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## Human Subjects Research Guidelines for Undergraduate Researchers: An Analysis of Institutional

Review Board (IRB) Websites at Top Liberal Arts Colleges in the United States

## Abstract

Teaching students about the ethics of Human Subject Research (HSR) should be a fundamental component of students' education about research. In this article, we analyze the Institutional Review Board (IRB) websites of top-ranked Liberal Arts Colleges (LACs) to examine their framing of HSR carried out by undergraduate students. Our descriptive quantitative analysis from 50 top-ranked LACs in the United States indicates that a majority of IRB websites provide information about undergraduate research, and most include information about students' classroom-based research. Our qualitative content analysis of a subsample of ten colleges' IRB websites provides information on how they inform and educate about issues including informed consent and highlight different resources for students including their research advisor, and disciplinary standards. We conclude by discussing recommendations for IRBs in their accessibility to undergraduates.

Keywords: liberal arts; IRB; human subject research; undergraduate; ethics

### Introduction

The study and instruction of ethics has often been relegated to philosophy and religious studies curriculums in undergraduate education (Callahan and Bok 2012). Teaching research ethics is often embedded within disciplinary methodological courses and may or may not encompass comprehensive instruction on human subjects' protections (Brinthaupt 2002). Liberal Arts Colleges (LACs) in the United States are a particularly interesting site to examine how the institutional committee in charge of safeguarding human subjects' rights and ensuring their protections—the Institutional Review Board (IRB)—discuss undergraduate research. The IRB is a central location for information about safeguarding human subjects' rights in research and may be an important resource for faculty and students alike conducting human subjects research (HSR).

In LACs, which are focused on undergraduate education, IRBs can serve the purpose of educating the college's community about ethics and respect for persons in the context of data collection involving human subjects. That is, even for scholarship that does not meet the traditional, federal definition of research (for example, data collection that is solely for a class project), IRBs can provide resources for informed consent, for example, which is a best practice regardless of whether the data is for a student project limited to a class or is intended to be incorporated into a scientific publication. As one LAC's IRB website notes, its mission extends beyond reviews of research proposals and indeed "the IRB strives to create a culture of respect for, and awareness of, the rights and welfare of research participants.<sup>1</sup> This is accomplished through continual education of our faculty and student researchers, collaboration and open dialogue between researchers and the IRB" (Swarthmore College 2022).

<sup>&</sup>lt;sup>1</sup> We use human subject and participant interchangeably and note that the official language is that of human subject. However, most social scientists, the authors included, prefer the term participants over subjects since we view the research as not being done "on" subjects but rather "with" participants. However, the terminology is diverse where others prefer interlocuters, respondents, or other terms.

human subjects and ethics in relation to undergraduate research on public-facing websites. We begin by reviewing the literature on LACs, noting their particular role in the landscape of higher education. We then turn our attention to guidelines surrounding human subjects, reviewing existing literature on undergraduate research involving human subjects and finally, the role of IRBs in LACs before introducing our data and methods.

### Background

#### Liberal Arts Colleges (LACs) and Undergraduate Research

In the United States, LACs are universities that focus, often exclusively, on undergraduate education. They are typically characterized by small classes, with faculty typically concentrating heavily on teaching responsibilities. While there is significant variation, LACs are typically small (enrolling two to three thousand students, as compared with tens of thousands for many research universities) and characterized by low faculty to student ratios. Historically, their mission is to prepare students to be citizens and to be in service of their communities in addition to the focus on Socratic modes of education (Cech 1999). In general, LACs tend to foster good practices which motivates a special interest in their practices and approach to undergraduate education, as they may in turn serve as pedagogical models (Pascarella et al. 2004).

LACs are characterized by close student-faculty relationships, and students have ample opportunities to engage in research and experiential learning. This approach is in line with scholarship that finds that undergraduate research is a high impact learning practice (Ritchie 2021; Seifert et al. 2010). Undergraduate students can participate in research by engaging in faculty-led research and by "developing their own research projects in independent studies and senior capstone projects" (Cooley, Garcia, and Hughes 2008; Ritchie 2021:120). Compared to students at larger institutions, students from LACs more frequently attend postgraduate studies, sometimes related to and motivated by research experiences in their undergraduate careers (Mahatmya et al. 2017; Richman and Alexander 2006). Our

research begins with the premise that LACs "offer learning opportunities in the responsible conduct for research for both students and faculty" (Richman and Alexander 2006:171).

#### Federal Guidelines for Research with Human Subjects and the Common Rule

Most HSR carried out at a post-secondary institution in the United States goes through an IRB review process guided by "the Common Rule", i.e., subpart A of the 45 Code of Federal Regulations (CFR) Part 46, which establishes the requirements for all IRBs. The Common Rule defines what qualifies as HSR. Several factors determine whether a research project needs to be reviewed by an IRB. First, a human subject refers to "a living individual about whom an investigator (whether professional or student) [is] conducting research."<sup>2</sup>

Second, although the term research is used for a variety of tasks completed in university settings, for the purpose of IRBs, "research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."<sup>3</sup> To be considered research then, a project needs to be conducted with the intention of providing generalizable knowledge to be shared outside of the institution. For example, if a student conducts a project on a public figure, alive or deceased, this is not considered research because this research does not provide generalizable knowledge. Research carried out in the context of a course that will not be disseminated beyond the classroom does not need to go through IRB review. However, the IRB *can* be involved in these kinds of activities by providing guidance, for example, the National Science Foundation (NSF) notes:

"Since the Common Rule exempts classroom exercises (see FAQ Does research conducted as a classroom exercise count as human subjects research?), the IRB has no mandated role to play in reviewing such exercises. However, the IRB typically is the only institutional store of expertise about human subjects protections, and may in principle be involved in such research in an oversight function. The following suggestions are offered as guidance for institutions seeking to

<sup>&</sup>lt;sup>2</sup> <u>https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102</u> (Department of Health and Human Services 2018)

<sup>&</sup>lt;sup>3</sup> <u>https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102</u> (Department of Health and Human Services 2018)

protect participants from harm in such situations without overburdening IRBs with needless review responsibilities"<sup>4</sup>

Therefore, although not officially required to deal with these kinds of projects, IRBs at undergraduateserving institutions may choose to involve themselves, for example via departmental review. These guidelines then leave room for interpretation, and it is perhaps not surprising that some IRB chairs do not understand their function as educators in all HSR matters (e.g. Martinez 2023).

On other occasions, research projects will be subject to IRB review if they are funded by one of the departments and agencies that follow the Common Rule. However, even if a project is not federally funded, if the institution has chosen to conform to the regulations on its Federal Wide Assurance (FWA) filed with the Office for Human Research Protections (OHRP) at the U.S. Department of Health and Human Services, it will also be subject to IRB review. In general, university IRBs follow the Common Rule as a way to support ethical fairness to participants and to guard against potential institution liability (cf. Schrag 2010). However, IRBs can also be used as used a tool to protect the university's reputation and as such serve additional functions (cf. Baumann et al. 2015; Hedgecoe 2016; White 2007).

#### Undergraduate Research Involving Human Subjects

Undergraduate research has several functions. While some functions may be defined in congruence with federal guidelines of what research is, undergraduates conducting research may also serve a pedagogical function, i.e., learning how to do research. According to the Common Rule, these projects are not considered research and are therefore not subject to IRB review (OHRP, 2017). However, some argue that all student-led projects, including those conducted in a classroom, should go through IRB reviews as this experience will support students' development as researchers (Kallgren and Tauber 1996). IRBs can also take different approaches to explaining their role to undergraduate researchers, related to both within-classroom research that serves a primarily pedagogical function, and

<sup>&</sup>lt;sup>4</sup> https://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp#conducted

which is not systematic, generalizable, and publishable research, but also as it relates to undergraduate research with the same goals as faculty-lead research.

Teaching ethics related to HSR occurs across disciplines including psychology (e.g., Kallgren and Tauber 1996; Zucchero 2008), sociology (e.g., Kraus 2008; Sweet 1999), anthropology (e.g., Allan 2018), education (e.g., Nolen and Putten 2007), exercise science (e.g., Senchina 2011), and computer science (e.g., Estes, Mallory, and Sobiesk 2016). Learning about research ethics can also be part of the broader regular university experience (Rissanen and Löfström 2014). Medical research aside, although disciplines beyond the social sciences also focus on research ethics these areas of study involve less contact with human subjects for undergraduates (e.g., Mabrouk 2016). In all disciplines, teaching research ethics can arise in the context of mentor/trainee responsibilities, publication practices, peer review, research misconduct, conflicts of interest, and social responsibilities of researchers, among others (Olimpo et al. 2017).

Historically, IRBs have prioritized a natural science and biomedical model and understanding of research with and involving humans, which has been critiqued as of limited relevance to social sciences and other areas of inquiry because of different methods and risks (Schrag, 2010). Despite scholars' criticism about IRB oversight for social sciences (Hamilton 2005; Schrag 2010; White 2007), educating students about the nature and function of IRBs may provide important information in the context of discussions about the ethics of HSR (Kallgren and Tauber 1996; Ritchie 2021). These student interactions with IRBs can be real (Allan 2018; Estes et al. 2016; Kallgren and Tauber 1996) or "fake," as part of an assignment or as mock proposals (Ritchie 2021; Sweet 1999). Although student led-projects carried out in a classroom do not need IRB oversight, including an outward-focused stance in facilitating classroom research can help students better understand what research beyond the classroom entails (Allan 2018). Submitting proposals for IRB review can help increase students' awareness of research benefits (Allan

2018). Thus, depending on the instructor's perspective, classroom-based studies may also be submitted for IRB review even though such review is not strictly necessary.

#### IRBs in the Liberal Arts Context (LACs)

IRBs at LACs are usually run by faculty volunteers (Babb, Birb, and Carfagna 2017). These members represent different disciplines as well as include a community member not affiliated with the university (Office for Human Research Protections 2022). Including a variety of voices seeks to ensure that IRBs are knowledgeable when reviewing proposals and sensitive to different disciplinary conventions. Further, IRBs can consult experts if they are not familiar with a research area and/or research methodology.

At large research institutions, IRBs are usually part of Human Subject Research Protections Programs (HRPPs) (cf. Baumann et al. 2015). HRPPs include more than the IRB committee such as "the institutional official, other compliance committees [...], grants/contracts offices, [...], and a host of activities beyond the review of individual studies" (Baumann et al. 2015:2). At LACs, IRBs might be the only visible and/or publicly listed committee focusing on HSR. Therefore, at LACs, a variety of questions related to research that are not technically under the purview of the IRB might be directed to the IRB, nonetheless. In contrast, some HRPPs at larger institutions have staff members in charge of implementing education for the research community, including courses about "regulatory basics for new investigators, and special topic discussions such as conducting research with vulnerable populations, adverse event reporting, and safety monitoring for more experienced investigators" (Baumann et al. 2015:14). While some have lamented the bureaucratization of ethics approvals (Wynn 2016), IRBs at LACs have the potential to be a centralized source of education and information to students about ethical research conduct.

Although IRBs started as a requirement for federally funded research (Stark 2011), their influence quickly moved to both funded and unfunded HSR (AAUP 2006). Research at LACs can be of

both types, but, given the focus on undergraduate teaching, we might expect higher rates of unfunded research at LACs than at their research university counterparts. In addition to the source of research support, IRBs can target three main areas for review that include HSR: biomedical, social, and behavioral research. Because LACs do not have medical schools, they produce more research on social and behavioral sciences than in medical sciences. Most IRBs in LACs are then different than the national average where "it has been estimated that about 25% of research reviewed by local IRBs each year in the US is not biomedical" (Richman and Alexander 2006:172). Understanding undergraduates' training and education in research ethics in the LACs context may be of particular import as social scientists are sometimes inadequately trained in research ethics (Wassenaar and Mamotte 2012).

Since student-led research projects are often reviewed by IRBs, we might expect a close relationship between IRBs and students mediated by their faculty advisors. Moreover, as students are regularly invited to participate in HSR at LACs (Richman and Alexander 2006), they may often have a double view of the IRB as researchers and as participants in research. In fact, because of the close relationship between students, faculty, and research, "the distinction between education and research is blurred" (p. 167). For example, the differences between in-class projects and research-based classes (Cooley et al. 2008) might not be clear to faculty and students (Allan 2018).

However, communication between faculty and IRBs at LACs can be more conducive to successful implementation of reviews than communication between faculty and IRBs at larger institutions. Babb, Birb, and Carfagna (2017) carried out 26 interviews with qualitative sociologists working at six research universities and three LACs. Participants working at LACs reported more informal conversations with IRBs as they "experienced their IRBs as groups of named individuals with whom they could have back-and-forth conversations, [while] research university scholars often experienced their IRBs as faceless bureaucracies" (p. 98). Some of the interviewees had also been members of IRBs, perhaps because of the smaller size of the faculty at LACs. Despite these features of IRBs at LACs, researchers still find

difficulties when submitting research proposals for review. The clarity of IRB websites can help alleviate some concerns and misunderstandings by delineating the scope of research and the IRB's procedures for approval.

### **Research Questions**

In this article, we examine how information about research conducted by students, including classroom projects with only pedagogical goals, are communicated publicly on the IRB websites of topranked LACs in the United States. Specifically, we seek to answer two research questions: First, what proportion of IRBs from top ranked LACs in the US address students' HSR and classroombased research on their websites?

Second, how do IRBs from top ranked LACs in the US discuss students' and classroom-based research ethics related to human subjects?

# Data and Analytic Strategy

Our mixed-methods analysis draws on two nested sets of data. First, we consulted the U.S. News and World Report 2022 Rankings of National Liberal Arts Colleges (US News & World Report 2022). We selected the top 50 colleges listed in the rankings and collected information about the size and ranking of each institution. We opted to focus on the IRB websites of elite liberal arts colleges for two primary reasons. First, top-ranked liberal arts colleges are typically leaders and other institutions in their same category may view them as exemplars, making them a particularly important sub-sample to examine. Second, there is evidence that there is more emphasis on research in elite liberal arts and four year colleges and top-ranked LACs IRBs may then be more likely to include information about student researchers (Bodenhorn 2003; Joy 2006; Keohane 2006).

On average, the colleges in our sample enrolled 2,026 students, as reported for the most recent year data was available sourced from university websites. Since there are tied rankings, we ended up with more than 50 institutions, but opted to not examine the United States Naval, Military, and Air Force

academies given their unique features beyond a liberal arts education. We also did not examine Barnard College given its context within a larger research university (Columbia) nor our own institution which was part of the sample. We proceeded with a sample of 46 institutions which represents the top liberal arts colleges not tied to the United States armed forces and should provide some information on what "elite" institutions do in regard to student research.

After settling on this sample, we identified the IRB website for each institution and coded for the presence of the following information on the publicly available website: first, classroom-based research; second, information more specifically about undergraduate research; third, whether the IRB reviews all research (as compared with only federally funded research requiring it); and fourth, course-based research that the Common Rule may not categorize as research, that is, student projects that would not be traditionally classified as research, because they are not intended to be shared beyond the classroom. This provides an overview of what features are publicly available about the institutions IRBs and human subjects' protections. Importantly, there may be colleges that have specific IRB information or resources contained on an internal website that is accessible only to those affiliated with the institution. Therefore, we reiterate that our analysis is of publicly available data.

We argue that examining these public websites is important for transparency for members of the LAC's community and those beyond, for example for people that may be participating in research, about human subjects and research guidelines at the institution. LACs' websites, as is the case of any other websites, serve "to create/consolidate the image of the sender" (Askehave and Ellerup Nielsen 2005:130). As an example, one LACs' IRB website indicated four key functions in their homepage including an educational mandate: protection to participants, compliance with federal and state regulations, education for both "regulatory and educational purposes", and support "regarding issues related to scientific, ethical, and legal standards of research."<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> https://irb.richmond.edu/

Beyond our quantitative analysis, we were interested in examining not only how many institutions provided information on different dimensions of research, but also conduct a qualitative analysis of *how* the IRB website discuss undergraduate and classroom research. Therefore, we randomly selected ten institutions of the larger and conducted a content analysis of their IRB websites. This set of ten colleges and their IRB websites are then a random subsample of the top liberal arts colleges. In particular, we wanted to examine how information about what counts as HSR is discussed, as well as how classroom-based research and student research are addressed. In doing so, we are able to examine not only how many but the content of elite LACs public communication about undergraduate research in relation to IRB and the protection of human subjects. In our results, we quote from publicly available websites. We opt, however, not to name the institutions, though they may be recognizable to readers. This decision was not due to a concern about privacy (one can search for these quotes) but to shift the focus away from any one college's website and instead present results that should be indicative of the landscape of top LACs.

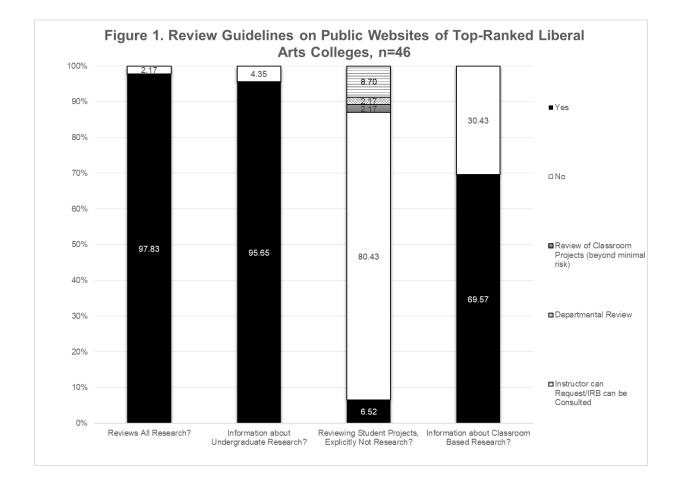
# Results

### Quantitative Analysis of Websites

Figure 1 contains information about trends in top ranked liberal arts colleges IRB websites. Overall, we find that slightly over 95% of the institutions' IRB websites we examine include information about undergraduate research on these publicly available websites. Further, over two-thirds of the college IRB websites we examined include information on classroom-based research. This suggests that overall, and consistent with the understanding of LACs as focused on undergraduate education, including "learning by doing," student research, and an emphasis on faculty-student interaction, the overwhelming majority of IRB websites we examined explicitly address undergraduate research.

More specifically, the IRB websites of approximately 98% o of the colleges in the sample indicate that they review all research on their websites. Finally, only approximately 7% of institutions' websites

indicated that they reviewed research that was not explicitly research according to the Common Rule that is not shared beyond the classroom and intended to contribute to generalizable knowledge—while about 2% of the institutions mandate departmental review according to their IRB website, while another 2% indicate that faculty can request that such research be reviewed or that IRB should/can be consulted. The large majority, roughly 80% of these top-ranked liberal arts institutions' IRBs do not review what is not considered "research" by IRBs according to their website.



#### Qualitative Analysis of Top Ranked Liberal Arts Colleges' IRB Websites

#### What HSR Does IRB Review?

Consistent with Figure 1 where nearly 98% of the IRBs review research projects according to their websites, the randomly selected subsample of ten IRBs' websites analyzed placed heavy emphasis on the role of ethics in HSR. Indeed, all ten of these IRBs review research projects under the definition of "research" (i.e., generalizable, systematic, and shareable). However, whereas some IRBs hold a pedagogical stance regarding reviews of projects by including specific language about student researchers, other IRBs seem to focus more heavily on governmental requirements for IRB review. That is, they seem to regard the necessity of IRB reviews as a regulation than as part of the ethical development of the students.

Some IRBs emphasized the importance of IRB reviews for projects related to the National Institutes of Health (NIH). For example, one of the IRB websites, although requiring review of all kinds of research, only required researchers to complete training if working on NIH funded projects: "Training in HSR is strongly recommended. Key personnel on NIH-funded human subjects research are required to obtain such training, even if the research is exempt from IRB review" (College 19).<sup>6</sup> As another example, although the IRB of College 45 required training for all researchers, it also emphasized in its website the importance of training for NIH-funded research: "Since 2000, the National Institutes of Health (NIH) has required education on the protection of human research participants for investigators and all key personnel involved in the design or conduct of NIH-funded human subjects research."

Requirements for training prior to seeking IRB approval varied depending on the stance that the IRB chose, which included: 1) only researchers working on federally funded projects that required IRB oversight needed HSR training, or 2) all researchers working on HSR required training (see examples

<sup>&</sup>lt;sup>6</sup> We use the college number as the general citation given that these are the "authors" and "owners" of these websites, but underscore that we are citing the IRB websites of these same colleges.

below). However, even when not requiring training, IRBs would sometimes make recommendations for training, as discussed on College 19's IRB website:

"Regardless of IRB review category, we strongly encourage faculty, students, and staff who will be conducting research with human participants to complete an available training course on the ethics of such research. This is only required for key personnel on NIH-funded human subjects research (even if the research is exempt from IRB review), but familiarity with the relevant ethical principles helps to guarantee that [College 19] researchers always treat their study participants in an appropriate and ethical manner."

In this way, training is encouraged rather than required and the IRB takes on an educational role rather than solely a regulatory one. A more stringent approach is discussed on College 44's IRB website which mandates training for everyone: "REGARDLESS of funding agency requirements, the [College 44] IRB requires that ALL [College 44] researchers involved in "human subjects" research must complete the CITI Human Subjects Research Educational Program." By mandating training, albeit by a third-party organization, IRBs are promoting additional, more formal education for researchers. This training may be particularly important for undergraduate student researchers that may not have had much if any formal educational instruction on HSR. In fact, the IRB of College 11 discussed research conducted within classes where the faculty member had submitted their own certification of IRB training, they "strongly recommend (but do not require) assigning CITI training as part of the course for your students' education and future research preparation." Thus, the connection between research methods classes and the college's IRB is clearly indicated. Although this connection could be understood as a mere emphasis on regulation, by emphasizing that this training contributes to "your students' education, by emphasizing that this training contributes to a submitted training is a pedagogical resource for instructors.

Overall, in our discursive analysis of ten IRB websites, we noted different approaches to training: seven IRBs required training as provided by the Collaborative Institutional Training Initiative (CITI Program) for all university members conducting research (as College 44's IRB website quoted above); one required CITI Program training for NIH-federally funded projects (College 19's IRB website quoted

above); one did not include information on training on its public website (College 33's IRB website), and College 26's IRB website only required training for IRB members. The CITI Program "identifies education and training needs in the communities we serve and provides high quality, peer-reviewed, web-based educational materials to meet those needs" (CITI 2022). Universities and other institutions can subscribe to gain access to different courses and materials, and individuals can gain certification both for general HSR as well as other competencies, for example leadership or working with animals, but they can also complete more specialized training in HSR in courses such as "Essentials of Public Health Research."

Beyond references to CITI training, mentions of the Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research 1979), a foundational document that includes "basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects,"<sup>7</sup> were also frequent. For example, six of the ten LACs explicitly mentioned the Belmont Report, five included a link to the report in their website, and two required reading it (though without clear enforcement of this directive). Links to the OHRP website were also frequent, i.e., six of the websites included at least one link to it and two mentioned the OHR without including a link. College 19's IRB website also included links to the Declaration of Helsinki and the Nuremberg Code.<sup>8</sup> Specific links to disciplinary ethical standards of behavioral and social sciences, such as the American Psychology Association (APA) or the American Sociological Association (ASA) were not present in the ten websites we examined.

Altogether, our analysis of websites suggests that, while some IRB websites emphasized the importance of seeking HSR's approval for federally funded research, there were no IRBs in our sample that discussed seeking review exclusively for those projects. Thus, these IRBs reviewed all HSR but required different degrees of training from university members to start their projects. Beyond their

<sup>&</sup>lt;sup>7</sup> https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

<sup>&</sup>lt;sup>8</sup> This link actually brought the reader to the following site with several bibliographic references, but where the Nuremberg Code was not easily located: https://history.nih.gov/display/history/Publications

administrative function, some of these IRB websites can serve as a resource for locating additional information and resources for learning about the ethics of HSR. By serving as a repository of information from other websites including CITI training, IRBs appear to fulfill an educational function. Nevertheless, based on the links provided as resources for further reading, much of the information is centered on biomedical research than on social and behavioral research.

#### How is Undergraduate Research Discussed?

While the overwhelming majority of IRB websites from colleges in the sample included information on undergraduate research, an overall count does not allow us to examine what kind of information was provided, and how protection of HSR in the context of undergraduate research is described. Our content analysis of the randomly selected subsample suggests that most of these colleges' IRBs recognized the importance of undergraduate research at their institution as being in line with any other kind of research conducted at the institution, e.g., faculty-lead research.

Although each website discussed who was subject to IRB review, the order of members being subject to IRBs (e.g., students, faculty, staff) was presented in different ways. For example, the IRB website of College 14 reads: "IRB approval is required for research performed by employees and students of the College, and to research by outside individuals or groups involving [College 14] students or taking place on its campus." In this case, the jurisdiction of IRB is seen as those affiliated with the institution, but also those conducting research with or about students at the college or other aspects of the college. The IRB website of College 26 too mentions that any research, conducted by anyone working at the college, specifically noting visiting researchers and its students is subject to IRB review: "The purpose of this policy is to provide a single, comprehensive standard for protection for human subjects of research conducted by students, staff, faculty or visiting researchers at [College 26]." Requiring LAC IRB approvals for research projects that had have already been reviewed by another IRB is not a Common Rule requirement. While such policies may be motivated by an interest in protecting the

campus community, scholarship also suggests that such rules may constitute a form of gatekeeping that represents IRB overreach and can be used by university administration to protect the reputation of the college (for example by not approving "embarrassing" research) which may threaten academic freedom (cf. Emmerich 2016; Hedgecoe 2016; Schrag 2010; Stark 2011).

Most websites that mentioned undergraduate research discussed it alongside and subject to the same rules as faculty research. Importantly however, many college IRB websites emphasized that students were required to have a faculty advisor. Although not all IRB websites discussed faculty advisors, none explicitly indicated that faculty advisors or sponsors were not required. This is again, consistent with the focus on faculty-student relationships that are prized in the LACs context. College 11's IRB website noted that student research, whether or not it required IRB approval, required faculty sponsorship or supervision: "Student Research—exempt or non-exempt—requires a faculty sponsor." Some websites provided even further details, for example College 44's IRB website indicates that all consent forms required advisor information, in addition to student and IRB information: "Three contact names and phone numbers should be on all consent forms: the researcher's, the faculty advisor and the IRB administrator."

Several websites were explicit in listing the kinds of research projects that undergraduate usually carry out so that students were aware of what the term "research" might refer to:

"Research subject to review thus includes but is not limited to pilot studies, honors theses, Master's theses, Ph.D. dissertations, class projects or independent research aimed for publication, whether such research takes place on or off the [College 33] campus (including work done outside the United States), as long as this research involves human subjects or data derived therefrom" (College 33)

In this case, class projects were discussed as needing review if they are thought to be shareable or would be shared beyond the classroom. Importantly, LACs conferring graduate degrees are rare, and in that way College 33's IRB website is an exception. The websites we examined in detail in our subsample appeared to be geared to a wide audience as public facing websites, and importantly, provide examples and instructions that would be accessible to undergraduates as well as the general

public.

Since LACs focus on teaching, there were sometimes mentions of class-specific projects

classified as research. Some IRBs offered ways for instructors to reduce the amount of work and time

involved in IRB reviews for exempt research projects by asking instructors to submit a blanket protocol

for the whole class. The example below clearly defines what classroom-based projects need review and

discusses the possibility of a blanket protocol for exempt projects.

"For Class Instructors: If your class will be conducting a human subjects project that is intended or likely to be **published or presented publicly** (outside the classroom), we ask that you apply in advance of the semester for **a blanket protocol** to cover exempt projects. This blanket protocol should describe the range of research topics you will be working with in class projects, a general consent document, representative survey questions (if applicable), and how you plan to protect participant identity and secure data. The IRB will review the general scope of the work, with the consent, identity, and data protection aspects. If you plan to assign the same project for multiple classes, you may list the classes in the protocol description" (College 11, emphasis added)

Though blanket protocols were not commonly discussed, we take this as an example of how

IRBs appear knowledgeable and responsive to the (perceived) needs of classroom instructors and

students of carrying out research projects in a semester timeframe. This consideration is beyond their

goal of protecting participants and speaks to the context of LACs and instructor needs and priorities

therein.

Our subsample of IRB websites discussed informed consent as an important component of

ethical research for all kinds of researchers. There was a focus on having participants understand and

consent to being involved in research and be clearly informed of the risks and benefits. In this way, IRB

websites were doing the important work of educating and emphasizing participants' rights.

*"Informed consent.* Before participating in research it is important that participants are aware of the objectives of the research, the procedures to be followed, the associated risks, and the potential benefits. More detailed information about informed consent policies at College 7 can be found on our policies page and you can follow this link for a Consent Form Example" (College 7)

It was a frequent practice for IRBs' websites to include examples of informed consent. Figure 2 is

an example provided in the IRB website of College 21 of the beginning of a consent form that

researchers can adapt. The focus on undergraduate research ethics is clear in discussion of the possible

sites for sharing findings including in the context of a "student thesis" and a "class presentation."

Moreover, the fact that a scholarly publication is a "remote chance" might pertain more to students

than to faculty underscoring the educational focus of IRB beyond what is mandated federally under the

definition of "research."

Figure 2. Consent Form for Research Adaptation (College 21)

Title of the Study: [insert study title]

Researcher Name(s): [insert researcher name(s) and contact information, plus advisor name(s) and contact information if applicable]

The general purpose of this research is to [insert a sentence describing the general purpose of the research]. Participants in this study will be asked to [insert a sentence describing the general procedure of the research]. Findings from this study will be used [insert a sentence describing where the findings will be presented. Will they appear in a student thesis? A scholarly publication? <u>A research</u> conference? A class presentation? A presentation to the administration? etc. It is a good idea to be as thorough as possible. For example, if there is even a remote chance that findings may be published in a scholarly journal, state that here.]

In brief, IRBs appear to be responsive to the types of research that faculty and students alike

might conduct at LACs and take an instructive and educational role, beyond only providing instructions

and technical resources for applicants.

## Approaches to Classroom-Based Research

According to the definition of research, projects that are designed with the goal of teaching students how to do research and where the collected data or findings will not be shared outside of the classroom are not subject to IRB review. From the subsample of websites for which we conducted a content analysis, half of them included information on these kinds of projects. We focus on how these IRB websites discuss these student projects because this is an important educational opportunity for IRBs. Further, both faculty and students need to know the difference before deciding when to submit a project for IRB review. Interestingly, we find that even if such review is not necessary, some IRBs remind faculty and students of the importance of following ethical guidelines as well as opening the door to students to submit the project for IRB review.

Moreover, projects carried out in the classroom were not always labeled as not needing IRB review: "Briefly describe the project (in language understandable to the lay reader) and the procedures to be used in the research. [...]. If the project is being carried out in the context of a course, briefly describe the educational objective of the research exercise" (proposal application form, College 14). As discussed in the previous section, the fact that a project is carried out by students in the context of a course project does not necessarily mean that the project does not need review. We found that IRBs that explained classroom-based research made a pre-emptive effort to clarify that class-based projects may also need IRB review by providing some of the main characteristics of what HSR entails, that is, shareability and generalizability.

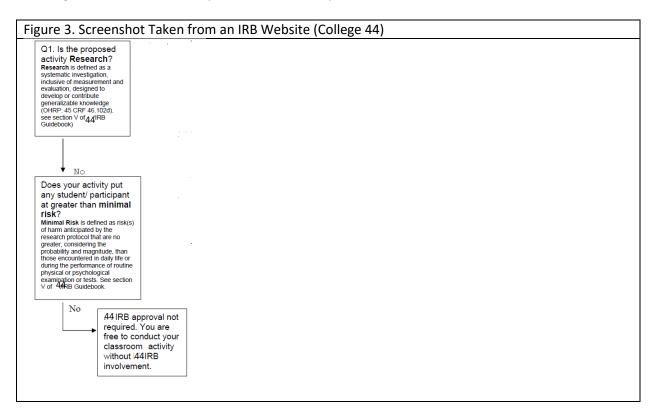
As the following quote demonstrates, "generalizable knowledge" was often identified as the key for distinguishing between both kinds of projects, i.e., those needing review as compared with those for which it was not required: "When course-related projects are intended to develop or contribute to **generalizable knowledge**, they are subject to federal guidelines and are required to undergo IRB review and approval, prior to the initiation of the research activities, including contact or recruitment of subjects" (College 7, emphasis added).

#### Delineating the Role of IRB in "not Research"

When websites explicitly indicated what kinds of projects did not need IRB review, the degree of detail and the parameters varied across the IRB websites of colleges. Whereas some focus on the issues of generalizability and shareability by indicating "for the sole purpose of a class assignment or teaching exercise," the following example provides more nuance as it includes information on the kind of participants (vulnerable populations versus non-vulnerable populations), degree of risk, and shareability: "If research is done for a class project, does not include vulnerable populations, involves no

more than minimal risk, and will not be presented or published (e.g., as a thesis, scholarly paper, or community forum), then this research does not require formal review" (College 7).

That is, while some IRBs attended to the shareable component of the definition of research, others focused on risk and the category of HSR involved. While all discussed consent in some form, others, such as College 7, were focused on the IRBs broader role in ensuring ethical contact with human subjects, and particularly vulnerable human subjects or data collection that involved some risk. In this way, IRBs again serve the important purpose of reinforcing the need for consent and care in dealing with data that involves human subjects, even if that data will not be shared beyond the classroom nor contribute to generalizable knowledge. This concern with risk was also apparent on the IRB website of College 44 since it highlights the need for considering risk in classroom projects, even in those projects that did not meet the definition for "research." Figure 3 contains a screenshot of a flowchart on College 44's website which not only points out that projects that are neither research as defined by CFR nor involving minimal risk do not require IRB review but provides a definition of minimal risk.



In addition to pointing to broader ethical standards, other sources of authority were alluded to, for example disciplinary guidelines: "Projects that do not meet the federal definition of research as outlined in the CFR should still heed **ethical and disciplinary standards** in collecting data from human subjects" (College 34, emphasis added). Further, IRB websites often indicated an awareness of their educational role. In particular, some IRBs directly addressed the difficulty of discerning when a project needs or does not require review or that a project could evolve so that it ended up needing IRB review even if it did not start out that way. Several IRB websites encouraged faculty to contact them under such circumstances, for example: "College 7 IRB encourages faculty members who anticipate that course-related projects may develop or contribute to generalizable knowledge to consult with the IRB early in the semester in which data will be collected" (College 7). In this way, IRB fulfills an educational and advisory role, in addition to a strictly regulatory one.

Figure 1 indicates that 80% of the total sample of IRBs did not make any explicit comments on their websites about reviewing classroom projects that did not require IRB review. From the subsample of ten colleges whose IRB websites we analyzed, two of the IRBs explain when they require review or discussions of projects not requiring IRB. For example, College 26's IRB website clearly emphasized that classroom projects did not need review. Instructors were then the ones in charge of ensuring that the students follow ethical guidelines, and instructors were expected to train students on research ethics for their discipline.

However, instructors could use the IRB as a resource to discuss ethical issues and even request a review: "Student research practica as defined above do not require Board review, unless the instructor chooses to invite Board review. [...] It is the **responsibility of the faculty member** to include research ethics and principles of responsible research when teaching research techniques" (College 26, emphasis added). The IRB then places the responsibility on faculty but is also seemingly willing to be "invited" to

review such projects. Further, this college's IRB website explicitly discussed teaching—that is, pedagogical instruction and education—of research techniques by faculty in the context of faculty-based research. While this seems like we should take it for granted, we should not. A review of academic articles on teaching research methods finds that most do not discuss ethics, and point to this as an important pedagogical gap (Wagner, Garner, and Kawulich 2011). It is unclear whether such instruction would be more or less common in substantive courses, and the review is over a decade old. However, the attention to the instruction of ethical concerns with research and data collection is important, though seemingly rare.

Beyond having students confer with instructors, follow disciplinary and CFR recommendations, and an emphasis on consent even in data collection endeavors that did not count as research, another possible source of authority suggested in some IRB websites were academic departments:

"Departments are encouraged to develop an internal review process for research involving human subjects undertaken by their students and faculty. Such internal review should conform to the relevant discipline's Codes of Conduct and Ethics. Although departmental review cannot substitute for Board review when it is required (for "research projects" as defined above), departmental review will facilitate Board review. Departmental review can also be used to teach responsible conduct of research." (College 26, emphasis added)

College 26's IRB website suggests that departments can take on the role of reviewing HSR by

students and faculty. The benefit of such a review, it notes, is that it allows for disciplinary attention, and, again with a pedagogical focus, allow for teaching research ethics and responsible research even for data collection which does not "count" as research at the federal level. This approach concurs with recommendations provided by the NSF and underscores how HSR can and should be integrated into broader discussions of research in conversation with disciplinary standards.

### Discussion

Overall, our analysis reveals that most high-ranked LACs have IRBs that review HSR net of the funding source. Only one college did not have an IRB website.<sup>9</sup> Our quantitative analysis finds that 96% of the schools' websites explicitly mentioned students as researchers (see Figure 1). Of the two schools that did not indicate so, one did not have an IRB, while the second school's IRB website was only available behind a password, that is, the LAC did not have any publicly online available data that we could access and was therefore coded as not providing information about undergraduate research on their publicly available website.

The IRB websites from schools in our sample stressed the importance of having a faculty advisor for student research. That is, if students conducted research, this was always in the context of their studies with an advisor who could also be a faculty member in one of their classes. Students' contact with IRB in LACs is often mediated by a faculty advisor. Most schools also required students to complete training in HSR. We believe that undergraduate students who conduct research at LACs can learn about human research ethics through their interactions with the IRB, which suggests a pedagogical potential.

We find that 70% of the websites also included information on classroom-based research (see Figure 1). This information helps students and faculty members reflect on the differences between classroom-based projects that require IRB review and those that do not. Nineteen percent of the IRB websites indicated that those pedagogical projects could also be subject to review by IRB (or in one case by the department) if they posed above minimal risk or if the instructor decided they needed review. We found that in general, IRBs at LACs were open to faculty members who wanted to discuss their classroom projects. This possibility fits with some scholars who have proposed that students can use IRB research proposals to learn about the ethics and particulars of HSR (e.g., Kallgren & Tauber 1996). Nevertheless, IRBs seem to be aware of the time-sensitive nature of classroom projects (e.g., Estes,

<sup>&</sup>lt;sup>9</sup> Two articles in the online student newspaper confirm that the school did not have an IRB at the time of writing.

Mallory, & Sobiesk 2016). To address this, several IRBs mention blanket protocols, departmental reviews and/or planning as soon as possible and early in the semester.

Consistent with LACs' general missions, LACs' IRB websites seem to function as an educational resource—a source of information for those teaching and learning about ethics in HSR. For example, instructors are encouraged to use websites' materials in their classes, share information about third-party training, and/or to further discuss their questions with IRB members about their projects meeting the definition of research or not. Therefore, we find that these websites have a purported educational mission consistent with the LAC context of the IRB (Stark 2011). Although IRBs have been criticized for overstepping beyond their original role (White 2007), as we saw with the examples of colleges' IRB websites indicating duplicating reviews (Emmerich 2016), this pedagogical role can be positive in that it brings attention to ethical guidelines and treatment of people. Despite this positive function, because of their emphasis on regulations, website information and links to resources seem heavily skewed towards biomedical research. Thus, there was a variation in the pedagogical commitment of these websites to social and behavioral sciences. Nevertheless, the focus on undergraduate students as researchers and/or as potential researchers is consistently apparent on these websites.

### Research Agenda

This study has offered an analysis of the discourse surrounding HSR for undergraduate students in elite LACs. Our analysis provides evidence of different approaches, but overall attention to the nuances of undergraduate data collection as related to risk, creating general knowledge, and the intended audience. However, future research should investigate whether and how such framing compares with attention to undergraduate research at research-oriented universities. Since those institutions receive higher levels of grant funding and involve graduate education, we might expect a lower percentage of IRBs mentioning classroom-based research and possibly even lower incidence of reviews of classroom-based research. Still, as research-intensive institutions also have a commitment to

undergraduate research, the differences might not be so striking. Further, while the information presented here should be relevant to those from a diverse set of institutions our sample is from the United States, and research suggests that there is more undergraduate research involving human subjects in US universities than in other countries (Rissanen and Löfström 2014). This suggests an important avenue for future research to examine whether these results are consistent with an international sample.

Future research should also seek to gain more insight into how stakeholders, including students, understand the role of the IRB in undergraduate education, its integration with the curriculum, and the role of IRBs in educating students about ethics and human subjects' protections. Relatedly, it would be helpful to have information on how often IRB websites are consulted as well as who bears responsibility for their content and updating, and whether IRB committees consider the website itself a pedagogical tool. Another area ripe for research is the role and information level of advisors. Our informal conversations with faculty at different institutions suggest that not all faculty members have the same degree of experience when navigating IRB reviews. We believe that further inquiry into how they approach HSR ethics with their students and research advisees would be important to consider in designing websites and training students. Similarly, exploring practices and perceptions of faculty members whose students carried out research projects in their classrooms, both those defined as research and as pedagogical practice, will also help to better understand the current panorama of undergraduate HSR ethics at LACs.

#### Best Practice Recommendations and Educational Implications

The focus of our study has been on how LACs' IRB websites frame and provide information to and about protection of human subjects, focused on undergraduate research. Although it is beyond the scope of our project to assess whether these websites presented the information in a pedagogically sound way, our analysis of IRBs' websites has yielded examples of how IRBs contribute to students'

development of HSR ethics. For instance, although it was frequent for IRB websites to include examples of informed consent and debriefing forms, which we considered a good practice as this could help inexperienced researchers, not all IRB websites were equally easy to read and navigate. Using FAQs seems a good strategy to make the IRB review less daunting as the language tended to be more pedagogically oriented in those sections. College 43's IRB website appeared clearly pedagogically oriented. We found this website user-friendly when explaining what the technical terms mean. Their definition sections offer examples to answer the questions in their application form. For example, they provide examples of what is private information, generalizable research, and minimal risk, among other terms. The excerpt shown in Figure 4 is provided to help student researchers and anybody else who needs to complete College 43's IRB application form. There are additional questions to guide the researchers when answering the other form's questions.

ξu	re 4. Screenshot of Q&A Section from College 43's IRB website
3)	Will your research place participants at greater than
m	inimal risk OR involve vulnerable populations?
	YES (or maybe) [Automatically sends you to complete IRB form.]
	NO [Continues to next question.]
Α.	MINIMAL RISK
Mi	inimal risk means that the probability and magnitude of harm or dis-
co	mfort anticipated in the research are not greater than those ordinarily
en	countered in daily life or during the performance of routine physical
or	psychological examinations or tests. Examples of minimal risk:
1.	Routine, non-sensitive data gathered for educational or employment
	purposes, where there is an expectation of standardized tests or regu- lar examinations
	Measures of mental status or memory functioning, outside of a clini- cal setting
3.	Standardized intelligence tests
4.	Personality inventories
5.	Consumer preference surveys
B.	EXAMPLES OF GREATER THAN MINIMAL RISK:
	Collection of individually identifiable data that could result in embar-
	rassment or other personal harm due to a breach of confidentiality
2.	Use of identifiable medical records or protected health information

Another frequent resource to help researchers were flowcharts. There were also links to

flowcharts from the Office for Human Research Protections government website. However, not all

flowcharts were equally readable. Websites often included specialized language that seems daunting for

first contact with IRBs. Other helpful tools were tables, charts, and other ways in which IRBs provided

information about not only what needed review but also the *level* of review.

OUTSIDE EXEMPT REVIEW	y Table Explain FULL BOARD
VIEW OF IRB	
cally Includes • Most No Risk for Applications rticipants • Minimal Risk No Public • Adult ssemination Participants = Class • 4 Categories: Projects = Educational = Research Settings Practicums = Tests, Oral Histories Surveys, Databases Interviews Quality = Benign surance Work Interventions = Existing Data Sets	<ul> <li>Some Applications</li> <li>Greater Risk</li> <li>Outside the 13 Categories (4 Exempt, 9 Expedited)</li> <li>Illegal/Incriminating Activity</li> <li>Vulnerable Population:</li> <li>Prisoners</li> <li>Children</li> <li>Pregnant Women</li> <li>Undocumented People</li> <li>Victims of Trauma</li> <li>Terminally Ill Patients</li> <li>Impaired Individual</li> </ul>

In our own conversations with faculty and students, we have found that the word "exempt" can be confusing as the technical term is not the same as the regular use term. Since those new to IRB regulations can confuse "exempt" with "outside of purview of IRB," Figure 5 can help avoid this common misunderstanding. Another approach to help researchers that we found interesting but not particularly common was including "departmental liaisons to the IRB," that is, faculty on campus that albeit not belonging to the IRB could help students when designing their projects and applying for IRB approval. Although other points in Figure 5 could provide further clarification, *e.g., does any research with children always need full board review?*, we believe this table is an excellent starting point for approaching IRB review. Importantly, some may view parts of these figures or tables as providing false or misleading information, for example there are situations in which interviews may require expedited or full board review depending on the type of information being collected. A table like this can complement a link to the Common Rule or to the OHRP website. Based on our experience with undergraduate researchers, including links to very technical websites without context might not help them in their understanding of ethics on HSR and their own college's IRB website can provide important introductory information.

# Conclusion

This article has examined top-ranked LACs' IRB websites as a source of information about the standards and requirements for HSR. In doing so, we contribute to conversations about teaching HSR ethics to undergraduate students as well as to the roles of IRBs in LACs. To summarize, we argue that IRBs can be fundamental towards developing students' understanding of HSR and protection of human subjects. Our results suggest that some IRB websites have a more pedagogical stance than others and provide varying levels of information. Nonetheless, our results are heartening in that within our sample we find that the vast majority of IRBs at top-ranked LACs review all research and provide at least some information about undergraduate research. Further, slightly over two-thirds provide information about classroom-based research and about one in five recommend some form of oversight and review (departmental, advisor, etc.) for undergraduate work involving human subjects even for work that does not meet the federal definition of research. Finally, most websites underscore the importance of informed consent and risk. Future research can work to better understanding how students', faculty members', and IRB members consider their role in developing students' HSR ethics.

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