ASPEN UNIVERSITY

2023-2024

IRB Handbook

4615 East Elwood Street
Phoenix, AZ 85040

Introduction

The IRB and related processes can be confusing. The goal of this handbook is to provide an overview of the process and answer frequently asked questions allowing you to successfully submit your IRB application and accomplish another important milestone on your doctoral journey. If at any time you have questions, please contact the IRB: IRB@Aspen.edu (always cc your chair on any communication with the IRB).

As a doctoral candidate, the IRB will come into play after the successful defense of your doctoral project proposal or dissertation proposal. Once your proposal has received all required approvals, you will submit an IRB application.

Absolutely no recruitment of participants, data access, data collection, or project/study implementation may occur prior to IRB approval.

Failure secure appropriate approval from the Aspen's IRB may result in serious actions including dismissal.

What is an IRB

IRB stands for Institutional Review Board. An IRB is an autonomous committee whose role is to review research with the primary emphasis on maximizing the protection of the rights and welfare of human participants. Research that is funded or supported by the U.S. federal government is required to adhere to the federal regulatory requirements for protection of human participants. ***However, Aspen University requires the same standards for all dissertation research and doctoral projects irrespective of funding source.*** The IRB is also used to ensure university compliance with HIPAA, FERPA and similar information privacy protection requirements.

While the composition of the IRB may change over time, consistent with federal regulation, the Aspen IRB has at least five members with varying backgrounds promoting a comprehensive review of activities commonly conducted by the Aspen University community. You will learn details about the IRB during your CITI training (described below). Appendix A (p. 11)also offers additional resources.

What is CITI Training

CITI stands for Collaborative Institutional Training Initiative. This initiative helps researchers gain a better understanding of how to best protect the rights and welfare of human participants. Issues related to the use of human participants in research is complex – this handbook in combination with training provided through CITI will give you the basics. **You must complete your CITI training prior to submitting your IRB application.** When it is time to begin this training, you will be prompted in the appropriate course. The training is lengthy; you will need to set aside adequate time to complete the modules. Each module has a quiz and you must pass with 80% - note taking is encouraged!

This 7-minute video explains the CITI training – including how to create an account and which courses you will need to complete prior to your IRB application submission.

Once you complete your training, save your certificates as you will need to upload them with your IRB application. To make the IRB application process efficient, consider creating an IRB folder and saving all the documents you will need for your IRB application in that folder.

Why Do I Need to Understand the IRB Process

As a doctoral-granting institution, Aspen University values both original research and the application of research in an effort contribute to knowledge in a field of study. The doctoral programs at Aspen University teach skills commiserate with a doctoral degree, which include understanding issues related to human participants in research. Thus, experience with the IRB process is built into every doctoral program and every doctoral candidate is required to submit an IRB application and receive formal approval prior to conducting any dissertation research or implementing any doctoral project.

Candidates in the DNP program with experience conducting Quality Improvement (QI) or Quality Assurance (QA) projects where IRB approval is not standard because the activity is not deemed "research" may logically question the need for the IRB to review their DNP Project.

It is true that not all work that we would colloquially call "research" is considered to be research under the Common Rule (the Common Rule is a short name for "The Federal Policy for the Protection of Human Subjects" and was adopted by a number of federal agencies in 1991 and revised in 2018). The Common Rule defines research as: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." To decide if a certain activity meets the regulatory definition of research, two factors are assessed: 1) whether the activity involves a systematic investigation, and 2) whether the activity is designed to develop or contribute to generalizable knowledge. Whether or how an investigator shares results with the scientific community is not the deciding factor for whether the activity was designed to develop or contribute to generalizable knowledge.

For example, information is published that comes from activities that do not meet the Common Rule's definition of research. And sometimes results from activities that meet the Common Rule definition for research never get published. Publication of results is sometimes used, incorrectly, as an indicator that a project meets the definition of research. It is not publication, nor the intent to publish that matter, *it is the intent of the project that matters.*

Distinguishing between QI/QA and research can be difficult. If the intent of the data collection is to contribute to "generalizable" knowledge, or if the results are applicable outside of the project

setting or population, the activity is usually classified as research. If the QI/QA results stay entirely in-house and are used for administrative purposes only, many organizations do not consider this research. There is no regulatory guidance on the meaning of generalizability. The essential consideration is whether it was the *principal investigator's intent to contribute to a body of knowledge*.

While projects with a QA/QI focus may not always seem to fit the legal definition of research, doctoral dissertations and projects within Aspen University programs require going beyond simple QI/QA in-house initiatives.

In short, as someone pursuing a doctoral degree, it is important that you understand issues related to research with human participants, whether you will be conducting an original research study or implementing a project based on QI/QA principles.

Remember: Absolutely no recruitment of participants, data access,

data collection, or project/study implementation may occur prior to IRB approval.

What Principles Do I Need to Understand

The Belmont Report identifies basic ethical principles and guidelines that address ethical issues arising from the conduct with human participants in research. This report identifies three principles: respect for persons, beneficence, and justice. Each principle carries equal moral weight and they sometimes conflict with each other. Thus, the principles must be considered as an equal obligation with conflicts requiring careful consideration and "balancing." The principles and their corollary obligations are explained in the table below.

PRINCIPLE	OBLIGATION
Respect for persons: You respect individual autonomy and allow the freedom of choice. This principle requires that individuals with reduced autonomy (also known as vulnerable) are protected.	· Adding safeguards for those who may be vulnerable to coercion or undue influence
Beneficence: Maximize benefits to participants, science and society, while minimizing harm to participants and others.	
Justice: When selecting participants, there is equitable distribution of both the burden and benefits of the study/project.	

Aspen's IRB will review your IRB application, considering these principles as well as questions such as:

- Has appropriate permission(s) been granted from all collaborating institution(s)/organization(s)?
- Are all public-facing materials clear and free from spelling and grammar errors?
- Does the study/project use procedures consistent with sound research design/evidence- based practice?
- Is the study/project sound enough to reasonably expect results to answer the proposed question(s)?

Application Process

How is My Application Reviewed

Research studies/projects fall into one of three categories: exempt, expedited, and full board review. Given the mission statement and goals of the doctoral programs at Aspen University, most dissertation research and doctoral projects fall into the exempt or expedited categories, which in general means there is ***no more than minimal risk to participants***. Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Occasionally a study/project will require a full committee review, for example collecting ***sensitive information*** (see below for examples) and/or proposing participants from a ***vulnerable population*** (see below for a partial list of vulnerable populations). While your CITI training will go into depth regarding levels of review, some frequently asked questions are included here.

What are the differences between exempt expedited and full board review catagories

The definitions of studies/projects that are exempt or eligible for expedited review per federal regulations can be confusing to anyone who is not trained as an IRB reviewer. The IRB application is designed to gather the information needed to determine the appropriate level of review for your study/project. Most IRB applications submitted by the Aspen University community are exempt, some are expedited, and very few require a full board review.

Neither you nor your chair or committee members have the authority to determine the review level; this is determined by the IRB.

The categories are covered in more detail in your CITI training and definitions can be found here:

- Exempt (with or without limited review)
- Expediated

Studies/projects that are not exempt ***or*** eligible for expedited review require a full board review and ***must be reviewed at a convened meeting of the IRB***. Full board review usually involves research that is greater than minimal risk and/or vulnerable populations but also includes minimal risk research that does not meet criteria specified in the exempt/expediated categories. The good news is that you don't classify the level of your study/project; just complete an IRB application under the guidance of your chair and the IRB will do the rest!

Regardless of the level of review, every IRB application is processed, and a letter is sent to the candidate when the IRB has reviewed and approved the study/project. ***As a reminder: absolutely no recruitment of participants, data access, data collection, or project/study implementation may occur prior to IRB approval.***

Who decides the level of review

The level of review is determined by the IRB Chair or designee, not the candidate, chair, committee members, other faculty, administrators, or site collaborators. The IRB application is designed to collect all the information needed to appropriately process your study/project.

What are sensitive topics

Any interview, survey or questionnaire that proposes to

investigate opinions, behaviors, and/or experiences regarding, but not limited to, any of the following topics:

- Sexual orientation, incest, rape, sexual molestation, deviant sexual behaviors, or attitudes regarding sexual conduct, practices of contraception, abortion and/or pregnancy
- Substance use and/or abuse including, but not limited to, alcohol, marijuana, steroids, amphetamines, narcotics, and any prescription medication legally or illegally obtained
- Questions regarding mental health (e.g., suicide, depression, obsessive compulsive behaviors including, but not limited to, gambling, smoking, eating, etc.)
- Traumatic experiences of an individual, including war or combat experiences of veterans

What is a vulnerable population

People who are considered vulnerable are those who require greater protection than normal against the potential risks of participation. For example, they may have difficulty providing voluntary, informed consent due limitations in decision-making capacity or situational circumstances or because they are especially at risk for exploitation. Vulnerabilities ultimately relate to challenges to the ethical principles of respect for persons, beneficence, and justice. Some common vulnerable populations include:

- Subordinates of the researcher (e.g., students, employees)
- Pregnant Women
- Individuals who are incarcerated (i.e., prisoners)
- Individuals with a debilitating mental health/psychiatric condition (e.g., PTSD, depression, bipolar disorder, etc.)
- Individuals with a cognitive impairment
- Residents of a facility (such as a mental health facility, nursing home, treatment center, etc.)
- Individuals with a life-threatening illness or condition (e.g., cancer, HIV/AIDS)
- Individuals who are educationally or economically disadvantaged
- Older Adults (people over 65 years of age)
- Indigenous Peoples
- Individuals who have experienced traumatic events (e.g., abuse, death, natural disasters)
- Individuals involved in a crisis (e.g., war, natural disaster)
- Veterans
- Homeless/Unsheltered individuals
- Individuals who identify as LGBTQ+(Lesbian,Gay,Bisexual,Transgender, Queer/Questioning)
- Immigrants or Refugees
- Individuals who are not fluent in the language the study is being conducted in (e.g., non- English speakers in studies conducted in the United States)
- Individuals with diagnosable addictions

If you are proposing to work with a vulnerable population, you will need to demonstrate to the IRB that your procedures are ethically sound, that the risks to participants are as minimal as possible, and that the scientific contributions and potential benefits of your study are significant enough to warrant exposing vulnerable individuals to the risks and burden of participation.

See Appendix B (p. 11)for additional information related to work with sensitive topics and vulnerable populations.

Aspen University does not allow studies or projects that require a participant

to introduce a substance into their body, whether orally, topically, by injection, or any other means (e.g., supplements, medication, food, suppositories, etc.).

What does a full review entail

A full review requires calling a meeting of the IRB

committee. Members will review the application and proposal prior to the meeting. The committee will discuss the application during the convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research/project to be approved, it must receive the approval of a majority of those members present at the meeting. The doctoral candidate may be invited to answer questions from the committee during the meeting.

How long does an IRB review take

Complete applications (i.e., those submitted with ***all required materials)*** are processed as follows:

- Within 5 business days: Applications for which the study/project is reviewed as exempt or expediated
- Within 21 business day: Applications for which the study/project requires a full board review take substantially longer (remember, a full committee must not only be convened, but have time to review the material prior to the meeting)

Students are encouraged to work with their chair and committee to determine ways to pivot ideas that require a full review. For example, if you are interested in the relationship between acute childhood trauma and learning, instead of interviewing children who have experienced trauma you might instead interview school counselors or teacher who work with these children.

Your IRB application is read and approved by your chair prior to submitting to the IRB. Failure to include a completed application will delay your review.

What are the possible outcomes of an IRB review

The following dispositions are possible:

- Approved: The study/project may commence
- Modifications Required to Secure Approval: Changes are required so that the study/project will meet criteria for approval
- Disapproved: The IRB has all the information it needs to make a determination, but the study/project does not meet criteria for approval
- Deferred: This disposition is only used if an application is incomplete or a quorum is not met for a full board review

All applicants will receive written notification of the IRB's decisions. It the activity is disapproved, notification will include reasons for the decision; you will have an opportunity to respond in person (e.g., over phone or a video call) or in writing.

Your IRB Application

The IRB application package (i.e., the application along with supporting materials) is designed to collect the information the IRB needs to determine the level of review required and the disposition of the study/project: approved, modifications required, or disapproved. To approve a study/project, the IRB must determine that:

- The risks to participants are minimized
- The risks are reasonable in relation to any anticipated benefits to the participant, and to the advancement of knowledge
- The selection of participants is equitable
- If applicable, informed consent/assent will be sought and documented
- There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data
- Where any of the participants are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect participants
- Appropriate site permission is secured

The following sections provide information that will allow you to provide comprehensive information on your

application and in your supporting documents, reducing the likelihood that the IRB will request additional information or modification prior to approval.

Site Permission Approval

Many studies/projects occur in collaboration with another site, institution, or organization (e.g., a clinic, school, or company) and you will need to submit permission from this site with your IRB application (see Appendix C (p. 13) or examples and use the template in the lounge as a starting point).

Note: DNP candidates,

this is not the same thing as an immersion site agreement.

If the entity where you are conducting your study or implementing your project ***has their own IRB***, typically you will seek their approval prior to submitting to the IRB at Aspen. If you are in the EdD or DSCS program work with your chair to determine required approvals. If you are in the DNP program it is your responsibility to determine if there is IRB oversight at your project site. Note: If the organization requires a conditional approval from Aspen prior to reviewing your application, reach out to IRB@Aspen.edu for guidance (always cc you chair).

Informed Consent

If your study/project will involve human participants, you will need to secure their informed consent to participate. Often there is confusion as to when an informed consent form is needed.

DNP candidates: unless required by your site, you often do not need an informed consent form. For example, if you are focused on a quality improvement project and assessing nurses' understanding of an established EBP protocol for the use of a clinical screening form, and then collecting data via a chart review to determine how the quality improvement initiative impacted screening, the IRB would not require an informed consent form from the nurses. However, you will need to provide a permission form from the site, granting you permission to implement the project. If in doubt, please email the IRB: IRB@apsen.edu (always cc your chair on any communication with the IRB).

The informed consent form represents a contract of confidentiality and ethical principles between you and the participants. Your consent materials must be clear and understandable, which means you should use non-technical, straightforward language. Specific regulations require that you present key information to facilitate understanding and ensure consent includes sufficient detail to assist an individual with making a decision regarding participation. Unless specifically waived by the IRB, informed consent must be documented by a written consent form approved by the IRB and signed by the participant or by the participant's legally authorized representative.

If your study/project requires a consent form, use the template available in the lounge and tailor the content accordingly (see Appendix D (p. 14) for examples).

The informed consent form is the "documentation" of consent. Although the "documentation" of informed consent is important, the "process" of informed consent is where participants are protected and why the IRB application requires you to include details related to the process of consent in your application.

HIPAA

When applicable; if no medical records are used, then HIPPA does not apply

- **HIPAA** applies when medical records (electronic, archival, paper, etc.) are used at any point during the research/project process
- A **HIPAA Authorization Form** should be submitted with a protocol when HIPAA applies

Renumeration

Payment or gifts for participation

- Guidelines permit remuneration to participants as long as the remuneration does not unduly influence participants to enroll or continue participation
- The consent process and form must clearly outline remuneration plans
- Receipt of remuneration may not be contingent on completion of the research
- The IRB must review and approve remuneration plans, and determine that they do not represent an

undue influence to enroll or continue participation

Data Collection Storage and Protection

The IRB will review the data you are proposing to collect to ensure it is aligned with the goals of your study/project. You will be asked, on the IRB application, to explain the data you are seeking to collect, how it will be collected, where it will be stored, who will have access to it, how it will be protected, and how and when it will be destroyed. To fulfill privacy requirements, security measures first and foremost aim to assure confidentiality. That is, that information that can identify a participant is accessed only by appropriate persons for appropriate reasons.

One of the best ways to increase protection of data is to code it in a manner so that only you can link the data to individual participants. The log cross-referencing the participant identification number with the name of the participant should be stored in a separate location from the data. If the study involves electronic data, then the log with identifiers should be stored on a separate server or computer system from the data.

While de-identifying the data from the identity of the participants is the ideal method in terms of protecting confidentiality, sometimes this is not possible as doing so would compromise the utility of the data for scientific purposes. In an effort to minimize risk, the IRB may request that data be de-identified as soon as the data analysis is complete and the dissertation or doctoral project has been approved by the university.

Another consideration is the storage and transmission of electronic data. Use care with flash drives or external drives that can be lost or stolen (alternates include cloud-based storage that requires a password and/or two-step authentication).

Studies/projects involving sensitive data such as illegal activities or protected health information (PHI) should have a comprehensive data security plan as this type of data requires additional safeguards. Data are considered sensitive when disclosure of identifying information could have adverse consequences for participants or damage their financial standing, employability, insurability, educational advancement, reputation or place them at risk for criminal or civil liability. The data security plan should minimally include plans for authentication of those who have appropriate access to the data (for example, appropriate password protection), appropriate firewall for the computer system, anti-virus and anti-spyware software, encryption of the data files, and secure location and storage of the computer systems and servers. Additionally, the research/project plan should provide considerations to mitigate risks of storing data on laptops and flash drives.

Permission to Use or Modify an Instrument

Many authors allow for non-commercial use of their tools by researchers without requiring written permission, a license, or a fee. For example, surveys developed at the RAND Corporation are freely available and no permissions are needed. A directory of free survey instruments can be found here.

Some authors request or require that you obtain explicit approval to use their measures even if there is no cost. This can be motivated by a desire to keep track of how widely a scale is being used and to make sure the user has the most recent version and understands the correct way to apply the tool. For example, the Kidney Disease Quality of Life (KDQOL™) surveys are provided without charge to those who register.

If you are going to modify an instrument or protocol, you must include the author's permission.

Quality of Your IRB Application

Your IRB application tells the IRB a great deal about you. Give the IRB confidence about your professionalism and capabilities based on a well-written, accurate submission. Applications that are not complete, contain errors/typos, or that provide inconsistent information will be delayed.

Appendix E includes a checklist to assist you with the submission of your IRB application.

It is important that do not submit an application with missing documents, inconsistencies, typos, or grammatical and spelling errors. Further, typos and errors in your recruitment materials, informed consent form, or instruments may steer potential participants away from your study/project or make them question your credibility. For this reason, and because your status as a doctoral candidate reflects on the reputation of Aspen University,

the IRB may ask you to revise materials that will be seen by potential participants for accuracy and clarity.

You will need Adobe Acrobat Reader installed on your computer and a digital ID configured to sign your IRB application.

Depending on your device, downloading the program and configuring your ID should take approximately 5-10 minutes. Click here for Adobe Support or review the details included in the IRB Submission Checklist (Appendix E (p. 15)**).**

Once I have IRB Approval am I done with the IRB

No. At the very least you will submit an IRB Close Out Form upon acceptance of your Dissertation or Doctoral Project by the university (i.e., when the Dean or Dean's designee approves your final manuscript post the passing of your oral defense).

There are other reasons you need to contact the IRB:

- IRB Change Request Form – If you need to make a change to ANY aspect of your study or project (e.g., a change to a survey interment, informed consent form, where the study or project is taking place, or how participants are being recruited, etc.). The IRB must approve the change(s) ***before you proceed.***
- IRB Continuing Review Form – Your study or project will be approved for one year. If your study or project will exceed this timeframe, you must submit to the IRB and receive approval to continue.
- IRB Events Reporting Form – When to use this form is described in detail in the next FAQ.

An unanticipated problem or even occurred during my study-project what do I do

An unanticipated problem that requires reporting to the IRB must meet three criteria. A reportable unanticipated problem is any incident, experience, or outcome that is:

- Unexpected
- Related or possibly related to participation in the research
- Places participants or others at a greater risk of harm

If all three criteria are met, complete an IRB Events Reporting Form within 48 hours and submit to the IRB.

Other events that may require reporting to the IRB include deviations from an approved study plan and violations of the terms of approval. If any of these occur, complete an IRB Events Reporting Form within 48 hours and submit to the IRB.

If *anything* unanticipated happens during your study/project, contact your chair immediately. They will help you decide if reporting to the IRB is required. If in doubt, contact the IRB: IRB@Aspen.edu and be sure to cc your chair.

IRB Forms

When to Use Them and Where to Find Them

All forms can be found in your program's lounge. If you cannot locate a form, please contact IRB@Aspen.edu.

- **IRB Application** – Submit this when requesting initial approval for your study/project.
- **IRB Close Out Form** – Submit this when you have passed your oral defense ***and*** your final dissertation/doctoral project has been accepted by the university. This is essentially a notification to the IRB to close out your file.
- **IRB Change Request** - Submit this when any changes need to made to an approved study/project. Changes cannot be made without IRB review and approval. The type of review will depend on the magnitude of the change and the effect of the change on the risks/benefits ratio.
- **IRB Continuing Review Form** – Submit this form when your study/project exceeds the initial one-year approval time frame (i.e., if you study/project is still in progress after one- year of receiving approval, you must submit this form).
- **IRB Events Reporting Form** – Submit this form for any of the following:
- Adverse events or unanticipated problems involving risks to participants or others
- Deviations from an approved study plan and violations of the terms of approval

Appendices

Appendix A

Office of Human Research Protections (OHRP)

- Office for Human Research Protections
- Protection of Human Participants: 45 CFR 46

Ethical Principles & Codes

- Belmont Report
- Declaration of Helsinki (World Medical Association)
- Nuremberg Code

HIPAA

- IRBs and the HIPAA Privacy Rule (NIH)
- NIH Guidance on Protecting Personal Health Information in Research (NIH)
- NIH Guidance on Research Repositories, Databases, and the Privacy Rule (NIH)
- NIH Guidance on Clinical Research and the HIPAA Privacy Rule

FERPA

- Videos produced by the Department of Education about Protecting Student Privacy
- Guidance on the Application of FERPA and HIPAA to Student Health Records
- HIPAA versus FERPA Infographic

Appendix B

Children and Other Vulnerable

Populations

Vulnerable Populations

- If any vulnerable group participates in research, you must provide specific safeguards for that group to prevent coercion and added risk
- If the adult participant is unable to consent, additional safeguards to protect their rights and welfare must be considered
- All consent and assent must be provided in the participants' primary language
- The IRB committee may ask you to elaborate on how you will engage adults with cognitive impairments (e.g., adult assent, verbal script, etc.)

Assents (Children and Mentally Impaired Adults)

- Assents are required for children in research (when developmentally appropriate)
- Assents are required for adults who are mentally impaired, including participants with head injuries
- You must obtain parental/guardian permission prior to obtaining the child's assent or the mentally impaired individual's assent
- A written assent should be used for children between the ages of 13 and 17
- An oral assent should be conducted for children between 7 and 12
- For mentally impaired adults, written consent should be the first choice; if this is not possible, then oral assent and a written approval from the guardian is needed
- Submit a script for the oral assent to make sure it is developmentally appropriate for the age of the child or mentally impaired adult
- If an assent form is missing from a proposal and the IRB committee feels it is appropriate to use, the protocol cannot be approved and will be postponed

Parental/Legal Guardian Permission

- Signed parental permission is required for most studies involving minors
- Best practice is for both parents to sign the parental permission for a child's involvement in research (assuming that both parents are alive, not incarcerated, and in the geographical area)
- Legal guardian permission is required for studies involving mentally impaired adults, if the adult has a legal guardian

Consent of Non English-Speaking Participants

If you are planning to enroll non-English speaking participants, then ***both*** of the following must be done:

1. A translated version of the consent form, any questionnaires, or materials given to participants. This must be reviewed and approved by the IRB prior to their use according to 45 CFR 46. 116 & 117.

- Documents can be translated via a certified translation service with their stamp on the consent form, and any other documents that require translation; or
- You can have the English version translated into language of choice, and a back translation into English done by an independent person. You must make sure that the original English and translated version are the same and include a note with the submission that this process was completed

And

2. This requires that a person fluent (i.e., can read and speak the language) be present as a witness to the consent process to verify that the consent was understood.

- Person obtaining consent can speak the language of choice, but a witness who is independent of the study and is fluent in the language must be present to verify that it was informed and not coerced
- The person obtaining consent cannot serve as the witness

Appendix C

Site Permission Letter Template

See the lounge for a word doc version of this template.

Your chair will assist you in determining what information should appear in your letter. When in doubt, contact the IRB: IRB@Aspen.edu and cc your chair on all communication.

Note: DNP Candidates – this is not the same thing as an immersion site agreement.

This letter is required from any clinic, institution, organization, company, group, etc. where you will conduct your study or implement your project. For example, if you are implementing a QI protocol at a clinic, the appropriate person at that clinic must give you permission. If you are interviewing/surveying faculty or teachers, then the appropriate person(s) at that college/university or district office and school must give you permission. If you are posting a recruitment announcement to a LinkedIn group, the group owner must give you permission. Your chair will assist you in determining the permissions you need for your specific project/study. *When in doubt, contact the IRB: IRB@Aspen.edu and cc your chair on all communication.*

The site you are working with may have a standard letter/template.

Please check with them before using the following template.

The letter must:

- Be printed on letterhead (emails will not suffice)
- Include your name
- Include the title of your project/study
- Include a 1-3 sentence purpose
- Include a statement that your protocol has been reviewed
- Include a statement about what is being permitted at the site
- If applicable, clearly state any restrictions
- Be signed by the appropriate person who attests that they have authority to grant such permission. *For DNP candidates this is typically a Chief Medical Officer or Director. For EdD students this is typically an authority at a district office, like a superintendent, or a college/university department head.*
- Include the title of the signatory
- Include an email address and phone number of the signatory

This is a sample template. If the signatory indicates they do not have their own template, then draft a letter using the template below, on their behalf. Replace the blue font with details from your study. Delete all other extraneous font. Before providing the document to the signatory, ensure that you have checked for spelling/grammar errors and that all the font is black. Be sure to communicate that the letter MUST be on letterhead when it is returned to you.

Date

Dear IRB Administrator,

After reviewing the proposed Doctoral Project/Dissertation: Title of Your Project/Study, I have granted authorization for Doctoral Candidate's Name to conduct the project/study at our

Clinic/Hospital/School/Company/Organization, and I attest that I have the authority to grant such permission. *[If you are collecting data from a school you need permission*

from both the district office and from each school as schools may have different criteria for what can be collected and how they will help]

I understand the purpose of the project/study is to state the brief purpose of your project/study.

[Articulate the purpose of in layman's terms in 1 – 3 sentences]

[The next section of the letter must articulate exactly what activities will occur at the site]

The Clinic/Hospital/School/ Company/Organization will allow the following over the duration of the project/study:

Examples

- *Assess knowledge of the ED staff and guidelines published by the Emergency Nurse Associations (ENA) evidence-based, clinical practice guidelines (CPG) on Difficult Intravenous as a quality practice initiative for staff/providers/participants related to a new evidence-based intervention at Aspen University Hospital's Emergency Room.*
- *Work with the quality department or the facilities designated specialist to gather de- identified patient data specific to the measurable patient outcome.*
- *Nurse Nancy is required to follow all HIPPA and all Personal Health Information (PHI) policy and procedures related to obtaining, storing, and destroying of HIPPA and PHI protected data.*
- *Interview teachers in their classrooms during lunch (I have reviewed the semi-structured interview questions).*
- *Send emails to employees inviting them to take an online survey assessing perceptions of leadership (I have reviewed the survey).*
- *Post a flyer in the main building common area and use a private office for interviews (I have reviewed both the flyer and the interview questions).*
- *Access to de-identified client data and will be required to submit a copy of their final dissertation manuscript.*

If the IRB has any concerns about the permission being granted by this letter, please contact me by phone or email *[whatever is the preference of the person granting permission]*.

Sincerely,

[Authorizing Official's signature - a 'wet' signature is best; however, an e-signature is sufficient]

Title [*The signatory must be an administrator with oversight and responsibility over the clinic/hospital/school/company/organization]*

phone number email

address *[if address does not appear in letterhead]*

Appendix D

Informed Consent Form Template

See the lounge for a word doc version of this template.

Your chair will assist you in determining what information should appear in your letter. When in doubt, contact the IRB: IRB@Aspen.edu and cc your chair on all communication.

Instructions: This template includes the basic areas required in an informed consent form. As each consent form must be tailored to the specific project/research, you will see blue font throughout the template. Type in the information specific to your project/study where you see the blue font. When you see project/study, or project/research choose "project" if you are working on a doctoral project and "study" or "research" if you are working on a dissertation. When you have created your consent form, change all font color to black and delete this page.

Important notes:

- Complete your CITI Training prior to drafting your Informed Consent Form as this training includes information that will assist you. This video provides

details related to CITI Training.

- Pay close attention to detail including spelling/grammar as this document represents you, your committee, and Aspen University. Use a spell and grammar checker.
- This form should be written in layman's terms, below the 9th grade reading level (for example an 8.9 is sufficient). Avoid unnecessary scientific terms or jargon. Evaluate the readability using The Flesch Grade Level Readability Formula.
- Missing or incomplete information, spelling/grammar errors, and inappropriate readability will require revisions at the IRB approval stage, so please take care when creating this document and ensure your entire committee has read and approves of the document (a great place to ensure this unanimous approval is to directly ask for it during your proposal oral defense).

Note: If your project or study involves interacting directly with minors outside established or commonly accepted educational settings you will need both parental consent and minor assent forms, and your project/study will require a full board review. Please contact the IRB for guidance.

Appendix E

IRB Application Checklist

The following are required with every application:

- Chair-approved IRB Application with chair's signature*
- University-approved dissertation/doctoral project proposal (Chapters 1-3) in MS Word
- Your CITI Training Certificate(s) of Completion
- IRB Cover Letter that briefly describes your submission and lists all documents being submitted with your application

If applicable, submit:

- Site permission in the form of a signed letter on official letterhead from the organization giving approval to implement the project/research in the target setting (see Appendix C (p. 13))
- Informed consent form (see Appendix D (p. 14))
- Assent form (see Appendix B (p. 11))
- HIPAA Authorization Form
- Participant Recruitment Materials (e.g., flyer, social media post, email, etc.)
- IRB approval(s) from other IRB(s) (e.g., practice site; another college/university)
- A copy of your instrumentation (e.g., survey questionnaire, interview questions, protocol, screening tools, etc.)
- If instruments where purchased, a copy of the proof of purchase
- If instruments require permission to use or modify, a signed permission letter
- Any other materials that are being used for your research/project that will assist the IRB in the review, for example a protocol, training, checklist, explanations related to the use of deception, vulnerable populations, etc.

* You will need Adobe Acrobat Reader installed on your computer and a digital ID configured to sign your IRB application. Downloading the program and configuring your ID should take approximately 5-10 minutes.

- Go to Adobe Acrobat Reader
- Click Download PDF Reader (you do not need Acrobat Pro DC)
- Download and install the application
- Open the IRB application within Adobe Reader
- Click the signature box and you will be prompted to configure your ID à create a new digital ID à save to file à enter in the required information à sign

Step-by-step guides can be found a Adobe Support.

All the above documents should be labeled clearly and submitted in a single email to IRB@aspen.edu. An incomplete submission will result in the delay of your study.