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**IRB Review Form – Faculty & Staff Version**

*Prior to completing this form, please review the IRB Handbook – Faculty & Staff Edition*

**Investigator Information**

First Name

Last Name

USU Email

Phone

**Immediate Supervisor Information**

First Name

Last Name

USU Email

**Confirm completion of CITI Training.** Have you completed the required CITI online training?

Not sure? View this video:[**CITI VIDEO LINK**](https://drive.google.com/file/d/18vluXi0SD6Uqqk1V0FzVPAvZCABVpmkJ/view?usp=drive_link)

*If no, stop and view the video and complete your training before proceeding.*

**Title of proposed project/study** *We recommend 12 words or fewe*r:

**In one sentence, state the purpose of your proposed project/study**

**List the clinical or research question(s) your project/study will answer**

**Where is your proposed activity taking place? Note: if your activity is happening at USU, see policy 211 and ensure you have approval from the Office of Institutional Research and Assessment before you proceed.**

Name of Organization

Address

**If applicable, list the person at the organization responsible for approving your project/study.**

Name
Title

**If the activity is taking place outside of USU, do you have an Organization Permission Letter signed by this person?**

 *If no, stop and obtain this prior to proceeding as you will need to include it with your IRB Review Form submission.*

**Does your project/study require approval from an IRB at the Organization? *(refer back to your Organization-Specific Project Permission Document).*** *Select one*

[ ]  No

[ ]  Yes, and I have it (this will be submitted with your IRB Review Form)

[ ]  Yes, but I need approval from USU’s IRB to apply (submit documentation that this is required with your IRB Review Form)

**PART 1: Screening to determine if activity is human subjects research**

***Section A - This section is for Investigators proposing quality improvement projects. If this does not apply to you, skip to Section B.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **#** | **Consideration** | **Statements** | **True**  | **False** |
| 1 | Purpose | The primary aim of the project is to: Improve the quality of care for a specific group or population during the project implementation, and/or improve practice, procedure, process, and/or operations or efficiencies | [ ] True | [ ] False |
| 2 | Background | There is sufficient evidence for, or acceptance of, this mode, approach, or method, based on evidence-based practice or published guidelines/toolkits | [ ] True | [ ] False |
| 3 | Method | The implementation of the project is time-limited (for example, 6-to 8-weeks) | [ ] True | [ ] False |
| 4 | Risk | The project risks are minimal\* and no more than usual care (including the unavoidable minimal risk in implementing any changes made in processes of care) | [ ] True | [ ] False |
| 5 | Data Source | The project only involves people (patients, staff, etc.) who are ordinarily seen, cared for, or work in the setting where the activity will take place, and/or uses de-identifiedrecords that are available at the organization | [ ] True | [ ] False |
| 6 | Project Design | My project contains *at least one* of the following:* A control group
* Randomization to different groups
 | [ ] True | [ ] False  |
| 7 | Funding | My specific project is funded by an external source or grant | [ ] True | [ ] False |

*\* Minimal risk means that 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 (see federal regulations* [46.102(i)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102) at <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46>).

**Scoring Directions:**

1. Did you answer FALSE to any of the statements in items #1-5?
2. Did you answer TRUE to item #6?
3. Did you answer TRUE to item or #7?

If you answered “YES” to any of the above (a-c), your project is considered human subjects research – continue to Part 2.

If you answered “NO” to all three statements (a-c above), your project is not considered human subjects research; however, you are expected to adhere to ethical principles during the implementation of your project.

* By submitting this document, you certify that the information provided is complete and accurate.
* Compile the documents listed below as you will need to upload them with your IRB submission:
	1. IRB Review Form
	2. Three CITI Training Certificates (not completion reports)
	3. If applicable:
		+ Approval letter from OIRA if your project/research is being conducted on USU constituents, or
		+ Organization Permission Letter (see IRB Handbook for details about what must appear in this letter)
	4. If applicable, HIPAA Confidentiality Agreement
	5. If applicable, IRB Approval from the IRB at the organization or documentation that they require review by USU’s IRB prior to their review
* You must receive a determination letter from the IRB before you begin your project.

Submit your documents here (if clicking on the link does not open the form, double check that you are logged into your USU google account and clear your cache): <https://forms.gle/742bTPqdH3cbYvLJ9>

***Section B - This section is for Investigators proposing systematic literature reviews or archival/secondary data analysis on de-identified data. If this does not apply to you, skip to Part 2.***

Read each statement and answer *YES* or *NO*.

1. Is your project/study a Systematic Literature Review (all the data you plan to use will come from published materials)? *Select Yes or No*

[ ]  YES -   Your activity does not meet the definition of research with human subjects. Complete the requirements listed below and submit to the IRB for review.

[ ]  NO – continue to the next question

1. Will your project/study rely solely on archival data (known as secondary research, this is a type of research that utilizes data that has already been collected)? *Select Yes or No*

[ ]  NO – Continue to Part 2.

[ ]  YES – if yes answer the following questions:

* 1. Who owns the data? Include a link if the data are publicly available. Note: If you are proposing to use data collected on USU Constituents, you must include an approval from the Office of Institutional Research and Assessment (OIRA, see Policy 211: Research with USU Constituents).
	2. Describe the data including the number of data points and variables you will have access to. You may choose to include a code book or other description of the data to your IRB submission.

* 1. Are the data de-identified? De-identification means there is no way for you, as the investigator, to determine the identity of the participants. Thus, de-identified data cannot include some commonly collected information such as: names, emails, physical addresses, student/employee numbers, telephone numbers, IP addresses, social security numbers, photos, or any other unique code or number that is tied to the participant. *Select Yes or No*

[ ]  YES – Your activity does not meet the definition of research with human subjects. Complete the requirements listed below and submit to the IRB for review.

[ ]  NO – Continue to Part 2.

If you answered YES to #1 or #2c, then your activity does not meet the definition of research with human subjects; however, you are expected to adhere to ethical principles during the implementation of your dissertation.

* By submitting this document, you certify that the information provided is complete and accurate.
* Compile the documents listed below as you will need to upload them with your IRB submission:
	1. IRB Review Form
	2. Three CITI Training Certificates (not completion reports)
	3. If applicable:
		+ Approval letter from OIRA if your project/research is being conducted on USU constituents, or
		+ Organization Permission Letter (see IRB Handbook for details about what must appear in this letter)
	4. If applicable, IRB Approval from the IRB at the organization or documentation that they require review by USU’s IRB prior to their review
* You must receive a determination letter from the IRB before you begin your research.

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**PART 2: IRB Review for Research with Human Subjects**

**Complete Part 2 if:**

* Determination from Part 1 is that ***you are conducting human subjects research***

**Instructions**

* Answer the questions below and submit all required documents to the IRB for review.
* You must receive a determination or approval letter from the IRB before you begin your research
1. **Research Category– Choose only ONE category** (if your research does not fit neatly into category A -D, then describe it in E. ***Choosing more than one category will result in your IRB submission package being returned.***

Which of the following categories describes your research?

[ ]  A. Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students’ opportunity to learn or assessment of educators who provide instruction. Examples include research on regular and special education instructional strategies, research on the effectiveness of or the comparison among instructional techniques, or classroom management methods.

[ ]  B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. Examples include interviewing people or collecting data via a survey about a specific topic.

*If you selected this category, is identifiable information being collected (e.g., names, emails, etc.)*? *Select Yes or No*

 [ ]  YES

 [ ]  NO

[ ]  C. Research involving behavioral interventions that are not expected to cause physical or emotional harm, in conjunction with the collection of information from an adult participant through verbal or written responses. Examples include assessing a construct pre and post an intervention, like a mindfulness class.

*If you selected this category, is identifiable information being collected?*  *(e.g., names, emails, etc.)*

*Select Yes or No*

 [ ]  YES

 [ ]  NO

[ ]  D. Secondary research (e.g., archival data analysis)

*If you selected this category, is identifiable information in the data set?*  *(e.g., names, emails, etc.)*

*Select Yes or No*

[ ]  YES

 [ ]  NO

[ ]  E. Other (explain)

*Before moving to the next question, stop and confirm that you selected only one research category (A-E) for question 1. If you selected more than one, select the one which best describes your study.* ***Choosing more than one category will result in your IRB submission package being returned.***

1. Is this research funded? *Select Yes or No*

*[ ]* YES -If Yes, title of grant or funding source

*[ ]* NO

1. Conflicts of Interest. Do you or any individual who is associated with or responsible for the design, conduct of, or reporting of this research have an economic or financial interest in, or act as an officer or director for any outside entity whose interests could reasonably appear to be impacted by this research? *Select Yes or No*

[ ]  YES - If yes, provide an explanation here

[ ]  NO

1. Protected Health Information. Will health information or specimens be collected or reviewed? *Select Yes or No*

[ ]  NO (skip to next question)

[ ]  Yes (If yes, include a HIPAA Authorization Form with your submission package)

* If yes, are the data identifiable? (i.e., is any information collected or included in the data that can link a participant to the research?)
* If data are identifiable, how are data being protected?
1. Deception/Concealment. Will deception or concealment be used? *Select Yes or No*

[ ]  NO

[ ]  YES - If yes briefly describe and justify its use here

1. Sensitive Information. Will you be collecting sensitive information, that if disclosed, may place your participants at personal or professional risk (e.g., civil or criminal liability or damage to their financial standing, employability or reputation)? Please see the IRB Handbook for a definition of sensitive information (that includes questions about mental health, trauma, etc.). *Select Yes or No*

[ ]  NO

[ ]  YES - If yes, briefly describe and justify the risk and describe protections to be put in place to minimize this risk

1. Describe your participants
	* What are your inclusion criteria?
	* What are your exclusion criteria?
	* Describe how participants will be recruited, including who will do the recruiting and if appropriate what permissions have been secured. You will need to submit copies of all communication used to recruit or solicit participants (social media posts, emails, etc.) and appropriate permissions (e.g., if you are posting a flyer in a physical location, you need permission to post, if you are posting in a private group on LinkedIn or Facebook, you need permission from the group administrator, etc.):
	* Will participants receive compensation or other incentives? *Select Yes or No*

[ ]  NO

[ ]  YES - If yes, explain the type (e.g., gift cards, cash payment, course credit) the amount, and timing of compensation or incentive in the box below. Note: Compensation plans should not be contingent on the completion of the study to avoid coercion or undue influence.

* + Describe how informed consent will be obtained from participants prior to the

collection of any data. If the participants will be minors or other persons who are not legally able to provide informed consent, identify who will consent on their behalf and the assent process. You will upload the informed consent form, and if applicable, the assent form (required for minors) for review.

* Briefly describe what your participants will be doing or what will happen to them so the IRB may evaluate the level of risk.
1. Will your research target any of the following protected classes? (see Policy 700-14 and 700-15)

[ ]  Children/minors under age 18 (or the age of majority of the state in which the child resides in)

[ ]  Pregnant women

[ ]  Prisoners

[ ]  Cognitively impaired or mentally disabled

[ ]  Educationally or economically disadvantaged

If you selected any of the categories above briefly justify the appropriateness of conducting research on this population and what additional protections will be in place to mitigate risks

1. Will your research involve persons with a clinical diagnosis, such as PTSD or depression (past or present) ***or*** research in a clinical setting, such as a hospital or doctor’s office? *Select Yes or No*

[ ]  NO

[ ]  YES - If yes, briefly discuss possible consequences and/or additional stress and consequences of participating in research, and what supports or referrals you will have in place to address them

1. Will your research target persons from different cultures or international contexts? *Select Yes or No*

[ ]  NO

[ ]  YES - If yes, briefly describe steps taken to ensure cultural responsiveness

1. Data collection. Briefly describe how data will be collected (e.g. Internet or pencil and paper assessment or survey, individual interviews, focus groups, observation with field notes, etc.)
	* Will information be collected in a manner that would allow participants to be identified directly (through name, email, code, ID number, etc.) or indirectly (through evidence or clues, like a face or voice recording or combination of gender, age, ethnicity, etc.?) *Select Yes or No*

[ ]  NO

[ ]  YES

* + Will a recording be made (audio/video/both?) *Select Yes or No*

[ ]  NO

[ ]  YES - If yes, what type of recording is being made (audio/visual/both) and explain who will have

 access and when and how the recordings will be stored and destroyed

* + Will an existing instrument be used and/or modified? *Select Yes or No*

[ ]  NO

[ ]  YES - If yes, please submit the signed permission form or proof of purchase of access to the instrument, if appropriate.

* + Briefly describe the procedures for protecting participants' anonymity and maintaining confidentiality in data collection, storage, and reporting
1. The IRB will review your application and determine the following:
* The research proposed fits into a minimal risk category (see Policy 700-3)
* The selection of subjects is equitable
* Informed consent is appropriately sought and documented
* When appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure safety of subjects
* There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
* Where any of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the research to protect subjects

**Is there anything else the IRB may need to know to make these determinations?** If yes, describe:

**What supplemental materials are you including with your IRB Review Form? *(Check all that apply).***

[ ]  REQUIRED: Three CITI Training Certificates (not completion reports)

[ ]  Informed consent form(s)

[ ]  Organization Permission Letter

[ ]  If collecting/analyzing data on USU constituents, approval from the Office of Institutional Research and Assessment (see Policy 211)

[ ]  IRB review and determination **and/or** approval from collaborating organization(s)

[ ]  Participant solicitation/recruitment documents

[ ]  A copy of your instrumentation (e.g., survey, interview questions, protocol, tools)

[ ]  Permission to use or modify an existing instrument

[ ]  Proof of purchase for instruments that were purchased

[ ]  HIPAA Authorization Form (required when HIPAA applies)

[ ]  Other (describe)

**Attestations – If you agree, check each box**

[ ]  I certify that the information provided in this IRB Review Form is complete and accurate.

[ ]  I understand that I have ultimate responsibility for the conduct of my research, the ethical performance of protocols, the protection of the rights and welfare of human participants, and strict adherence to the protocol and any stipulations imposed by the United States University Institutional Review Board.

[ ]  I understand that it is my responsibility to ensure that the human participant’s involvement and data as described in the approved proposal submitted with my applications is consistent with that contained in this IRB Review Form. I will submit modifications and/or changes to the IRB as necessary.

[ ]  I agree to comply with all United States University policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human participants, including, but not limited to:

* + Ensuring protocols are conducted by qualified personnel.
	+ Implementing no changes to approved research without prior IRB approval in accordance with United States University policy; when changes are required, submitting an Amendment Form (see Policy 700-29 and 700-32)
	+ Promptly reporting any unanticipated problems, events, or protocol deviations using the Events Reporting Form and if applicable, informing the contact person at the project/research site (see Policy 700-31)
	+ Promptly providing the IRB with any information requests relative to protocols.
	+ Promptly and completely complying with IRB decisions to suspend or withdraw approval for research.
	+ Obtaining continuing review prior to the expiration of the approval (approval will automatically expire one year from approval date). If your research extends beyond the approval time frame, use the Continuing Review Form (see Policy 700-28)
	+ Maintaining accurate and complete records, including, but not limited to, all informed consent documents for a minimum of 3 years from the date of research completion or the length of time required by the organization where your research is taking place.
	+ Complying with federal, state, and local laws and regulations and sponsor terms and conditions.
	+ Upon the passing of the final course in your program you IRB record will be officially closed.
* You must receive a determination letter from the IRB before you begin your research.

Submit your documents here (if clicking on the link does not open the form, double check that you are logged into your USU google account and clear your cache): <https://forms.gle/742bTPqdH3cbYvLJ9>