’ve already done it, you will go through a kind of training. Many institutions use what is called Citi Training – and that’s C-I-T-I training, I’ll link to that in the show notes so you can follow that if you’re interested. And that training is really based on the Belmont Report, and sort of the history of why the IRB came to be, the main things you need to know if you engage in human subjects research to make sure that what you’re doing is really ethical. Now, another important thing that is sort of related to all of that, is the federal regulations are available, online, for anyone to look at. You can also pretty easy find an IRB member handbook, so you can kind of fully understand the process of IRB, and the Belmont Report is also available for you to read. So I think a lot of people think about the IRB as kind of an intimidating process, where you may not be entirely sure of what you need to do, and yes, every campus is different in terms of what they’re going to ask for, but really the foundational components of the IRB are really available for you to check out. So I would encourage you to look at the federal regulations, look at the Belmont Report, track down an IRB handbook, if you really want to gain a little bit more perspective or just more confidence in working with the IRB.

Alright, so let’s talk a little bit more about the IRB’s levels of review. Typically here are three levels of review for the IRB, and I’ll start at the most basic one, and that is projects that are considered to be exempt, and exempt projects are the ones that have the lowest level of risk. So some of the research that we do here at the ecampus research unit are exempt projects because they’re survey based projects that are asking for information that is pretty basic information. We may be asking about educational practices, or we may be helping faculty to do classroom research, and many of these things that we’re asking about or that we’re measuring that students may be doing, are things that they may be doing anyway in the classroom and so it falls under that exempt category of review. Now the exempt category of review actually has several categories within it, that sometimes you’re asked to go into those categories and say, “Yes, my research falls under this specific area, and that’s why it’s exempt”. I think there is seven or eight categories in there that you can look at. So at the exempt level, you can typically just work with an IRB professional at your institution, they can review your application and proposal, and tell you yes indeed this is exempt, and help you get through the process of completing your IRB. The second level is what is called expedited, and this is where you may have a little bit of an increased risk for the participants with your proposal, but it’s not enough risk that necessitates a full board review. So this is a process where you’ll typically have a couple committee members from the IRB review your proposal but they’re reviewing it outside of the time when the committee meets. So they might have it emailed to them, or passed on to them by the IRB professionals at your institution, they review it, and they may come back to you with questions or feedback for revisions of things that you might need to do with your application or materials before it can be approved by the IRB. The third level of review is when you have a full board review and that means that your project has enough risk that everyone on the board needs to review it and to be able to ask questions and offer comments. The project that Adriane Brown talks about in number 43, episode 43 of the podcast, is actually one that necessitated a full board review. In part this was because Adriane was working with what was considered to be a vulnerable population. At the very least, she was working with minors, but she was also working with a population of people who were at risk for, or who had previously had eating disorders. And for those couple of reasons alone, she necessitated a full board review. It is very common for vulnerable populations to necessitate a full board review. So if you’re doing work with children, with pregnant women, with prisoners, or with other populations people might consider to be vulnerable, that will automatically bump you up into that higher risk category, where everyone needs to review your proposal and make sure that you’re really mitigating as much risk as you can for your subjects.

A couple other things that are kind of just basic things to know about the IRB, and I’ve mentioned this before, the full board review works on a timeline, typically once a month, where they meet to review applications. So you’ll want to plan ahead because of that timeline and make sure you’re going to be able to complete your IRB application and get approved before you actually start the research, because you cannot start the research without that approval. So you’ll want to make sure and build IRB into your timeline, and I always give myself a huge buffer of time to make sure that I’m going to have the approval way before I need it, and I’m not going to feel rushed. Especially if I’m doing research that starts at the beginning of a term, if it’s classroom research, I really want to make sure I have enough time so that I don’t feel rushed with the IRB. So you’ll definitely want to plan ahead. The other thing that’s important to know is when you are approved with the IRB, depending on your level of risk and the level of review you’ve went through, it’s time limited. So you might need to circle back to the IRB after a year, or sometimes less, update them on how the project is going, and this is something you’re really responsible for as a PI. Your IRB office may give you the courtesy of a reminder email when you’re kind of coming up to that date, but it’s really important to mark your calendar when you get approval from the IRB, so that you know when to circle back and kind of re-up your application. So that’s an important kind of thing to know, that it’s time-limited in terms of the approval.

So those are some IRB basics, I’m going to go ahead and take a brief break. When I come back, I’ll talk about some of the typical components you’ll find in an IRB application. Back in a moment.

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# Segment 2:

**KL:** In this segment I thought I would talk a little bit about the typical components of an IRB application and again I want to offer that disclaimer that every campus is a little bit different. On some campuses this process is typically done online, on other campuses this is a paper based process, and all the different components I’m going to talk about are pretty general, it could be that your campus requires less or more than what I’m mentioning here. So our campus actually has, at Oregon State, a really helpful website that has a lot of materials, all the different review categories and decision trees, very clear instructions about what needs to go into an IRB application, and it’s possible your campus has that as well. Also I encourage you to check that out.

So one of the things that you’re going to put together for an IRB application is the application itself. And at a few different campuses that I have worked at, this is paperwork that the IRB actually provides, where you’re just giving kind of some basic information about the proposal, and this I think helps them to flag if there’s certain things they need to be paying attention to in terms of extra paperwork. So you’ll include things like the title, the different people who are going to be involved – so if you are going to be acting as the PI or if you have study team members, their names might go on this application as well. You’re going to give some basic information about what the project is about, and then they include some questions, they do here at Oregon State, about is this a project that involves certain chemicals, or is this a project that involves biological materials, or other kinds of things that may or may not be applicable to your work. And this application in some ways serves as a cover sheet for everything else that you’re going to be turning in. One way to think about IRB applications is that they really are kind of a package – you’re pulling together a package of information so that you can share in a really kind of holistic way, all the different components of your research project.

So once you have your application, one of the other pieces that you’re going to need to provide is what is called a protocol document, and sometimes this is combined with the application document, and sometimes it’s separate kind of Word document that you are drafting. Again at Oregon State, we have a very detailed protocol outline, and there’s a template and again, this might be something your institution has as well. And in the protocol document, this is where you go into pretty extreme detail, about what you’re planning to do for your research, who is involved in your research, in terms of the subject population, are there different kinds of eligibility requirements for your research, how are you going to consent other people who are engaged in your research, what exactly are they going to be asked to do, all the different things you need to outline. Sometimes this protocol document includes things like a data management plan, sometimes it’s a separate document, it depends again on your IRB and how they have created the process for you to complete. But the protocol is, in most cases, at least in my experience, the most lengthy document, that you’re really putting all the details into that document. It could also include a short literature review to kind of contextualize your project. So I often treat the application and protocol creation for a new IRB project, as kind of preliminary way to pull together my own materials that I might end up using for things later on when I’m actually writing up the results of my study. So it’s a nice way to kind of get a jumpstart on things like your literature review that you’re going to need later on anyways if you choose to publish your results.

You will also need to include in your IRB package consent documentation, and in some cases this will actually be the drafted document that people will complete and sign. In other cases, it’s more like an explanation of the research, and this is particularly true if you’re waiving consent or waiving documentation of consent, that you might just need to inform people about what the research is doing. In many cases, because I do a lot of survey research, we’re not having people sign papers, we’re having people check a box saying that they consent based on explanation and reading of the research. So consent documents can be pretty wide ranging, in terms of what you’re required to turn in, but there are really specific components that need to be in a consent document based on federal regulations. So for example, a typical consent document will need to include the fact that what you are asking the person to do is considered to be research, and so you need to use that word, research, in the consent document. So there’s different kinds of factors like that, that you’ll want to go to your IRB and make sure you know exactly what needs to be included in that consent document. It’s also possible that your IRB has examples of language that they want you to include, or some kind of template you can use to design your consent documentation.

You will also want to include in your IRB package, any kind of instrumentation or interview protocols or focus group protocols that you might be including in your research. So, for example, when we do our survey work here at Ecampus, we have instruments that sometimes we create ourselves, and we need to have those instruments drafted before we begin the IRB process. Part of this is because, and this kind of makes common sense, that in order to assess the level of risk for our participants, they need to know the kinds of questions that we’ll be asking them. Now this can be a little bit harder when you have research where you’re not sure, maybe it’s phased research, and so you’re not sure what questions will come up later. Maybe you have an initial interview stage, and then you think there will be additional questions that come out of that initial stage. And in my experience, I’ve had very good experiences with IRBs, really talking to them about that kind of research, and having them kind of assist me in thinking through the materials they might need in order to approve that research, even if I’m not entirely sure what the latter phases are going to look like if it’s more exploratory.

For your research project, you will also have a range of recruitment materials, these might be email drafts or various, like a newsletter posting or a flyer or different kinds of things that you’re going to use to get people recruited for your project. And all of these recruitment materials need to be included in your IRB packet as well. I had a recent IRB approval that I went through about a year ago where I had a pretty intensive recruitment process that included informational webinars to really explain to people what we wanted to do, and the data was collecting from a couple different places on different campuses. It was a national study, 15 different campuses helping us to recruit, and so I actually ended up creating a flow diagram of all the recruitment materials and then labeling them, so that the IRB could really understand what I was trying to do, and all the different people who might be involved in recruitment, all the different messaging. And this can be everything, like what I mentioned, from emails to social media posts, anything that you might be using to help recruit people into your study. So all of your recruitment materials will need to be collected for this as well.

There are probably also, depending on your research, a range of miscellaneous forms that might be related to what you are trying to do. So we have a couple of examples that we have here at OSU, that I have not had to use, just because my research hasn’t fallen into those areas, are forms that are related to specifically biological materials, if that’s something you’re going to be collecting. Forms that are related to regulation safety, if that’s part of your research, sometimes there’s also conflict of interest forms that need to be filled out. So it’s also possible that your IRB application package will also include a range of other forms.

Now, you may be already thinking that this sounds kind of daunting, and again, I want to remind you, don’t be intimidated. It is always pretty clear, and you can always meet with an IRB professional on your campus to really go over everything to include. The other thing I think is helpful to know, is that once you have gone through the IRB process, if you discover that you’ve made some kind of mistake or that you need some kind of change or modification, you need to add a survey question or something like that to an instrument, you can go through a modification and revision process with your IRB, where they will approve those kinds of things. So, although you want your application to really be as accurate as possible, there is a process you can go through if you discover some kind of error or need to make a change after the approval process has occurred. And again, this is something probably outlined on your IRB website at your institution, you can talk to them about that.

So those are some of the major components of an IRB application. I’m going to take another brief break, and when I come back, I’ll talk about some tips for success when working with the IRB committee. Back in a moment.

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# Segment 3:

**KL:** In this last segment I thought I would talk about some general tips for success when you’re talking with an Institutional Review Board, in terms of making sure that you’re giving them everything you need, and making the process as easy as possible for everyone. I do want to mention that this is something that I have wrote an article about, related to the scholarship of teaching and learning more specifically. I was looking for something to offer to faculty about working with the IRB more specifically for scholarship of teaching and learning projects and couldn’t find something. So I worked with a couple of IRB professionals, and we co-wrote an article, so I will link to that in the show notes if that’s something of interest to you. And I’m also going to offer again, a repeated disclaimer that it is entirely possible that the things I’m saying in this episode are different on your campus. So I want to be really clear about that, and also it’s possible some of the language I am using is not as precise as an IRB professional would use, I am not an IRB professional, and so I want to be really careful that you are not taking everything I am saying as being applicable on your campus, so I definitely would talk to your own IRB professionals.

Alright, so some tips for success. The first tip I have is really, and this is something that Adriane echoed in episode 43, don’t skimp on the details. If you think that your IRB is going to want something on your project, you should include it. The more detail, the better about your project, and the IRB really wants to help you to conduct your research, so they will talk you through the kinds of things they need to know, they’ll let you know if anything is missing from your project or your application. But from the very beginning, you should really try to offer as much detail as possible. The second tip I have, is when you’re in doubt, ask questions. If you’re not sure what level of review you’re going to fall under, or what kind of paperwork you need to do, or if you have to do CITI training, or any of those kinds of things, call your IRB and ask them a question. I have memorized the number for my IRB locally.

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And when I’m in the midst of my application and heavy research periods, I’m calling them frequently, to make sure I’m giving them what they really need. Recently for example, I called my IRB because I’m going to be involving several national organizations in a recruitment strategy for a new national project we’re working on here at the research unit. And I wanted to know if I needed to include letters from each of those organizations, really clarifying how they were specifically going to be engaged in the recruitment process. And as you can imagine, that would have added an extra layer, in drafting those letters and getting them signed and there’s four or five organizations we’re planning to work with; and I checked with my IRB and said, “Is this an exempt project? Is this something you need me to do or can I just be very clear about the recruitment strategies and protocols?” And they said, “No, you don’t need to include any of those letters.” So sometimes it actually saves you some work. And you want to make sure you’re giving them all they need, but also check to make sure that you’re thinking they might need something when actually they do not. The third tip that I have is that strong IRB applications breed strong IRB applications, and what I mean by that is that it is not uncommon that I go back to a previous IRB application that is using a very similar research design, and to take some of that language from my earlier application to inform a later application. And this is specifically true around things like consent documents or areas of my protocol, where I know things aren’t going to change, in terms of a data management plan, or something where I already have something, I know it’s been approved by the IRB and I can modify it and use it in a new proposal. So this is something I think to keep in mind is the stronger proposals you have from the beginning, the better your proposals are going to be later on. The fourth tip that I have is to really get to know the process and the players in the IRB at your institution. If you have not yet engaged with them and know you need to, it’s important to go and meet with someone in the IRB office, get on a first name basis with them so you can check in with them and feel comfortable asking questions if you need to, and really understand what their process is. And again, it might be different than some of the things that I’ve mentioned in this episode, so look at the website, see hwat the paperwork is, figure out how you can submit it – is it something that can be submitted via email or online or is it paper based. What are all the kinds of things that you might need to know to be successful and one of those pieces is definitely when the committee meets on a monthly basis, so that you can make sure to build in your timeline as much time as you might need to. My fifth tip, is if you have the opportunity, I would recommend joining your IRB and being on the committee for a term, so that you really understand what they do and the kinds of questions they’re asking. And this can really give you a deep knowledge of the federal regulations, and a deep knowledge of the review and it’s certainly informed my own work that I sat on an IRB for several years at a previous institution. Even as I move from institution to institution, and things change, I really feel like I have a strong foundation about the kinds of things I need to know in a general way about the IRB. The sixth tip that I have is to remember the purpose of the IRB. If at any point you get frustrated with the process, you feel it is too much paperwork, it feels daunting, maybe you have a bad experience as you’re working with the IRB, remember the core reason why we have this to begin with. And that is to make sure that our research subjects are protected and that we’re not putting them through any level of risk that we might need to in order to get the results for our research. And I think that is such an important reason and component of why the IRB exists, so I always think it’s a little bit helpful for me, maybe when I get frustrated with the logistics, or the level of detail or just the time that it’s taking, I always remind myself of the overall reason why it’s there. And so that’s something to keep in mind. And then the seventh and final tip that I want to offer is to really try to seek out a mentor, or to look for examples of people who’ve been successful with the IRB. And this is something that again I would say is institution specific, you’ll want to look for people who’ve gone through your institutional process, and who’ve been able to that in a successful way. And, if you can, join someone else’s IRB application, maybe you are working as co-investigator, or as research staff, where you can see kind of what the process looks like. The very first time I ever went through IRB was as a graduate student on a faculty member’s project. And that really helped me to see the whole process of that particular institution where I was, and to get a general sense of just what the steps were and what I needed to know that would be included. The other thing too I think about that is finding a mentor, you can also look for examples from people who might be willing to share them in your department. Or just check with your IRB office, because they might have things they can share with you that would be really helpful for you doing an application, especially if it’s for the first time.

So those are my tips for your success with working with the IRB. I guess an extra tip, a final, final tip that I would offer is to remember to be nice and polite

[*laughs*]

To your IRB committee and your IRB professionals. They are working as hard as they can to really help you to get your research through this process. And I think sometimes it can feel like the IRB is a little bit combative, you know we’re fighting against them to get our research done, and I really think about it in the opposite way. The IRB is meant to be an ally, and they’re really trying to help us to get our research done in a way that is ethically and that is protecting our subjects. So just keep in mind, the nicer you are, the happier they will be to see you come through, and they will be that much more willing to work with you and help you get your research through.

So hopefully this episode was interesting in terms of learning more about the IRB. Please feel free to check out the show notes, if you want to see some additional resources that we’ll be posting there, and thanks so much for listening! I’m Katie Linder and we’ll be back next week with another episode.

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