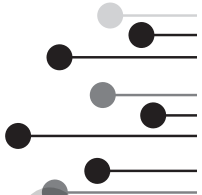


CHAPTER
2

IRB Considerations Hidden in Your Research Study and Coursework



Chapter Purpose

This chapter applies regulations in IRB protocols to the unique needs of a research project for which researchers will seek human research participant approval—reviewing key areas where IRB protocol sections apply to a study, exploring research design and methods through an IRB lens, and helping student researchers and faculty who work with human participants successfully prepare for protocol development and submission. This exploration includes ethical considerations focused on time commitments for research participation, compensation for research participation, and data collection guidance that emerged with the COVID-19 pandemic. In addition, I discuss issues associated with confidentiality and look at identity, power, and conflict as ethical mandates in the context of a study, focusing on researcher roles and issues of position, positionality, and embodiments. Later in this chapter, I strategize about how students and instructors can plan to use coursework to advance IRB protocol development process.

Check Locally: State- and Institution-Level Policies of Human Participant Research

What we do in higher education tends to be connected to campus roles and grounded, in some way, to work in local program or institutional contexts. From ritualistic activities in classes and special events on campus to routine office hours and ongoing service commitments, we often start or end our work where we affiliate institutionally. For research projects, this is particularly clear

Learning Objectives

- Understand regulations related to sampling and selecting participants and identify ethical considerations in data collection instruments and procedures
- Articulate considerations for storing and managing participant files during data analysis and specific protections in reporting results and findings
- Reflect on how the intersection of identity, power, and conflict in the context of a study shape interaction between researchers and research participants and, ultimately, outcomes of data collection
- Explain how the principle of “no retrospective consent” requires researcher to plan ahead and anticipate when to secure IRB protocol approval
- Discuss strategies to leverage graduate or undergraduate classes to conduct IRB-approved studies, including data collection for thesis and dissertation research

with requirements for research protocol review and approval from your campus IRB. While researchers may initiate projects off campus and situate studies in sites far from where they interact with each other in their faculty or student roles, they must follow procedures set up under an institutional system of research governance. If your research involves human participants and is done under the auspices of your work as faculty, staff, or student, then you can expect to work with your campus IRB office to ensure compliance with federal, state, and/or institutional IRB policies.

Over the course of the latter-half of the 20th century, government-sanctioned and government-executed atrocities in human experimentation led to violent brutality against vulnerable groups in the United States and countries around the world that often resulted in physical pain and death. The exploitation and maltreatment associated with these events prompted public outcry and condemnation—and responses from governmental organizations to guard against abuses in biomedical and behavioral science experimentation in the future. What emerged was the *Nuremberg Code* and *Declaration of Helsinki*, abroad, and the *Belmont Report* and Common Rule in the United States. As a legal remedy and a set of statutory safeguards, the Common Rule sets up a system of research governance and guides review of research protocol on your campus. But while the Common Rule underpins this system of governance, what you do in the IRB protocol review process on your campus needs to be your focus.

At the local campus level, where students and faculty often initiate projects that involve human research participants, policies, procedures, and practices tend to shape researcher experiences in IRB protocol review and approval. Using the Common Rule and federal compliance with oversight from the US Department of Health and Human Services, most IRBs share characteristics, including procedural steps, forms, and records. As a process subject to regulatory oversight, IRB review frequently follows a similar course and orders general compliance requirements as follows (and as seen in [Figure 2.1](#)):

- **General project information**, including project title, researcher title and contact information, project funding sources, data sources/types, participant demographic categories, potential risk exposure, and data collection dates/instruments/procedures
- **Study procedures and protections**—with descriptive, step-by-step details related to project background/purpose/questions, participant sampling/recruitment and sample characteristics, data collection procedures, project risks and minimization of risks, study benefits and outcomes, confidentiality procedures
- **Guidelines on approval modifications with changes to research procedures**, from unforeseen or unusual conditions—the COVID-19 pandemic—that require you to undergo an accelerated review or where a

Figure 2.1 General Requirements in IRB Protocol Review

General project information
Study procedures and protections
Guidelines on approval modifications with changes to research procedures
Consent forms and bills of rights (if applicable)
Letter(s) of permission (if applicable)
Data collection instruments and recruitment material
Researcher qualifications

blanket statement that authorizes changes to protocols that meet a specific, narrow set of criteria

- **Consent forms and bills of rights** (the latter, if applicable) for participants—including minor assent forms/parental consent forms, if needed, and video/photographic media release form, if needed
- **Letter(s) of permission** from gatekeepers/sponsors at site(s) where you will recruit and collect data, if applicable
- **Data collection instruments and recruitment material**, including flyers, text/email/mail invitation letters, and social media posts
- **Researcher qualifications**, including a curriculum vita/resume, if requested

Of course, local IRBs vary in many ways, too, including asking for information/material in a specific order and requiring additional forms/information than what appears in the list here. Your best bet is to consult your IRB office or committee early and frequently as you develop your protocol.

You can see how standard IRB review is when you look across institution of higher education and observe how compliance procedures tend to look alike. Indeed, general features of campus IRB guides or manuals relate to IRB authorization, organization, operations, policies, and procedures. Further, institutions tend to include guidance on levels and outcomes of IRB review and regulatory protections for vulnerable groups. I list these frequently shared features of campus IRB guides in the callout here.

General Features of Campus IRB Manuals/Guides

- Federal IRB regulations—Common Rule, Belmont Report, federal legislation
- Campus research governance authorization, organization, and operation
- Campus roles and responsibilities related to human research participation protections/IRB
- Common/general definitions related to IRB protocol approval, including research that qualifies as/is subject to human research participant oversight
- IRB review procedures, including levels of review and outcomes of review, and protocol submission processes and systems
- Regulatory/policy provisions for IRB protocols, including protocol sections related to recruitment, consenting, and collecting data—procedures—from/with participants
- Regulatory/policy provisions to protect vulnerable populations and greater-than-normal risk procedures and use of deception in procedures
- Contact information/location of campus IRB staff and office

Of course, even with multiple common elements, campus IRB guides vary in how they present similar or overlapping information. For example, Texas Women's University (2018, p. 15) IRB guide states simply what the institutional function of its IRB is: "The function of the IRB is to review and approve, require modifications in, or disapprove all research activities with human subjects." In somewhat more technical terms than Texas Women's University, Indiana Wesleyan University's (2017, p. 6) IRB guide offers the following statement on its IRB function: "The Board will uphold the Code of Federal Regulations Title 45, Part 46.108, 'IRB functions and operations' and function following the guide of the Code of Federal Regulations Title 45, Part 46.103, 'Assuring compliance with this policy.'" More directly, the Indiana Wesleyan University's IRB guide states: "The IRB has purview over all research that involves human subjects" (p. 6). More on an operational definition and distinguishing characteristics of IRBs in Chapter 3!

In another example that relates to definitions of human participant research and eligibility for regulatory oversight and review of research, the University of Michigan IRB—Health Sciences and Behavioral Sciences (2016, p. 4) includes a brief question that researchers must ask themselves at the start of the IRB protocol approval process:

The first question that must be considered is whether your project fits the regulatory definition of *research*, and, if so, whether it involves *human subjects*. If your project constitutes human subjects research, you are required to submit an IRB application.

Similarly, the University of Tennessee Knoxville Institutional Review Board (2012, p. 14) offers the following advisory comment to campus researchers near the start of its manual: “Prior to preparing a research application, investigators should determine (1) whether the project involves research, as defined in federal regulations, and (2) whether the project will involve human participants.” Still, the basic message in these examples is similar: check first if your study requires/qualifies for IRB review.

While researcher training on ethical research principles and research governance tend to be required by campuses, and be offered through the Collaborative Institutional Training Initiative (CITI), IRBs may use slightly different approaches/requirements. In the case of Salem State University (2017, p. 7), a training requirement is stated clearly: “Faculty, staff, graduate and undergraduate students submitting proposals to the IRB must obtain training through the Collaborative Institutional Training Initiative (CITI), Social Behavioral module, and present CITI certification as part of their IRB proposal as supporting documentation.” In another example, Rutgers University (2016, p. 21) poses a question and responds to the question:

DO I NEED SPECIAL TRAINING? Yes. All persons planning to conduct human subjects’ research—faculty, staff, students, and faculty advisors of students—must complete an online research ethics and compliance education program, prior to IRB approval of proposed human subjects’ research, including research that may be deemed exempt. The online program is called Collaborative Institutional Training Initiative (CITI Training).

In another example, Plymouth State University Institutional Review Board (2016, p. 10) includes a provision for a three-year training cycle: “Plymouth State University requires all individuals involved in the conduct of human subjects research to complete human subjects protection training [via CITI] and to recertify every 3 years. IRB approval will be withheld if these training requirements are not met.” More on variations in IRB protocol approval approaches at the campus level later in this book, including a discussion on campus IRBs in Chapter 4, Chapter 5, and beyond!

Collaborative Institutional Training Initiative Website

<http://about.citiprogram.org/>

IRB Connections to Your Research Study

Most researchers start their formal IRB protocol approval process in an online platform or an electronic form on their desktop. Wherever you are in the course of a study, human research participant work tends to be done directly in the contexts of a research project—from initial conceptualization, review of the empirical and/or theoretical literature, development of a research framework, design of a methodological approach, and reflection of researcher roles—so a natural place to work on an IRB protocol is in thinking about and writing the dimensions of a proposed study. In fact, at the very early start of a project, setting up a system to identify and mark—by highlight, cut and paste, track changes, comments, etc.—what study material can be used to complete an IRB protocol will benefit you as you get to the point where you need protocol approval to collect, analyze, and manage research data.

Before you go down the route of IRB protocol development, you need to consider if your study meets the Common Rule requirements for human subjects research. You can find the regulatory definition of what constitutes human subjects research in Chapter 1. If you need to consult your IRB office to confirm whether your study qualifies as human subject research, plan to reach out and inquire. As a first step, your campus may have a formal process to determine if your study meets the definition of human subject research. If your study meets the statutory requirements, you can plan to document connections between IRB protocol sections and dimensions of research projects. Quite literally, you can use sections of a thesis or dissertation, for example, in sections of an IRB protocol—for example, details about a research sample and data sources from a dissertation proposal can inform IRB protocol requirements to describe sample characteristics and recruitment procedures. You can see these connections in [Table 2.1](#) below.

Table 2.1 General Connections between IRB Protocols and Social/Behavioral Science Research Proposals

General IRB Protocol Section	Details of IRB Protocol Section	Related Research Proposal Component
Study background	Research project summary; research background/problem; and research questions and/or hypotheses	<i>Introduction-research context; research purpose and significance, problem, questions; empirical literature review (concise summary); conceptual literature (brief description)</i>
Participant sample and recruitment procedures	Study population and sample demographic description; identification of research sample as	<i>Research sample and data sources, including descriptions of sampling frame and/or sample strategies</i>

General IRB Protocol Section	Details of IRB Protocol Section	Related Research Proposal Component
	vulnerable category, if applicable, and descriptions of extra protections (per regulations) if applicable—vulnerable category/research sample; description of participant recruitment procedures, including use of a screening tool and deception, if applicable; description/inclusion of recruitment material, including text of written recruitment material and script of oral recruitment protocol; description of consent procedures and inclusion (attachment) of consent form for all participant groups, including minors; description of broad consent, if applicable	<i>(specific sampling strategy and application of strategy), description of general group characteristics of population/sample, and discussion of ethical treatment of research participants</i>
Research methods and study instruments and procedures	Detailed description and inclusion (attachment) of data collection instruments, including instruments translated into languages other than English; descriptions of data collection procedures—including details of all procedural steps in context of data collection; time commitment for each step in the data collection process; compensation for participation in procedures, and deception in data collection procedures, if applicable	<i>Data collection instruments, including a description of connections between research questions and survey or interview questions, if applicable and a descriptive list or account of elements of data collection instruments; data collection procedures, including justification of procedures, links between design and procedures, and detailed descriptions of procedures</i>
Study risks and minimization of risk	Descriptive summary of potential risks to participants associated with study procedures and researcher strategies to mitigate risks	<i>Research sample and data source, including sampling strategies and ethical treatment of research participants; data collection instruments and procedures</i>
Participant benefits and study outcomes	Descriptive list of direct benefits to study participants and general benefits to communities/society; summary discussion of how study risks are reasonable, viz. potential study benefits; description of anticipated scholarly outcomes related to the research purpose	<i>Research purpose and significance, research problem, questions; empirical literature review (concise summary); conceptual literature (brief description); limitations and delimitations, including a discussion of the scope of the study</i>

(Continued)

Table 2.1 General Connections between IRB Protocols and Social/Behavioral Science Research Proposals (Continued)

General IRB Protocol Section	Details of IRB Protocol Section	Related Research Proposal Component
Confidentiality/data management and storage procedures	Descriptive summary of strategies to maintain confidentiality of participant information; specification of plans to securely store and access research data/study records, including identifiable data, coded data, and deidentified data; descriptive list of steps to code/deidentify study records; discussion of final disposition of research data, including long-term storage and/or destruction of data files	<i>Data collection procedures, including detailed descriptions of procedures; data analysis procedures, including processing of research data (e.g., survey data, digital audio and video recordings), and descriptive list of analytical procedures</i>

While there is not a one-for-one exchange of information from a proposed study to an IRB protocol, procedural dimensions of a study can generally be used to inform protocol sections.

Study Background and Initial Justification of a Project

If any section of a research proposal and IRB protocol align well, the research framework of a proposed study and study background from an IRB protocol do. This is not quite a cut and paste text job—but probably as close as you can get. In fact, as you frame an investigation with a statement of the research problem (gaps in current knowledge and practice), research purpose (what you hope to do and accomplish in a study), and research questions (that guide what you do in the field—what you look for, where you go, and with whom you interact), you can move information over to an IRB protocol section that requires you to articulate a brief statement about the research context. Here, you can briefly summarize the broad research contexts and specific patterns of the empirical research and theoretical literature, offer a concise description of the research problem, and include research questions and/or hypotheses. You can see these direct connections in Kemie’s (2018, p. 4) dissertation draft, where he presents his study’s primary research question—“What factors shape African American students’ participation in student equity program development in California community colleges?” Earlier, in his IRB protocol, Kemie (2017, p. 2) includes the same question: “What factors shape African American students’ participation in student equity program development in community colleges?” Similarly, Franco (2017) included two primary research questions in his dissertation draft as follows: “Accordingly, the

following questions guided this study: (1) What factors shape the transition experiences of first-year, first-generation foster youth in comprehensive regional public universities? (2) How do family and social backgrounds influence college transition of first-year, first-generation foster youth?” In his IRB protocol, Franco (2016) presented the following research question: “How do family and social backgrounds influence college transition of first-year, first-generation foster youth?” You can see in both Kemie’s and Franco’s work that the research questions carry over nearly directly from a proposed study to an IRB protocol.

In a similar pattern, you can slightly reshape a research context and problem—informed by and grounded in the literature—from your proposed research study to your IRB protocol. Here, summarizing what justifies your research project as a synthesis of the major themes in the literature can function well in an IRB protocol. For example, Franco (2016) included the following summary statement on the research problem in his IRB protocol as a way to articulate the project’s background:

Most research on foster youth that exists revolves around the K-12 educational experiences of these students. Research also exists articulating the outcomes and conditions foster youth face after high school graduation, but there is little research exploring foster youth in the college setting. While there is an increased focus on higher education, the research as a whole is in its infancy.

In his draft dissertation, you can see how Franco’s (2016) work on the study’s research problem connected well to his IRB protocol:

With the documented low levels of educational achievement and limited insight into the challenges facing foster youth, we know little of the lived experiences facing college-age foster youth in higher education. Researchers have sought to understand how and why these students succeed in college and how the first-year transition experiences affect their overall achievement, (Davis, 2006; Wolanin, 2005; Barrat & Berliner, 2013). We have a basic understanding of the challenges that foster youth experiences have on students, but we need to understand more about their experiences to help staff, faculty, and administrators assist foster youth overcome the obstacles that prevent them from achieving their educational goals. The lack of comprehensive research on foster youth in higher education has left these youth from being identified, which has caused many college and university faculty and staff to ignore this population (Barrat & Berliner, 2013; Davis, 2006). This lack of research has prevented not only the population from being identified but also prevented services from being provided to these students, which has prevented foster youth from receiving the services needed to improve their outcomes. Most studies have focused their research on K-12 issues, physical, and mental health challenges and the

conditions leading up to higher education, but little has been recorded during their time in college (Wolanin, 2005). While there exists today a renewed push for further research on foster youth in higher education, there has been little data to explain the low retention rates we see from foster youth in their first-year in higher education.

Here, Franco used a descriptive summary of the research problem presented in his draft dissertation for his IRB protocol.

Anticipated Outcomes and Benefits—Connecting a Project to the Involvement of Human Research Participants

When you discuss the background of a research project in an IRB protocol, you may consider including a description of the study's significance and/or rationale, but you need to be cautious and limit what you include in a context and background section of an IRB protocol. Indeed, the significance of a study—why communities of scholars and practitioners care about a project and why the research work justifies interaction with and involvement of human participants—can be used to analyze a risk–benefit ratio and describe benefits to participants and others in society, two key IRB protocol requirements. A study's significance can be drawn from the second part of a research purpose—what you hope to accomplish—and a discussion of the study's implications for future research and practice. In her dissertation proposal, for example, Tatiossian (2018a, p. 4) describes the implications of her proposed study for school stakeholders, who “can use the information from this research to better understand the circumstances under which significant reform can take place.” She goes on to discuss how the implications of her study extend to research on charter schools. Using this information in her IRB protocol, Tatiossian (2018b, p. 26) indicates that her proposed study potentially benefits members of society, including check-marking the following statements:

- Contribution to the literature and broader knowledge base on your topic
- Improvement in a program, organization, or agency that serves the population under study

When asked to report on risk-benefits in her IRB protocol, Tatiossian's (2018b, p. 27) work on the implications of her research project can inform her check-mark of two of the following three items:

- The potential benefits to the research participants justify exposure of the participants to the risks.
- The potential benefits to humanity justify exposure of the participants to the risks.

Here, you can note that most studies in the social sciences, as Tatiossian's study is, generally do not directly benefit project participants. Unlike in the biomedical and health sciences—and even behavioral science—fields, where participants may experience a direct benefit from a drug therapy, exercise activity, or mental health intervention, social science studies tend to limit direct benefits to participants and, instead, contribute to broader needs of the community and society. This observation may be disappointing for graduate students and early career researchers, but an accurate understanding of how a study benefits participants is critical to justifying it.

In addition to a study's significance, a discussion of the limitations and/or delimitations of a study can be used to inform responses to IRB protocol requirements related to risk-benefits and benefits to participants and society. That is, when you discuss the boundaries of your study—the limitations or conditions that are generally beyond your control as a researcher and delimitations or conditions that tend to emerge from initial choices that you make as a researcher—you further specify how your work relates to others and society. For example, Kemie (2017) offered a limitation to his study that could be used to inform the benefits of the work to practice: “Lastly, rather than focus on student's perspective alone to develop theory, the study also examines perspectives of those in non-student roles— faculty and coordinators—for a more holistic view of factors affecting student participation” (pp. 6–7). In his IRB protocol, Kemie (2018) offered the following benefits to community colleges: “(1) Improve student equity program development at California community colleges. (2) Contribute to body of research that exists about African American community college students who are beneficiaries of the programs in which they are involved as program developers. (3) Improve the role of students as program participants in the discourse of equity program development at community colleges” (p. 5).

Participant Recruitment—Sampling, Inviting, and Selecting Individuals to Participate

As you conceptualize data sources for a proposed research project, you tend to focus on initial details on the context of early data collection: where, when, and how you will locate and access prospective participants. Here, exploring a research setting and context at a research site or sites, if applicable, and the strategies or techniques that you plan for site and participant sampling and steps in participant invitation and selection relate directly to what a campus IRB generally requires researchers to include in a protocol. For example, in her IRB protocol, Tatiossian (2018b, p. 13) explained how she planned to work with a gatekeeper for recruitment and sampling:

I will ask the Executive Director or Principal whom they think I can interview next from the identified teacher categories (sampling groups).

I would expect that they provide me with the name of a seed teacher or teachers who would be interested in participating in the study. This approach would be the first level of contact. After I meet with prospective research participants identified by the Executive Director or Principal, I will try and establish the second level of contact by providing them with the opportunity to learn more about this research project and decide whether they want to participate in the study and review/sign the consent form. This seed teacher or teachers will then direct me to another seed teacher or teachers who may have interest in this study.

Using pseudonyms for school names, Tatioosian (2018a, pp. 41–42) detailed steps in participant sampling in her draft dissertation proposal, focusing on the selection strategy and work with a gatekeeper in the field:

I used a combination sampling strategy of stratified purposeful, snowball, and theoretical sampling. For my stratified purposeful sampling strategy, once the gatekeepers gave me official permission to use the site for my study, I requested a listing of the charter school's entire staff roster and identified teachers by their direct experiences with the takeover situation, between May 2012 and September 2013, for a stratified purposeful sampling strategy. I requested that the school's current principal, at the time of the takeover, identify the seed teachers (teachers who came to work at Crepe Myrtle Elementary Charter School (CMECS) from the takeover organization's other school - Cypress Charter School), new teachers (those hired new to the organization, but not necessarily new to the profession), rehired teachers (those teachers who were employees of CMECS prior to takeover and who were rehired by the takeover organization) and not rehired teachers (those teachers who applied at CMECS during takeover, but were not chosen to continue). Capturing the voices, of this stratified purposeful sample of teachers was critical to ensure that all aspects of organizational change, from all perspectives, were gathered. After identifying the stratified sample of teachers, I used the snowball approach to lead me to those individuals who actually participated from each identified subgroup (seed, new, rehired, and not rehired).

Here, you can see the links between what Tatioosian planned—apparent in her IRB protocol—and how she followed general steps from her IRB protocol in fieldwork to sample, recruit, and invite participants, which she detailed in her dissertation proposal.

In some cases, what you propose in a research project informs what you include in an IRB protocol—but may change over time as your access to research sites, gatekeepers, and/or sponsors evolves in the field. You can see this pattern in Bergstrom's (2017, p. 43) dissertation research work, where he planned to “ask the current instructor to recommend an initial sample of students to interview.”

Continuing, Bergstrom said: “From then on, I will use [grounded theory’s] theoretical sampling to find participants who best suit my research needs.” Later, in his IRB protocol, Bergstrom (2019, p. 13) outlined updated recruitment procedures that reflected changes from working with folks at his recruitment sites. Here, he described “[e]mail recruitment message to all students enrolled in a relevant physics class at my campuses, with permission of their instructor. The email will simply be a digital version of the flyers I post on campus.” Bergstrom also included plans “to visit physics classrooms at [research sites redacted] to give a brief recruitment speech.”

If you plan remote data collection, then you can use what you propose for virtual recruitment, consent, and research activities in the IRB protocol. In the case of the IRB protocol that Paez (2019b, p. 15) developed, remote data collection started with recruitment, where he briefly described how he would interact with prospective research participants: “I will contact them via email, phone, and/or in-person, always with an acknowledgement of their contributions to my personal and professional growth.” For screening participants, Paez (p. 30) said: “During screening, if participants have additional questions that require a more in-depth response, I will suggest a brief Zoom session to resolve any issues or respond to questions in person.” While these examples illustrate social science research studies that use qualitative design and methods, the “where, when, and how you will locate and access prospective participants” needs to be included in protocols for studies across research contexts, including experimental and quasi-experimental studies, studies that use survey data collection—like public and restricted survey datasets—and studies that rely on administrative or institutional data, including FERPA and HIPAA protected data.

Data Collection and Analysis: From Interacting with Participants to Storing and Managing Research Data

While you can see direct connections between a study’s background and early data collection activities—sampling, recruiting, and inviting individuals to participate in a study—and an IRB protocol, an overlap in procedures and IRB requirements is a bit murkier. To be sure, campus research governance policies generally direct you to detail steps in data collection procedures planned for participants and any intervention(s) that you will use with participants. But while IRB regulations tend to require you to detail data collection procedures, in a step-by-step fashion, they may not explicitly ask you to articulate what you will do to make sense of information that you gather from people. That is, you will need to describe data collection and analysis procedures, in general, but specific steps in analytical work usually do not need to be detailed. By contrast, data collection procedures—and related study interventions—need to be detailed in depth and stepwise. Unlike in a research proposal, where descriptions of data collection tend to be detailed, the IRB protocol will require more minute detail of each sequential and recursive step of the process so that these details can be scrutinized in the review process.

You can plan to move descriptions about initial to final contact, field entry to field exit from a proposal to a protocol—but then you will need to reshape what you present to expand and elaborate on the descriptive details. Quite literally, Tatiossian (2018a) described, in her dissertation proposal, how she “scheduled all interviews within a period of one month with each set of interviews representing the stratified purposeful sample; that is, having each set of interviews include seed teachers, new teachers, and returning teachers” (pp. 48–49). Later, in her IRB protocol, she check-marked that she would use “[a]udio recordings, video recordings, and/or photographic images” in her data collection procedures. Still later in her IRB protocol, as an early and initial step in the process, Tatiossian (2018b, p. 15) described how she would do the work to contact folks to invite them to participate in the study, saying:

I will request that the school’s current principal, hired after the takeover, identify the seed teachers (teachers who came to work at SMBCCS [Santa Monica Blvd. Community Charter School] from the takeover organization’s other school), new teachers (those hired new to the organization, but not necessarily new to the profession), and returning or rehired teachers (those teachers who were employees of SMBCCS prior to takeover). I will send an email to the executive director, board chair, and principal of SMBCCS, as they are the gatekeepers of this study. The email will appropriately introduce myself, explain the research purpose, communicate the expectations for participation, and underscore the confidential and voluntary nature of this study.

For studies that use remote data collection, step-by-step discussions of procedures mediated by technology can be presented, as Paez (2019b) did. Here, Paez (p. 19) referenced data collection with personal and group interviews, offering the following descriptive details about virtual interaction via Zoom in his IRB protocol: “The individual interviews will be approximately 90-minutes in length, with the possibility of a brief follow-up if needed. Interviews will be digitally audio recorded and will occur in-person or via online platform (e.g., Zoom).” For focus groups, he (p. 18) shared, “Each focus group will last approximately 2-hours, be facilitated in-person and/or via Zoom (or other online platform) and be digitally audio recorded” Later, Paez (p. 31) articulated how Zoom interviews would go, saying:

For participants who will participate in semi-structured focus groups and individual semi-structured interviews via Zoom (or other online platform), I will ask them to review, sign, and send via email the consent form to me prior to the semi-structured focus group session. If they have questions about the consent form, I will be available via email or Zoom to discuss them prior to the semi-structured focus group session or individual semi-structured interview.

Paez indicated that he would connect with participants after interviews as a form of member check, if needed, saying: “If after the interview participants feel they would like to add something, I will schedule a brief 20–30-minute discussion by phone, zoom, or in person if possible.”

From a perspective of human research participant protections, how you handle personal information—what you do to manage the identifiable, coded, and deidentified data about research participant—forms the focus of IRB protocol work, and you must detail steps to securely store and manage data. So rather than detail each step to segment and code text in a thematic data analysis approach, you will need to discuss how you will prepare and work with data throughout the analytical process. Where can you start to look at the connections between a research proposal’s details in data collection and analysis and your IRB protocol is in a discussion of ethical treatment of participants in recruitment. For instance, in his draft dissertation, Franco (2016, p. 33) noted more generally that he “created pseudonyms and remove any personal details that can be used to identify them, such as any major or any identifiable characteristics that can be used.” Then, in his IRB protocol, Franco (2017, p. 5) went into greater detail:

Any information that is obtained in connection with this study and that can be identified with subjects will remain confidential and will be disclosed only with subjects’ permission or as required by law. Subjects names will not be used in the reporting of findings, and subjects will be assigned a random, three-digit number to protect subjects’ identity. Finally, no personally identifying information will be used in published reports, including institutional and/or programmatic affiliation.

You can move to details of data collection for inspiration on data storage and management strategies, too, as Franco did above. A final consideration in how you manage, store, and use data about participants focuses on presenting and disseminating research results. In fact, what you do here relates to your efforts to deidentify and code data in the analytical process. As you remove personal identifiers and redact personally identifying information about participants from data, you can develop a coding scheme that complies with campus IRB policies. Across study contexts, whether social science, behavioral science, or health science research and with quantitative or qualitative designs and methods, detailed, step-by-step descriptions of procedures need to be detailed in the protocol.

Special Topic: Identity, Power, and Conflict in the Context of Your Study

While not necessarily a direct part of an IRB protocol, discussions of identity, power, and conflict from your research proposal, if included, may relate to the recruitment and invitation of individuals to participate in study procedures. To be

sure, when working with members of vulnerable groups—children, individuals who are imprisoned, individuals with impaired decision-making capacity, and individuals who are economically or educationally disadvantaged—you must discuss safeguards/special protections in recruitment, consent, and study procedures. However, when planning a project with folks who are not members of a vulnerable group or groups, you can use and elaborate on what you detail in a research proposal. In research proposals where you describe your researcher roles, research setting(s), data collection procedures, and data analysis procedures, you may consider how details can be used to discuss issues related to identity and power in recruitment and consent procedures. For example, Paez (2019a, p. 97) described potential issues with former students who may participate in his proposed study:

Paradoxically, the roles I occupy could also leave me vulnerable to confirmation bias, thereby limiting the scope of the project. There is a possibility my interactions would be limited to surface examination of the topics because we may believe we “already know it to be true.” Participants may feel less inclined to share with depth and nuance if they see me as an ally and assume I “get it.” If any of the participants are previous students, they may interact with me in a way that shows respect but could also be viewed as deference. In other words, they may feel intimidated to share openly, or in ways that contradict or challenge what they perceive to be my assumptions.

Similarly, Johnson (2018, p. 17) talked about how his professional position, racial/ethnic identity, and gender identity may emerge in interview contexts and be challenging for participants. In this discussion, he said:

In addition to researcher bias, participant reactivity serves as my influence on the setting and my research participants. I run the risk of disrupting the ongoing social and institutional relationships when sampling, speaking to, and interviewing participants and informants. My role as an academic advisor can potentially affect data collection and participants as they may perceive my role as an advisor to be a position of power and feel less inclined to share personal details about their experiences, possibly out of fear of judgment and/or lack of trust. Additionally, while I am a member of the Black community, I am a Black male, and research suggests that Black women experience life differently due to their intersecting identities of being Black and female. As an educated Black male in a non-STEM field, my research participants may perceive me as someone who is privileged and may not understand what it means negotiate additional feeling of oppression based on their double-minority status.

The issues of power and identity that Paez and Johnson raise, respectively, can be detailed in an IRB protocol when discussing recruitment procedures—where use of strategies to protect participants in recruitment, consenting, and interviewing may be appropriate.

Human Research Participant Considerations in Your Coursework

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Spending so much time and investing so many resources in classes—for undergraduate and graduate students who are working on a research project that involves human participants—a natural place to situate IRB protocol development is in coursework. As a student researcher, one of the first considerations for you is *when* to secure an approved IRB protocol. In many cases, a decision about timing of IRB protocol submission has been structured for you by program design. Through a curricular sequence and/or series of events—qualifying exams or dissertation proposal hearing, for example—you can be directed to work with your dissertation chair or major program advisor to successfully complete a set of courses and exam(s) prior to turning attention to human research participant work. Fine, no problem, this is a reasonable way to approach IRB work, situated in a larger program context and advising relationships aligned with a developmental research approach.

In undergraduate and graduate program contexts, a consideration about when to go through the IRB process may be formally built into the curriculum. Even if set broadly as learning outcomes at the program level, in graduate school settings, students tend to need to meet a specific set of criteria prior to advancing to candidacy, at which point they may hold a dissertation proposal hearing—and this event often precedes IRB protocol development and submission. But why wait to start thinking about human research participant protections, or even drafting an IRB protocol, until these rituals? Going a step further, why wait to submit an IRB protocol until you propose? As you develop a research framework, including a methodological framework, for your study, you may develop and submit an IRB protocol—with chair or advisor supervision. What if data collection or analysis plans change between protocol submission and proposal approval? No need to worry, simply submit a protocol modification and you will be on your way to fieldwork! If you are an undergraduate student and are working on a senior thesis or capstone project that involves research with people—when do you go through IRB? If your program has specific steps for you to follow and/or you are working with a faculty advisor, can you start to conceptualize and draft an IRB protocol earlier in the research process? Here, I argue that this strategy can work well—whether you conceptualize, draft, and/or submit a protocol—to strengthen ties between your research project and human

research participant approval and get you into the field and collecting data more efficiently.

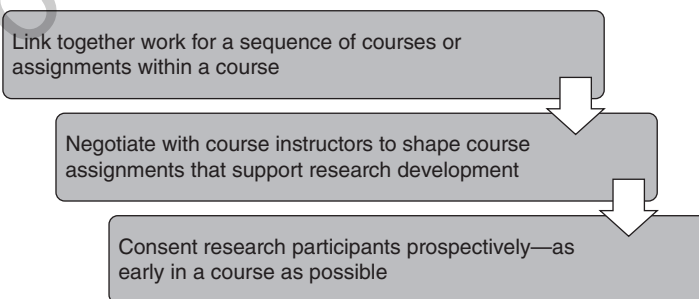
Leveraging Graduate or Undergraduate Classes to Conduct IRB-Approved Studies

As you initiate a research project and develop an early research framework, you have to think about how the project will fit into your broader work flow and current or anticipated professional commitments. As a student, these commitments tend to include courses and other program requirements like qualifying exams and, for the majority of time as an undergraduate and first few years as a graduate student, generally occupy a lot of your attention and focus! As with research work more generally, framing what you do from a research perspective tends to help to align your educational practice with scholarship. Here, reshaping what you are doing or will do for assignment requirements, instructional activities, etc. as a way to situate your capstone, thesis, or dissertation research project in your classes will benefit you as a student researcher and likely advance your research agenda (Figure 2.2).

Link Together Work for a Sequence of Courses or Assignments Within a Course

Given the curricular structure of academic programs—graduate-level, terminal-degree programs, in particular—a first-line strategy to advance your research work as a student is in a course-sequence or a series of assignments in a class. In graduate program contexts, students may have opportunities to situate research for a culminating experience—thesis or dissertation, for example—or IRB

Figure 2.2 Strategies to Leverage Coursework to Advance IRB Protocol Development



protocol development work in the curriculum. For example, the EdD program in educational leadership at California State University, Northridge codifies in the program handbook: “Candidates are assisted in planning, researching and writing the dissertation through research methods courses, Doctoral Saturday Seminars, and meetings with the Dissertation Chair and Committee” (CSUN, 2018, p. 3). In this case, methods courses, field-based courses, and once-monthly seminars tend to link assignment work to dissertation research projects. In fact, in CSUN’s education doctorate program, in the fall term of the second-program year, students enroll in courses that focus on the development of a monograph-length dissertation proposal—including a year-long dissertation seminar in which a major assignment is a draft of the first/introductory chapter, a field-based inquiry class where students work on a literature review, and an advanced applied methods course where a working draft of a methods chapter is the outcome. Within this set of courses, students may opt to align the development of their dissertation study with assignment work—although they are not required to do so and some may change or reshape what they completed for class as they transition to doctoral candidacy and focus exclusively on dissertation research.

Sharing the CSUN doctoral program’s curricular alignment with dissertation research, the University of California Los Angeles’ (UCLA’s) PhD program in higher education (Higher Education and Organizational Change) offers a year-long “research practicum” in which students in their second or third year of study generally enroll (UCLA, 2019). As a three-quarter course sequence, students focus on the design and implementation of a small-scale, action-research-type study—and they can pilot a dissertation research project for their work in the class. In most cases, students draft a summary version of an introductory chapter, then write a short background section that serves as a literature review and a proposed design and methods for data collection and analysis. With a proposal in hand, students move to the field to collect data, or secure secondary data to be analyzed—and work toward write up and discussion of results as a concise version of the final two chapters of a monograph dissertation.

Whether working in individual classes or a course sequence, you have a unique opportunity to develop a research project in curricular contexts. While this work may be conceptual or technical, in some classes descriptively detailing related literature, framing a research problem and purpose, drafting research questions, designing an approach to gather information may also involve logistical work in the field. Indeed, you can potentially plan for the collection of research data—and if these data involve human participants, then you have to consider how you will secure IRB approval before entering the field, administering a survey, etc. Framing assignment work as a pilot study—for example, for a thesis or dissertation—you can use findings to shape an emerging research framework, methodological approach, or specific data collection instruments and procedures. But you can do more, too, if you secure IRB approval prior to pilot data collection. You can use results from data analysis *to start to narrate the story of your research*

project, working on initial patterns and/or emerging themes from early data collection.

Negotiate with Course Instructors to Shape Course Assignments that Support Research Development

There may not be a one-to-one alignment of courses or assignments in a course with capstone, thesis, or dissertation research project development—perhaps because you are not quite set yet to do this work or the course content/learning outcomes or class assignments do not facilitate (or allow discretion for) student application of research project work. In the latter case, you have the right as a student to ask the instructor. Indeed, you have agency to discuss how you can best leverage assignments and instructional activities to learn more about and develop a related program requirement that requires collection of original data and/or original use of existing data. Why not chat with your instructor and negotiate a way to do this? This is a sort of coconstruction of the course and a participatory approach that supports student learning. You may consider the following points in your discussion with an instructor:

- **Frame your discussion in broader program contexts** that require you to complete a thesis, dissertation, etc.
- **Focus on the course objectives and/or learning outcomes** and ask about how reshaping an assignment or assignments align well with what you are expected to know, etc. after completing the class
- **Inquire about flexibility of the topic of an assignment**—for example, from a topic that the instructor selects to one that allows you more discretion to relate the topic directly to your research project
- **Discuss the possibility of swapping a current class assignment for an IRB protocol development assignment** that will allow you to work on sections of an IRB protocol and submit a draft protocol for review

The Principle of No Retrospective Consent

Perhaps the best place to consider IRB connections to your coursework is in the regulatory protections related human research participants. From a research governance perspective, the principle of no retrospective consent requires that researchers obtain consent from the individual (or legal guardian) whose personally identifiable information you seek to collect *prior to* collecting the information. Once you collect personally identifiable information from an individual (living, of course), consent cannot be ethically—under the Common Rule (Pre-2018 Requirements or 2018 Requirements)—obtained after the fact. In some cases, to be sure, consent to use deidentified/anonymized research data already

collected does not need to be obtained—e.g., in the case of retrospective studies. Whether your research project is exempt from consent or not should be determined by your local IRB, not you, so in all cases submit an IRB protocol for review in your institutional or organizational research governance process. With an approved IRB protocol or an exemption determination by your IRB, you will be set to move forward. Not undergoing IRB review and receiving such a notice could put you as a researcher and your institution at risk legally.

From a historical perspective, you can see the progressive development of the principle of no retrospective consent in the seminal documents related to human research participant ethics. As a response to horrific atrocities in biomedical experimentation—where verbal abuse, physical abuse, mutilation, and death often occurred—ethical rules, professional codes, and, eventually, legal statutes and national systems of research governance emerged. Indeed, the *Nuremberg Code*—codifying the very early principles of research ethics that emerged from the Nazi doctors’ trial in 1946–1947—starts with the idea of “voluntary, well-informed, understanding consent of the human subject in a full legal capacity” from the outset (National Institutes of Health). Later, the *Declaration of Helsinki* (WMA, 2013) goes into further detail, explicitly stating that biomedical researchers must consent prospective research participants prior to the start of a study. The exact order and specific steps are clear here: “After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject’s freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.” Like the *Nuremberg Code*, the provision in the *Declaration of Helsinki* starts with the principle that individuals consent freely and need study-related information to inform their final decision about participating in a study. This idea is at work in the following excerpt:

In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

Here, you can see how the *Declaration of Helsinki*, from the World Medical Association (WMA), explicitly details what information needs to be shared with prospective research participants so that consent can be informed and how consent can be refused or withdrawn, once given, at any time and without negative effects.

As one of the first principles of the *Belmont Report* (Office for Human Research Protections, 1979), respect for persons offers insight into why individuals need to be consented in the first place. The underlying assumptions about human beings underscore the need to obtain consent to participate in research: “An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others.” Applying this principle to research contexts, the *Belmont Report* demands that researchers give people “the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.” In broad terms, the *Belmont Report* lists what researchers need to do to consent participants:

- **General information** about the study, including but not limited to “the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.”
- **Language** used to consent participants, which should consider “[t]he manner and context in which information is conveyed is as important as the information itself.”
- **Approach** to consenting participants, which needs to include “conditions free of coercion and undue influence.”

More on consent procedures and consent forms in chapters (Chapter 6 and Chapter 7, specifically) that follow!

Consent Research Participants Prospectively—in Classroom Contexts

While the *Nuremberg Code*, *Declaration of Helsinki*, and the *Belmont Report* built an ethical foundation to guide researchers in consenting prospective research participants, the Common Rule (1981) developed a US regulatory framework to govern consent procedures with human participants. Both Pre-2018 Requirements and 2018 policy revisions (i.e., 2018 Requirements) mandate the use of informed consent and specific steps to document consent (or a waiver of written informed consent). In fact, the 2018 Requirements (Office of the Federal Register, 2018) expressly state that IRBs that oversee research governance for their organizations/institutions will require researchers to give participants a set of information “as part of informed consent” and to document or waive written informed consent.

Not only related to what type of consent but when consent must be obtained from participants, the Common Rule is clear about the sequence of steps in the process: “Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject’s legally authorized representative.” At the outset of fieldwork—before collecting any personally identifiable information to be used for research purposes—you must seek consent from participants. In consenting participants for a current project and seeking broad consent for future work, you have to share “the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.” You can see here that folks need not only to review information essential to informing their decision about whether to participate or not but also need a chance to discuss questions or concerns with you.

The 2018 Requirements include two new requirements that, taken together, present a more holistic approach to consenting participants and moves toward a less technical, more accessible format for presenting written informed consent forms to prospective participants. Here, the Common Rule (Office of the Federal Register, 2018) helps researchers to consider how participants may understand consenting via two integral dimensions of consent procedures that “begin with a concise and focused presentation of the key information” that facilitates “understanding the reasons why one might or might not want to participate in the research.” Overall, the Common Rule pushes researchers to think about what they are asking folks to do *from a research participant perspective* and to shape a consent form with “information in sufficient detail relating to the research” and “in a way that does not merely provide lists of isolated facts, but rather facilitates”—again—an understanding as to why someone would want to or not participate in a project. For specific information on what to include in a consent form, from the regulations, please see “What to Include in Informed Consent” and “Biospecimens in Research Require Additional Information in an Informed Consent Form.”

What to Include in Informed Consent

If you’ve worked on an IRB protocol and/or with your campus IRB, you’re probably familiar with what appears in general informed consent forms. Here’s what the Common Rule (Office of the Federal Register, 2018) says directly must be

included (text from Common Rule, bolded font added by authors):

1. A statement that the **study involves research**, an explanation of the **purposes**

(Continued)

(Continued)

- of the research** and the **expected duration** of the subject's participation, a description of the **procedures** to be followed, and identification of any **procedures that are experimental**
2. A description of any **reasonably foreseeable risks or discomforts to the subject**
 3. A description of any **benefits to the subject or to others** that may reasonably be expected from the research
 4. A disclosure of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the subject
 5. A statement describing the extent, if any, to which **confidentiality of records** identifying the subject will be maintained
 6. For research involving more than minimal risk, an explanation as to whether any **compensation** and an explanation as to whether any **medical treatments are available if injury occurs** and, if so, what they consist of, or where further information may be obtained
 7. An explanation of **whom to contact for answers to pertinent questions** about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
 8. A statement that **participation is voluntary, refusal to participate will involve no penalty or loss of benefits** to which the subject is otherwise entitled, and the subject may **discontinue participation at any time without penalty or loss of benefits** to which the subject is otherwise entitled
 9. A statement that the particular treatment or **procedure may involve risks to the subject** (or to the embryo or fetus, if the subject is or may become pregnant) that are **currently unforeseeable**
 10. Anticipated circumstances under which the **subject's participation may be terminated by the investigator** without regard to the subject's or the legally authorized representative's consent
 11. Any additional **costs to the subject** that may result from participation in the research
 12. The **consequences of a subject's decision to withdraw** from the research and procedures for orderly termination of participation by the subject
 13. A statement that **significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation** will be provided to the subject
 14. The **approximate number of subjects** involved in the study
 15. A statement that the **subject's biospecimens (even if identifiers are removed) may be used for commercial profit** and whether the subject will or will not share in this commercial profit
 16. A statement regarding **whether clinically relevant research results, including individual research results, will be disclosed to subjects**, and if so, under what conditions

Biospecimens in Research Require Additional Information in an Informed Consent Form

If your research project involves biospecimens, then your informed consent form needs to include one of the following statements, per Common Rule (Office of the Federal Register, 2018). These statements relate to broad consent, with the former statement requiring consent to use research data for future studies. Here's the Common Rule text:

A statement that **identifiers might be removed from the identifiable private information or identifiable biospecimens** and that, after such removal, the **information or biospecimens could be used for future research studies or distributed to another investigator for future research studies** without additional informed consent from the subject or the legally authorized representative, if this might be a possibility.

OR

A statement that the subject's **information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.**

As you can see, these statements indicate whether or not biospecimens/information will or will not be used in future research.

A final statement related to biospecimens in research relates requires researchers to include information on “whether the research will (if known) or might include **whole genome sequencing.**”

Note here that the above text is from Common Rule and bold typeface added by authors.

Given what we know about the Common Rule, for students with opportunities to do research related to a culminating project, thesis, or dissertation—how can you plan with the idea of no retrospective consent in mind? Before considering the unique contexts of your proposed or current project, you can likely turn to your campus' IRB site for ready-access to a consent form template. If your local IRB does not have a templated form for consenting participants or if you would like to review sample consent form, please see the appendices here. If you have or will have a working research problem, purpose, and/or questions and a developing sense of what approach to data collection you will use, then you can start to draft a consent form. Of course, you need to finalize plans for data collection—at least in early stages of a proposed project—before IRB review and approval, but a strategy that you can use at this point is to seek *broad consent* so that you can use research data collected as part of a class assignment or in conjunction with work in a course and for a later study. After coursework ends, for example, you would be able to use data collected for the assignment in your thesis, dissertation, etc.

Thesis, Dissertation, and Capstone/Culminating Project Data Collection in Class

Along with a strategy to consent prospective research participants, collecting data for research purposes in class requires you to plan a bit. Whether you are an undergraduate or graduate student—when you start a research project related to a capstone or culminating project, thesis, or dissertation that proposes to involve human research participants—the early questions that naturally arise relate to who, what, where, when, and why in the context of data collection. From initially conceptualizing ideas to formulating plans and strategizing about fieldwork, these features of a project generally precede formal data collection. In fact, the “why” usually relates to your research problem, purpose, and questions, or the research framework that guides a project. This question requires significant work in reviewing the literature and meaningful writing about what gaps in current knowledge and practice relate to what you would like to do in your study. OK, so this work can be done ahead of fieldwork—no worries about IRB yet. As a more conceptual dimension of research methodology, the rationale for why you propose a project may initially operate in the background or connect loosely to descriptive details about data collection. In fact, a research problem, purpose, and questions can be explored at any time and outside the IRB protocol approval process.

While research problems, purposes, and questions may drive a study, what I have observed in my teaching and advising work with students is a student focus on what will eventually form the research site and setting, data sources and sample, and data collection and analysis methods in a project. That is, I tend to see how students frame early thinking about a research project on who, what, where, and when in a study. Whom will I interview, observe, or survey? How will I do all of this work to gather information? These are natural questions early in an investigation and often lead students to next steps in the research process—to explore the empirical and conceptual literature, form a research problem, and draft research questions. Of course, these are foundational steps in a study, all of which lead to methodological work that puts students directly in contact with folks in the field. In the context of class assignments or activities, how do students connect this work to data collection?

For students, common questions that may be asked about class assignment work and research study development follow, and I try to answer these questions in line below. As you proceed with IRB protocol development—during or after completion of coursework—I emphasize close coordination with a faculty advisor/major professor/chair who can generally best support your research needs and respond to your questions about human research participation protections.

- When does a class assignment become a research study subject to campus research governance? What criteria should you use to assess their assignment work? When should IRB approval be sought for coursework that involves human research participants? *In general, if a class assignment*

involves more than practicing a data collection procedure or includes more than a publicly available secondary data without personal identifiers (anonymized), you need to seek IRB approval to proceed. That is, if what you are doing in class involves a living individual or individuals from whom/about whom you collect information or biospecimens and you intend to use the information or biospecimens for research purposes, then you need an approved IRB protocol on file. Even if your research may be exempt, your campus IRB needs to make the determination and you need such a determination on record. When in doubt, consult your instructor, major professor/chair, or campus IRB compliance officer. If you know or anticipate that class activities or assignment may involve the collection of research data from individuals, then plan to work on an IRB protocol as soon as practicable.

- Do I need permission to develop remote data collection procedures and/or virtual research in a class setting? *No! You do not need permission (from your campus IRB committee, at least) to design fieldwork activities and/or develop data collection procedures. Similarly, drafting, describing, and/or discussing procedural dimensions of a study—in a course or advising context—does not require IRB approval. When you move from writing about to using procedures with research participants, you need to secure an approved IRB protocol.*
- Should you conduct a pilot study in a class assignment and, if so, can your findings from such a pilot study in published research? *Yes! I encourage you to leverage what you do in class to develop a research project—including projects that form part of a thesis, dissertation, or culminating experience. If class activities or assignments support the design and/or implementation of a pilot study and you plan to collect research data from living individuals, then, by all means, move forward. Yes, your findings may be used for more than just study development—they can be used to publish study findings (i.e., for research purposes). You will need an approved protocol from your campus IRB—even if your study is in an exempt category—so plan to submit a protocol early in the term! Of course, I advise that you work closely with your instructor and major professor/chair to ensure what you are planning works well for class credit and advances your thesis/dissertation/etc. project.*
- Can you start to recruit research participants for thesis or dissertation research in work for a class? *With an approved IRB protocol, yes! Without IRB approval, avoid any recruitment activities with research participants associated with thesis or dissertation research in class. Of course, avoiding participant recruitment activities assumes that you will avoid data collection activities, too—just plan to not have any contact or interaction with research participants until you have an approved IRB protocol on file. That said, you certainly can do some exploratory work with gatekeepers or sponsors to guide you to a research site where you will have access to folks for your study—just limit what you*

discuss and do to general details and no individual-level records or data until your campus IRB approves your protocol. Doing early outreach with gatekeepers/sponsors at potential research sites will often pay off in helping you through the research governance process more efficiently.

- Do you need IRB approval to interview other students or minors who are part of a class assignment or pilot research study conducted in an instructional setting? *If you are simply practicing interview strategies or exploring survey item construction and the individual(s) with whom you are working are not the subject of your study, then—no—you likely do not need IRB approval. These types of activities usually do not relate directly to your thesis or dissertation research. Generally speaking, if you are collecting data about someone and from someone (living), then—yes—you need IRB approval. Even if you anticipate an exempt research determination, plan to submit a protocol for review. Unless your instructor indicates that a classroom exercise, field-based activity, or assignment is not subject to Common Rule policy or is exempt from review, then plan for IRB review.*

Faculty Considerations for Embedding IRB Work in Classes

For faculty who teach classes in research design, methods, dissertation writing and research development, and research fieldwork and field-based research, how do you approach the IRB process? What strategies have you used or can you use to facilitate student work with principles of ethical research, human research participant protections, and campus research governance? In social and behavioral science disciplines, research design and methods generally form the focus of classroom work associated with program research requirements, and considerations for IRB protocol development tend to be prioritized after covering topics essential to the practice of research. Indeed, in many instructional contexts, IRB protocol approval is not covered at all and does not necessarily need to be discussed as a curricular topic. For example, in undergraduate social science research courses or first-year, introductory research design and methods courses in graduate programs, direct connections between IRB and course content are limited. However, even in these courses, general discussions or specific applications of ethical research principles can be linked to conceptual and applied work in research design and methods. In more advanced research classes and thesis or dissertation writing classes, work that directly involves interaction with campus IRB can be incorporated into what you do in the classroom. Below are strategies about how you can link coursework to IRB work.

- **Reshape class activities or discussions to include dimensions of ethical research principles and/or human research participant protections.** A relatively simple change in a class discussion or activity

related to a research method or data collection procedure can extend to ethical considerations and protections for human research participants. For example, if a personal or group interview exercise requires students to draft an interview guide/protocol or practice interviewing someone, then you can add a short discussion or a brief reading on components of an interview guide that function to protect human research participants and/or what/how principles of research ethics can be applied to interview settings. In these exercises, topics to include can range from integrating human research participant protections in a pre- and post-interview sequence to including a discussion about identity, position, and power in research fieldwork in a segment on data collection procedures.

- **Incorporate opportunities to learn more about campus IRB policies and procedures.** Frequently, just learning more about a campus IRB office and/or policies and procedures is a way to start to get students to think more about human research participant protections in their research. Whether at the start of a project or near the point of preparing for fieldwork, requiring students to interact with IRB office staff and/or website/resources can support their research development. Here, strategies can range from inviting a campus compliance officer or analyst to guest present on campus policies/procedures and asking students to tour the campus IRB site and/or download resources (e.g., informed consent form template, bills of rights, etc.) to structuring class discussions to focus on IRB protocol approval.
- **Reframe research design/methods assignments to directly link to an IRB protocol.** Situating IRB protocol development directly in the conceptual work of research projects—framing a study's background, designing an approach to data collection and analysis, adding remote data collection and virtual research procedures to a study, and strategizing about fieldwork—can connect students to early and ongoing efforts to secure IRB approval for their investigations. When asking students to draft a research purpose or question or as students work on an empirical literature review, integrating a quick question or prompt in an assignment can invite students into a parallel process of research-IRB development that advantages them when they get to the fieldwork phase of a project and need an approved IRB protocol. In this example, as students form the background of their studies, they can sketch out a brief statement about the potential benefits of the study to participants and society; here, the dimensions of a research purpose—what you hope to do and what you hope to accomplish—can inform a statement about specific and broad benefits. Additional examples include requiring students to draft a research invitation (e.g., email invitation or text script for a survey or personal interview) as they write about participant recruitment and asking

students to discuss strategies for data storage and management in their data collection and data analysis plans.

- **Develop assignments that directly involve interaction with campus research governance.** This approach generally connects research work in class most directly with human research participant protocol development and student interaction with campus IRB. These assignments may be best suited for courses that include thesis or dissertation writing and/or development of a methodology section/ chapter of a thesis, dissertation, or capstone project. Assignment ideas here may include researcher training (even if not required by campus IRB policy) via the Collaborative Institutional Training Initiative (<https://about.citiprogram.org/en/homepage/>); registration (if needed) with a web-based campus e-IRB submission system; informed consent form drafting, protocol section writing; and/or protocol submission.

CHAPTER SUMMARY

This chapter appears as a bridge between the events that produced a system of regulation and governance in research that involves human participants and your research work that requires you to participate in the IRB process on your campus. Here, I moved from a conceptual look at human research participant protections and research governance to practical considerations and actionable strategies to support your work in IRB protocol approval. This chapter started with where you start—on campus—and discussed what you can look in the IRB process, including general forms and information that you may be required to submit. For most of this chapter, I discussed IRB connections to your study and links between IRB and coursework. With respect to the former, I explored how a study's research framework needs to justify involvement of human research participants and risks of harm in the course of an investigation, participant sampling and recruitment, and protections in reporting results and findings. I also considered how identity, power, and conflict may shape fieldwork in the context of a study. For students, I strategized about how to make the most of coursework—considering how frame course assignments or instructional activities, viz. IRB work to support thesis or dissertation research and negotiating with instructors to structure course assignments and activities to advance research projects and promote research development. Here, I looked closely at the principle of no retrospective consent and plans to work toward prospective consent of research participants in the context of a class or classes. This chapter ended with a discussion of how instructors can incorporate IRB work in their classes—several approaches can be considered here, including IRB assignments and/or assignments or activities that connect to IRB protocol development.

IMPLICATIONS FOR YOUR PROTOCOL: REFLECTIVE QUESTIONS TO ASK YOURSELF

1. What do you know about your local campus IRB? How have you interacted with the research governance/compliance process on campus? What more do you need to do to get acquainted with and learn more about IRB review and protocol approval?
2. If you are a student, what strategies to link coursework to IRB protocol development have you considered and/or applied in your thesis or dissertation (or culminating experience) research project? For faculty who teach research-related courses, do you have opportunities to incorporate IRB protocol development work in your assignments and/or instructional activities? If so, how can you connect or strengthen connections between research principles and practice and IRB?

CONCEPTS FOR PRACTICE IN YOUR IRB WORK

- Standard and local IRB policies and practices as research governance
- Conceptual and practical connections between research proposals and IRB protocols
- Strategies to navigate the policy and practice of “no retrospective consent”

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