

# DISCERNMENT

*Theology and the Practice of Ministry*

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Volume 8 | Issue 1

Article 1

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## What in the World is Research?

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### Recommended Citation

Sensing, Tim () "What in the World is Research?," *Discernment: Theology and the Practice of Ministry*. Vol. 8: Iss. 1, Article 1.

Available at: <https://digitalcommons.acu.edu/discernment/vol8/iss1/1>

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# DISCERNMENT

*Theology and the Practice of Ministry*

## What in the World is Research?

*Tim Sensing*

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*Abstract: Doctor of Ministry projects engage in robust field research involving data collection, analysis, and interpretation. Often, DMin students are entering the world of a social science field researcher for the first time. Words like “research”, “Institutional Review Boards”, and the non-sequitur “non-research,” fall outside the common vocabularies of even the professors. Navigating the language so one is not lost in translation fosters researcher confidence.*

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Early in grammar school, students are introduced to research. My earliest recollection of a research project involved comparing creation myths in various cultures. By my senior year at Purdue University, I wrote about the damaging effects of acid rain on the environment. Throughout my time in an MDiv program, writing descriptive research that involved extensive library time happened in every course. However, not until my DMin degree did I go into the field and gather my own data. The DMin degree introduced me to my own practice of congregational studies.

### The Nature of Research

*Research*, simply defined, is a family of methods that share common characteristics of disciplined inquiry. Research methods contain data, arguments, and rationales that are capable of withstanding scrutiny by members of an associated guild. Research prompts us to understand problems, ask questions, and pursue specialized modes of inquiry. Within the larger category of “research,” there exist various procedures that ask different questions and solve different problems. Jaeger’s classic text, *Complementary Methods for Research in Education*, describes seven standard *methodologies* for research. He lists them as (1) Historical Methods, (2) Philosophical Inquiry Methods, (3) Ethnographic Methods, (4) Case Study Methods, (5) Survey Methods, (6) Comparative Experimental Methods, and

(7) Quasi-Experimental Methods.<sup>1</sup> Shulman's opening chapter in Jaeger's book states, "What distinguishes disciplines from one another is the manner in which they formulate their questions, how they define the content of their domains and organize that content conceptually, and the principles of discovery and verification that constitute the ground rules for creating and testing knowledge in their fields. These principles are different in the different disciplines."<sup>2</sup>

What Shulman says about research in general is also true of qualitative research. Qualitative methodologies as research disciplines have their particular philosophical foundations and methodological integrity. Denzin and Lincoln offer the following definition of qualitative research, "Qualitative research locates the observer in the world. Qualitative research consists of a set of interpretive, material practices that makes the world visible."<sup>3</sup> Multiple methods are used to see the world in its setting, to interpret phenomena contextually.

Although there are many typologies, Patton's approach is typical. He states,

Decisions about design, measurement, analysis, and reporting all flow from purpose. Therefore, the first step in a research process is getting clear about purpose. The centrality of purpose in making methods decisions becomes evident from examining alternative purposes along a continuum from theory to action:

1. *Basic research*: contribute to fundamental knowledge and theory
2. *Applied research*: illuminate a societal concern or problem in the search for solutions
3. *Summative evaluation*: determine if a solution (policy or program) works
4. *Formative evaluation*: improve a policy or program as it is being implemented

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<sup>1</sup> Richard M. Jaeger, ed., *Complementary Methods for Research in Education* (Washington, DC: American Educational Research Association, 1988).

<sup>2</sup> Lee S. Shulman, "Disciplines of Inquiry in Education: An Overview," in *Complementary Methods for Research in Education*, ed. Richard M. Jaeger (Washington, DC: American Educational Research Association, 1988), 3-17, here, 5.

<sup>3</sup> Norman K. Denzin and Yvonna S. Lincoln, eds., *The Sage Handbook of Qualitative Research*, 4th ed. (Thousand Oaks, CA: Sage, 2011), 3.

5. *Action research*: understand and solve a specific problem as quickly as possible."<sup>4</sup>

Some authors are protective of their turf. Mixing methods is a taboo for them. If Patton is right, and purpose is the criteria, then multiple methods are often appropriate.

Merriam describes four characteristics that all qualitative research has in common. They include 1) a focus on understanding and meaning (how do people interpret their experiences?); 2) the researcher as primary instrument of data collection and analysis; 3) an inductive orientation to analysis; and 4) findings that are richly descriptive.<sup>5</sup> Furthermore, qualitative research systematically seeks answers to questions by examining various social settings and the individuals who inhabit these settings. Qualitative research is grounded in the social world of experience and seeks to make sense of lived experience. Qualitative researchers seek the meanings how humans arrange themselves and their settings and how inhabitants of these settings make sense of their surroundings through symbols, rituals, social structures, social roles, and so forth.<sup>6</sup>

Denzin and Lincoln, describing qualitative research, state,

Qualitative research is multi-method in focus, involving an interpretative, naturalistic approach to its subject matter. This means that qualitative researchers study things in their natural settings, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them.... Qualitative research involves the studied use and collection of a variety of empirical materials—case study; personal experience; introspection; life story; interviews; artifacts; cultural texts and productions; observational historical, interactional, and visual texts—that describe routine and problematic moments and meanings in individuals' lives. Accordingly, researchers deploy a wide range of

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<sup>4</sup> Michael Quinn Patton, *Qualitative Research & Evaluation Methods*, 4th ed. (Thousand Oaks, CA: Sage, 2015), 248.

<sup>5</sup> Sharan B. Merriam and Elizabeth J. Tisdell, *Qualitative Research: A Guide to Design and Implementation*, The Jossey-Bass Higher Adult Education Series, 4th ed. (San Francisco: Jossey Bass, 2016), 15–18.

<sup>6</sup> Howard Lune and Bruce L. Berg, *Qualitative Research Methods for the Social Sciences*, 9th ed. (Harlow, UK: Pearson, 2017), 12.

interconnected interpretive practices hoping always to get a better understanding of the subject matter at hand.<sup>7</sup>

Qualitative research produces culturally specific and contextually rich data critical for the design, evaluation, and ongoing health of institutions like churches.

### **The Nature of DMin Research**

The DMin degree finds residence in the field of practical theology.<sup>8</sup> The DMin is an advanced program oriented toward ministerial leadership (a sub-discipline of practical theology). The purpose of the DMin is to improve the practice of ministry for persons who hold the MDiv degree or its equivalent and are actively engaged in ministerial leadership. The Commission on Accrediting "2020 Standards of Accreditation" 5.3 states,

The Doctor of Ministry degree has clearly articulated student learning outcomes that are consistent with the school's mission and resources and address the following four areas: (a) advanced theological integration that helps graduates effectively engage their cultural context with theological acumen and critical thinking; (b) in-depth contextual competency that gives graduates the ability to identify, frame, and respond to crucial ministry issues; (c) leadership capacity that equips graduates to enhance their effectiveness as ministry leaders in their chosen settings; and (d) personal and spiritual maturity that enables graduates to reinvigorate and deepen their vocational calling.

5.5 continues by again emphasizing the rigor needed using the words "advanced" and "significant." "The Doctor of Ministry degree is an advanced professional doctorate that builds upon an accredited master's degree in a ministry-related area and upon significant ministry experience."

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<sup>7</sup> Denzin and Lincoln, *Handbook of Qualitative Research*, 3rd ed., 3–4. Currently there are five editions of the *Handbook of Qualitative Research*. All five editions are substantially different containing various authors and chapters and are more akin to volumes than editions. *Handbook of Qualitative Research*, 5th ed., 1–2, describes how terms and definitions are in flux.

<sup>8</sup> See Stuart Blythe, "DMin as Practical Theology," *Religions* 12 (2021) 1–31. <https://doi.org/10.3390/rel12010031> for a discussion of the various ways a DMin program connects to the larger field of practical theology,

The research seminar is designed to integrate the competencies developed in the DMin curriculum and to fashion a project appropriate for the student's particular ministry setting. All four student learning outcomes (or similar wording) listed in 5.3 are essential for shaping the competencies of the project. The project's prospectus describes the methodology that will be used for the project including the project's purpose, sampling procedures, intervention design, data collection and analysis.<sup>9</sup>

### Institutional Review Boards

Every university or seminary that receives funds from the federal government has a requirement to have a Human Subjects Committee or an Institutional Review Board (IRB) that reviews the research proposal.<sup>10</sup> When and why research is submitted to an IRB is often misunderstood. Sometimes a project is inspected by the IRB, and sometimes not. The rest of the article below explores the question of human subjects' research in the context of DMin projects.

When a project is deemed "human subjects' research" IRB approval is required prior to the project's approval and before recruiting participants. Approval is not just a hoop to jump through but intended to protect human subjects from exploitation by researchers. Approvals demonstrate your understanding of obligations as a researcher and that you have strategies in place for protecting research collaborators. A secondary consideration for the review is for your legal protection and to safeguard the university. While human subjects research is not permitted to use any kind of exculpatory language in consent forms or waive any liability, certainly the risks of liability are greater if IRBs did not exist.

Research is defined by the Department of Health and Human Services in the Common Rule or 45 CFR 46 as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Human subject is defined in 45 CFR 46 as "a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data

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<sup>9</sup> For more information about qualitative research and participatory action research see Tim Sensing, *Qualitative Research: A Multi-Methods Approach to Projects for Doctor of Ministry Dissertations*, 2nd ed. (Eugene, OR: Cascade, forthcoming in 2022).

<sup>10</sup> Research involving human participants must abide by the Federal Regulations protecting human subjects. The Federal Regulations for protecting human subjects have changed as of January 19, 2018.

through intervention or interaction with the individual, or (2) Identifiable private information.”<sup>11</sup>

DMin programs must provide the communication mechanisms between student researchers and the IRB. Most often this connection is made during the writing of the DMin project prospectus. It is the responsibility of the investigators to become familiar with and abide by the regulations and policies about human subjects. All members of the research team should complete ethics training, including the Principal Investigator (PI), Co-PI, Faculty Advisor, Co-researchers, research assistants, graduate assistants, and any other individuals who will be interacting with the

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<sup>11</sup> 45 CFR 46 “The Common Rule” <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>.

Other countries may have different requirements. Although an international DMin student’s program resides in North America, most likely their projects will be located in their home country. Since the human subjects of those projects reside internationally, it is the responsibility of the student to comply with the local national policies. The Common Rule specifically states, “(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research. (h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the *Federal Register* or will be otherwise published as provided in department or agency procedures.”

ACU currently has students in Australia, Ukraine, and Nigeria. ACU requires that projects be vetted by the policies of both countries. In Australia, for example, Human Research Ethics Committee (HREC) has stricter requirements. All human research, even undertaken in a classroom setting, requires either expedited or full approval by HREC. The expedited review is for those whose research projects are of negligible or low risk. Researchers should use the full review for projects with more complex elements or that are more than low risk (see <https://divinity.edu.au/research/human-research-ethics/>). For example, one Australian student at ACU was required by ACU’s IRB to complete an expedited application and the full HREC application when she planned to invite people with intellectual disabilities (maximum variation sampling) to be part of a practices development team for the purposes of writing inclusive liturgies designed to increase participation opportunities for others with intellectual disabilities. While the student is not including participants with intellectual disabilities to study that population as human subjects (gathering confidential or personal information), and the student is not planning to use the liturgies beyond the local context, both the US and Australian processes required more detailed information and monitoring because of the vulnerable population involved.

participants or handling identifiable, private data. The IRB should not approve a study protocol until the ethics training requirement is met.<sup>12</sup>

Depending on the nature of the study, students will complete the exempt, expedited, or non-research application for IRB approval. The difference between these designations involves the particular intervention, methods used, sampling choices, and intended future uses of the findings. Each program's IRB will have policies and procedures that will guide the student about which application to complete. Not all IRBs interpret 45 CFR 46 the same and it is incumbent for DMin programs to know the particularities of its home institution. In my experience, many DMin programs are familiar with exempt and expedited processes but not the non-research option.

IRBs are very familiar with research coming from the sciences, human services, and other social science fields. Generally, for example, the departments of Kinesiology, Psychology, Social Work, Education, Biochemistry, etc. will travel the hallway to the IRB office frequently seeking exempt, expedited, and full designations. However, the non-research option might not only sound new but also fishy. Nevertheless, 45 CFR 46 provides a pathway to consider non-research as a viable educational activity.<sup>13</sup> Theses and dissertations investigating biblical or historical topics (descriptive research) rarely come under the purview of the IRB. It is not even an afterthought for the IRB to address a student's research about dead

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<sup>12</sup> See the U.S. Department of Health and Human Services, "Code of Federal Regulations: Title 45, Public Welfare, Part 46, Protection of Human Subjects." <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm> or the American Anthropological Association. "Statement on Ethnography and Institutional Review Boards." <http://aaanet.org/stmts/irb.htm>. Mary Clark Moschella, *Ethnography as a Pastoral Practice: An Introduction*. (Cleveland: Pilgrim, 2008), 96–97, gives an example of a simple informed consent form and on page 112, an example of an IRB application.

Training courses in research ethics are required by some agencies, churches, or universities. Online options include Family Health International "Research Ethics Training Curriculum." <http://fhi.org/training/en/RETC/>. IRB Training is also available at CITI Programs (Collaborative Institutional Training Initiative) (<https://www.citiprogram.org/index.cfm?pageID=14&languagePreference=English&region=1>). Course programs include: Responsible Conduct of Research, Conflict of Interest, Information Privacy & Security, Human Subjects Research, and Good Clinical Practice. You can take courses either as an independent learner or through an affiliate organization. ACU is an affiliate organization.

<sup>13</sup> The 2018 Common Rule revisions attempted to make clear some areas of academic research that were deemed "non-research" by the Regulations, specifying clearly things like oral history, journalism, etc. However, no revision ever seems to encapsulate all of the possibilities (like quality improvement or program development).



people. Moltmann's subtle uses of Balthasar's ecclesiology never crosses the threshold of 45 CFR 46.

### Non-research and Scholarly Rigor

So, what about the non-research option for DMin projects? When considering the use of "non-research" as an IRB designation, DMin programs should consider that the new DMin Standards describes the DMin degree as a professional doctorate (Standard 5.5), compared to the PhD that is categorized as a research doctorate (Standard 5.14). That said, Standard 5.4 describes various components of the DMin, including research aspects. While 45 CFR 46 might have a non-research option, Standard 5.4 still utilizes the term "research." The ATS Standards state, "The degree culminates with a written project that explores an area of ministry related to the student's vocational calling, utilizes appropriate research methodologies and resources, and generates new knowledge regarding the practice of ministry."<sup>14</sup> Not only does Standard 5.4 utilize the word "research" for the DMin project, but Standard 5.9 uses the term for the professional doctorate.

5.9 These professional doctoral degrees have clearly articulated student learning outcomes that are consistent with the school's mission and resources. The outcomes focus on the degree discipline in areas related to advanced understandings of, and competencies in, appropriate theological disciplines, behavioral sciences, social sciences, research methodologies, and the integration of those areas in a well-designed doctoral dissertation, written project, culminating report on field-based research, or other summative exercises. If any courses in this degree are shared with other degrees, doctoral-level outcomes and assignments specific to students in this professional degree are made clear.

"The ATS Standards, then, tend to favor the term "professional doctorate" over "non-research doctorate," but schools have the freedom to use the term most appropriate to their context."<sup>15</sup>

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<sup>14</sup> The Commission on Accrediting, "2020 Standards of Accreditation," (Pittsburg: Association of Theological Schools, 2020), 5.4. <https://www.ats.edu/accrediting/standards>.

<sup>15</sup> Private email from ATS liaison who referenced Standard 5.4.

Does the non-research designation lower the bar for the DMin degree? No! Primarily, the argument in favor of using the non-research designation is a matter of definition not rigor. 45 CFR 46 has a very narrow definition of research to capture human subjects research, not redefining what research means to academia. What is intended by 45 CFR 46 is not a watering down of meticulous precision but to increase the protections provided for persons. Otherwise, it could be argued that all research in the classical theological disciplines is less rigorous.

#### Use of the Non-Research Option

How does a program proceed with using the non-research option? First, while Standard 5.4 uses the word “research,” non-research approval by the IRB requires you not to use the words “researcher” or “research” in the IRB application or prospectus. Otherwise, you introduce a contradiction of terms. Appropriate synonyms include study, project, investigation, or inquiry.

Second, while the new definitions given in 45 CFR 46 do not include DMin type projects, they are covered under quality improvement and program development. There is not a single definition given by the Department for Health and Human Services for quality improvement and program development because they are discerned on a case-by-case basis (some fit the definition and some do not). Some applications at ACU are deemed non-research because the student does not seek to contribute to generalizable knowledge. As long as it is program development that continues to be specifically designed for a single congregation, community, or organization and not intended for a larger audience, your project will be classified as “non-research” by the ACU IRB.

Additionally, many DMin projects are not, by definition in the Common Rule, using human subjects in their research. Most often, the participants in DMin research are collaborators. This is especially true for Action Research, the most common choice for DMin programs. The participants design curriculum, write vision statements, plan programs, implement practices, articulate new policies or procedures, etc. They are not gathering private and personal information that puts congregants at risk. They are fulfilling tasks that are considered routine professional practice. The DMin project simply formalizes those common professional tasks in a robust and rigorous educational context for the student’s professional development. However, if a project is designed to include sensitive, personal, and confidential information from congregants or other

community members, then the IRB will require and exempt or expedited review. These projects are human subjects research.

Even though DMin projects often employ focus groups, questionnaires, observations, and other qualitative tools of research involving living people, the protocols are not designed to gather personal and identifiable information from the participants. Gathering historical data, oral histories, opinions about programs, policies, practices, legal information, or brainstorming possibilities are excluded from the research designation. Evaluating the DMin project's purpose or final artifact through triangulation using qualitative measures is likewise excluded. Many DMin Action Research projects are not studying the people, but the practices of pastoral ministry.

Examples of non-research projects include community outreach, quality assurance, program evaluation, or quality improvement. Again, non-research projects involve the minister's work and activities within the normal parameters of professional practice. Additionally, non-research projects do not involve vulnerable populations as research subjects.<sup>16</sup> If a student indicates that a project's findings or artifacts will be used for publication, curriculum for non-local use, or other public dissemination, ACU will make a case-by-case determination about the "generalizability" of the project. Generalizability restrictions for the non-research category is primarily about the risks associated with confidentiality of participants. If that risk is not applicable (for the same reasons the project is not actually human subjects) then publication or wider distribution of the project's findings is beyond the scope of the IRB's purview. However, if in doubt about questions of human subjects or generalizability, ACU will ask for an exempt application.

Let me offer a short word about exempt and expedited applications. Exempt applications involve research that has minimal risks, does not involve prisoners, and is not FDA regulated. Exempt projects are deemed to be human subjects, but the risks about confidentiality and privacy are deemed minimal. However, if the risk for the loss of confidentiality is greater, like in the use of a focus group, then an expedited application is warranted.

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<sup>16</sup> Special or vulnerable populations include children, decisionally impaired, prisoners, students, and pregnant women or fetuses. Yes, for example, a pregnant woman might participate in a DMin project, but it is not for the purposes of studying her pregnancy. A student might collaborate with curriculum design because purposive sampling deems the student's perspective valuable, but that participation is not deemed as a "special population" by definition. Neither of these examples increases the risk to the participants because of their participation.

If DMin projects qualify for an expedited IRB application, two major categories are added to those applications. (1) Describe the activities, procedures, and/or interventions in the study and identify if they are “routine” or “research.”<sup>17</sup> Since it is human subjects, you answer “research.” Include who will conduct/administer the research activity. For example, if the student includes a focus group or small group interview, the expedited form is used because of confidentiality concerns. In this case, clearly articulate how you will communicate and protect confidentiality when using focus groups or small group interviews. (2) Describe all the research activities notating how “serious and likely” the risk is. It is assumed that studies involving expedited categories are still minimal risk as defined in the regulations. In the case of small group interviews and focus groups within DMin projects, risk is minimal because of the relationships that previously exist among the participants themselves and due to the non-sensitive nature of most interventions. Full Board Review is rare, if ever, for DMin projects. If a student’s project is designated as exempt, expedited, or full, the IRB will require various levels of follow-up reporting.

### **Recommendations**

So what? According to the Common Rule, non-research is a more accurate designation for most DMin projects. While the exempt category might functionally accomplish the same result as a non-research designation, it wrongly assumes that there is a level of human subjects research occurring. In my opinion, most (not all) DMin projects will not need to be submitted to IRB boards at all because the research is deemed non-research. Just like a PhD on Second Temple Judaism is not reported to the IRB, so too the DMin project designing a leadership selection process for new church plants.<sup>18</sup> Advantages of using the non-research designation include: 1) a busy IRB office is saved hours of tracking, auditing, and reporting; 2) decisions are made within hours rather than days or weeks; 3)

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<sup>17</sup> IRB ask this question to separate out the aspects of a study that may be part of a routine procedure and the parts that are the research. For example, maybe someone always presents a particular film in class, but now they want to assess students’ reactions to the film. Showing of the film, for them at this point, is a routine aspect of their course. It is only the student assessment that is the “research.” IRB ask about “routine” to try to limit overreach of the IRB into areas of standard practice.

<sup>18</sup> The same processes for the approval of the prospectus used for masters theses and PhD dissertations are adhered to. At ACU that includes approvals from the primary and secondary advisors, the DMin director, and ACU’s Associate Provost for Graduate Programs and Services.

the student is released from further obligations to report back to the IRB; 4) projects begin in a timely manner; and 5) the accuracy of accreditation audits is more accurate.<sup>19</sup> This is good news!

When is research not research? Let me put my tongue squarely in my check. Research is not research when the principalities and the powers play games with semantics. While the intent to protect human subjects is a serious matter, the designation of research as non-research is an odd way of defining it. Ask anyone who has completed a descriptive research dissertation at the University of Chicago (or any ATS accredited institution). Non-research is research. DMin students can engage their projects with confidence that their work still meets the high standards of validity and reliability required by all qualitative researchers in the social sciences. And the constructive praxis of DMin students is good news for the churches, communities, and organizations they serve.

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<sup>19</sup> In such instances, the DMin office will want to require appropriate ethics training, file non-research applications (example given below), and store all pertinent documentation about the discernment process in order to demonstrate the programs compliance with regional and ATS accreditation standards. The DMin office will want to clearly articulate the criteria used to differentiate when the non-research application is requested versus the exempt or expedited application that is sent to the IRB. To read more about policies, procedures, and practices related to qualitative research ethics see Sensing, *Qualitative Research* (the second edition is forthcoming from Cascade in 2022).

**Appendix One**  
**Human Subjects Resources**

45 CFR 46, "The Common Rule." <http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

The Belmont Report. <http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

OHRP Educational Resources. <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/resources-for-investigators/index.html>

**Appendix Two**  
**Example of an IRB Non-Research Determination Request**  
(adapted from ACU's IRB materials)

Title of Proposed Project:

Date of Request:

Principal Investigator (PI):

Faculty Advisor (If PI is a student):

Phone:

Email:

Address:

Point of Contact, if other than PI (Name, phone, email):

Ethics Training Completion Date:

**Site and Funding**

The project will be conducted:  On Campus  Off Campus

(If off-campus, please describe the site, whether you require and have permission to conduct the study at the site, and whether the site is accepting this IRB review or requires their own IRB approval.)

Is this project being funded by an outside agency?  Yes  No

If yes, please specify which agency:

My activity does not involve a systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).

(If no, then you cannot use this form. If yes, then one of the following must also apply.)

Quality Improvement that is not otherwise research as defined above: in which all participants are expected to benefit, all receive at least standard treatment, and the purpose is to evaluate process change in order to immediately implement program improvements.

Quality Assurance that is not otherwise research as defined above

Program Evaluation that is not otherwise research as defined above: the purpose is to assess the program's ability to meet objectives

Customer Service Experience: the purpose is to obtain feedback for use by the program's managers

- \_\_\_ Class Project: the purpose is to teach content, not contribute to generalizable knowledge. (Please note: data collected for class purposes 1) Cannot be used for research purposes outside of the classroom, 2) Must follow all ethical guidelines for human subjects research, and 3) Must be destroyed at the end of the class. Course instructors are responsible for ensuring these standards are met. Please use this exemption wisely. Retroactive approval cannot be granted.)
- \_\_\_ Case Report: when the report is of a small sample (no more than 3) and the activity is not a systematic evaluation of a hypothesis (not research).
- \_\_\_ Community Outreach: the purpose is to benefit participants or otherwise make improvements in the community, not contribute to generalizable knowledge.

### **Plan**

Please provide a narrative of the study plan that demonstrates the requirements for a non-research designation. Please address the purpose of the project, selection and consent of participants, participant demographics, intervention, and methodology. Describe your relationship with the potential participants. Delineate the risks & benefits of the project. This must be sufficiently detailed that the reviewer can determine the non-research qualification and category.

Will you be collecting identifiable demographic data or personal contact information? How will you protect privacy of the participants? Explain how you will insure the confidentiality or anonymity of your participants. How will your data be stored?

What do you plan to do with your findings and final reports?

If you plan to compensate participants, please describe:

### **Conflicts of Interest**

Do any of the study personnel have Conflicts of Interest to report?

\_\_\_ Yes \_\_\_ No

If yes, please list the individual, the conflict, and any plans to manage the conflict:



**IRB Request Appendixes**

Identify which items are included in the submission (Please submit all documents as separate attachments)

- Protecting Human Subject Research Participants Training Completion for all research team members (required).
- Training Certificates of Completion for all research team members.
- Vulnerable Populations Form (not included if non-research is approved)
- Participant Sampling materials
- Consent Form
- Data Collection Protocols
- Other: \_\_\_\_\_

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