**INSTRUCTIONS FOR SUBMITTING IRB PROTOCOL APPLICATIONS**

The Institutional Review Board (IRB) is an administrative body which adheres to federal regulations to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the University of Mary. The IRB has the authority to review, approve, require modifications to, or disapprove all research activities that fall under its purview, defined under both federal regulations and institutional policy. All research protocols which involve human subjects are required to be submitted and approved before *any* research data is collected.

**Research** is “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.” [45 CFR 46.102(l)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102).

**Human Subject** means “a living individual about whom an investigator…conducting research:

* Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
* Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” [45 CFR 46.102(e)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102)

Human subjects research may include surveys, interviews, behavioral investigations, retrospective interviews of medical information, experiments with blood and tissue, demonstration and services programs, and clinical trials. In addition, the FDA includes additional categories of reviewable research when an FDA-regulated product is in use, except for use of a marketed product in the practice of medicine.

There are three possible levels of IRB review: exempt, expedited, and full board. “Exempt” does not mean that your research is excluded from IRB review. If the project qualifies as exempt, then it is exempt from expedited or full board review. Researchers are not able to self-determine if a study is exempt, but instead should submit an Exempt Protocol Review if they suspect a project may fall into this category. After review, the IRB will determine a protocol application’s status as exempt or not.

**A. Instructions for IRB Protocol Submission**

1. **Visit** the [IRB website](https://my.umary.edu/ICS/Institutional_Review_Board_%28IRB%29.jnz), found under General Information, Faculty, or Student tabs on [my.umary.edu](https://my.umary.edu/ICS).
2. **Submit your CITI Training certificate(s).** CITI Training is required for all investigators, faculty advisors, or key personnel who will have access to data containing any personally identifiable information. Training certificates should be submitted using the [IRB – CITI Training Certificate Submission](https://forms.office.com/Pages/DesignPage.aspx?auth_pvr=OrgId&auth_upn=mpmcdowall%40umary.edu&lang=en-US&origin=OfficeDotCom&route=Start#FormId=Ee48rJtpi0Kz7T0wU72PA2MCCoff2MNIhShIPlj04UNUREZVWUZJUVhXVEFJRk5BMVoyN0pETjE3VS4u) form. No IRB Protocol Applications will be advanced for review until all project investigators have submitted the requisite CITI Training Certificates.
	1. **Required Modules:** each department has selected different modules that researchers must complete in order to perform research within their program. See the [CITI Training Instructions](https://my.umary.edu/ICS/Portlets/ICS/Handoutportlet/viewhandler.ashx?handout_id=6a490b0e-5b80-4879-b226-9d2197802fb2) document for details on which modules you are required to complete.
3. **Prepare your materials** for submission.
	1. All **supporting appendices must be included** with the IRB Research Protocol Application for review and approval by the IRB. See the [IRB Protocol Application Checklist](https://my.umary.edu/ICS/Portlets/ICS/Handoutportlet/viewhandler.ashx?handout_id=4f31e4c8-788c-4e9e-b3f9-53b8b16f4580) document for suggested appendices.
	2. IRB Research Protocol Applications must be carefully proofread and submitted free of errors and omissions. For student projects, **your faculty advisor must have proofed and approved your submission** in advance of your final submission to the IRB. Use the downloadable IRB Drafting Forms (available on the [IRB website](https://my.umary.edu/ICS/Institutional_Review_Board_%28IRB%29.jnz)) to perform your initial drafting, commenting, and review.
4. **Submit** your IRB Research Protocol Application. Once your IRB submission draft is finalized, use the draft document to copy and paste/transpose the information into the web-based IRB Research Protocol Application form for final submission. The IRB will not accept submissions via email or paper mail, except in the case of submissions from external investigators. Form links are available on the [IRB website](https://my.umary.edu/ICS/Institutional_Review_Board_%28IRB%29.jnz).
	1. Ensure that the email addresses and names you provide for all investigators and faculty advisors are correct. Errors in name spelling or email entry can result in delays as those people may not receive the necessary electronic signature requests or other messages from the IRB Office.
5. **Watch your university email** for follow-up messages from the IRB Office in the event of errors or omissions. Any delays in response time from researchers will result in delays in overall IRB approval time.
	* **Allow up to THREE WEEKS for Exempt Protocol review and approval.**
	* **Allow up to FOUR WEEKS for Expedited Protocol review and approval.**
	* **Allow up to SIX WEEKS for Full Board Protocol review and approval.**
6. The IRB Office will notify the Primary Contact if the IRB requires additional information, changes, or clarification about the research project. The IRB has the authority to request that a protocol undergo a different review level than originally submitted. The IRB also has the authority to require changes to be made to the protocol prior to approving it. If the necessary changes cannot be made, the IRB has the authority to disapprove a protocol entirely.
7. The IRB Office will notify the Primary Contact via email or mail of all approval or disapproval decisions.
	1. **Investigators cannot begin their research until notification of IRB approval has been received.**
	2. **Investigators are not permitted to make any changes to the research protocol without IRB review.**
8. **Close your project.** After a project has been completed, one member of the research team (generally the Primary Contact) is responsible for submitting the [IRB Research Termination Form](https://forms.office.com/Pages/ResponsePage.aspx?id=Ee48rJtpi0Kz7T0wU72PA2MCCoff2MNIhShIPlj04UNUNDQ2OThYVTZPUks2NlRMRjRPQjhZWkNRQy4u) to close out the project. **Please note that this is a graduation requirement for student projects**. Failure to submit this form may result in delays in degree conferral.
9. **What to do if…**
	1. There has been an **adverse or unanticipated event** that affects study participants. You are required to **report** this to the IRB **within 48 hours** of the event. Use the [IRB Incident Report Form](https://forms.office.com/Pages/ResponsePage.aspx?id=Ee48rJtpi0Kz7T0wU72PA2MCCoff2MNIhShIPlj04UNURUFBNkI1SVMxQkdKNTg4SDI5SzFDTUlJOC4u) to notify the IRB of any incidents.
	2. You would like to **make a modification** to a protocol that has already been reviewed and approved. You are strictly prohibited from implementing any changes without IRB review and approval, unless it is in urgent response to a participant health/wellbeing emergency. Submit an [IRB Modification Form](https://forms.office.com/Pages/ResponsePage.aspx?id=Ee48rJtpi0Kz7T0wU72PA2MCCoff2MNIhShIPlj04UNUOUFHREVQUTZUQVMzNU1LSTVSQ0hFSUxMUi4u) to request a modification to your previously approved protocol.
	3. Your **IRB approval expiration date** is approaching, but your study has not yet been completed. Submit an [IRB Renewal Form](https://forms.office.com/Pages/ResponsePage.aspx?id=Ee48rJtpi0Kz7T0wU72PA2MCCoff2MNIhShIPlj04UNUQVVRNjNRSllWR0xERUZJRU5OSFlKRE00SC4u) to request an extension. Keep in mind that **all** **Full Review** as well as select Expedited Review studies are required to submit for **Continuing Review** every 12 months until the study has been closed. Exempt protocols are approved for a maximum of three-year periods before Renewal is required.

**B. General Tips for Submission**

1. Be sure to complete all elements of each part of the IRB Research Protocol Application. One reason IRB applications are often delayed is related to incomplete application documents, missing CITI certificates, or missing appendices.
2. Role Definitions:
	1. **Primary Contact Person:** the person assuming the responsibility for communication with the IRB for any associated questions and communication related to approval status. This may be either a student or the project advisor depending on your academic department’s preferences. Check with your advisor if unsure.
	2. **Project Investigator:** all individuals working on the research/project (aside from the faculty advisor).
	3. **Project Advisor:** the faculty member responsible for oversight and contribution to your work.
	4. **Department Chair:** the head of the department or program, whose signature is required on student projects in addition to the project advisor’s.
3. The proposed start date cannot precede the anticipate time of IRB approval. If the date listed is before the IRB application submission or is a date that too closely approximates the submission of the IRB application, the application will be returned for revision.
4. The proposed end date should encompass the latest expected date of all research steps which include data collection from human subjects and/or data analysis which includes use personally identifiable data. Select a realistic end date. Continuing Review will likely be required for projects which extend longer than one year.
5. Maintain close communication with your course faculty/research chair/project advisor. The faculty chair/advisor is required to review and approve the IRB application draft prior to the student submitting the final application to the IRB.
6. IRB approval can take three to six weeks, depending on the level of review your project requires. Work diligently to have your IRB application polished and ready for submission in a timely manner. It is the responsibility of the student to initiate necessary faculty advisory collaboration to be successful.
7. Submission to the University of Mary IRB is required. However, it may also be required to achieve IRB approval from your research/project setting. IRB approval from the research/project setting (if determined necessary by the organization) is to be sought after University of Mary IRB approval has been obtained.
8. Carefully follow the instructions for each section of the application to ensure the content is in the correct section. Each section requires specific information. There is little redundancy of content from one section to another.
9. The writing must be succinct. Although one student will likely take the lead in compiling the IRB application, it must be reviewed by all members of the team to ensure the writing is scholarly and in fact meets the expectation of being clear, concise, and cogent.
10. All study investigators and faculty advisors must sign the submission before it can advance to IRB review. Please ensure that all project personnel are watching their email for the electronic signature request to come in, and respond to it promptly.

**C. Tips for Completing the Summary Section of the Application**

1. **PURPOSE FOR THE STUDY/PROJECT**

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| **Research** | **Evidence Based Practice Project/****Action Research/Performance Improvement** |
| In the first sentence, clearly indicate that this work is primary research. Describe the intent, need, projected outcomes, background information, justification or necessity for using human subjects, and potential significance of the results. The section should culminate with the research purpose statement. | In the first sentence, clearly indicate that this work is an EBP project. Describe the problem and/or background contributing to the purpose for completing this project. In this section, provide a succinct background to the project topic from the literature. Share information that supports the need for the project (e.g., interviews with or requests from organizational leaders at the project setting), findings from the organizational needs assessment, projected outcomes, or other rationale supporting the purpose for initiating the project. The section should and include the PICO question. |

1. **PROTOCOL**

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| **Research** | **Evidence Based Practice Project/****Action Research/Performance Improvement** |
| The protocol questions describe the research methods and design. 1. Identify your study design
	1. Quantitative (e.g., descriptive, experimental, quasi-experimental, ex-post facto, causal comparative, correlational, etc.); or
	2. Qualitative (e.g., phenomenological, case study, historical, ethnography, grounded theory, narrative analysis, hermeneutics);
	3. Mixed (i.e triangulation, embedded, exploratory, explanatory)
2. Describe the Study Population/Sample:
	1. Identify the sampling procedures; how you will gain access to population and how sample will be selected; location; proposed sample size/power study
	2. Outline the inclusion and exclusion criteria for subject eligibility
	3. Reference a letter of support if working with a cooperating organization(s). This letter should be on agency letterhead and submitted with the IRB application.
3. Explain the procedures to which humans will be subjected (anything the subject will be asked to do or have done to them relative to the study) including:
	1. Instruments (interview questions, surveys, screenings, observation forms, etc.) Put a copy of the instrument(s) in appendices and copyright permission for use if needed.
		1. appropriateness for population/setting
		2. reliability and validity
		3. how administered and scored
		4. interrater reliability
		5. type of response categories
	2. Duration (length of study, time commitment required)
	3. Intervention/treatment or procedures used
	4. Field testing or pilot procedures if used
	5. Data collection procedures. Explain all steps necessary to conduct study in order in which they are to occur. Recruitment, training, education, testing, interventions, etc.
	6. Include recruitment tools (e.g., emails, flyers, posters, follow-up emails/reminders, oral presentation/s, etc.) in appendices
4. Describe plan for data analysis:
	1. Quantitative - potential descriptive or inferential statistical tests to be used
	2. Qualitative - process for data analysis (transcription, coding and development of categories and themes)
 | The protocol questions outline the project recommendations and implementation plan. If working with a cooperating organization(s), approval letter on agency letterhead needs to be submitted with IRB proposalBegin the “Protocol” section by stating your project setting and your project participants. **Your participants in EBP/Action Research/Performance Improvement projects typically are the providers/nurses/staff affected by the change/s** (e.g., the change to their practice or introduction of a new process in their workplace) **implemented with the project.** Identify the project recommendations and steps for implementation of the change within the organization. Specifically identify what the project team will be responsible for, what the organizational stakeholders will be responsible for, and what elements the two will collaborate. Describe how project outcomes will be measured. What data will be collected for (not data analysis) project outcome measurements? If there are any tools, surveys, logs planned to document data related to the project, the student should reference them in this section and include them as an appendix to the IRB application. |

1. **BENEFITS**

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| **Research** | **Evidence Based Practice Project/****Action Research/Performance Improvement** |
| Describe any benefits, because of the research, that the subject and/or humankind may receive. Should be consistent with consent/assent form.  | Identify your project participants. Indicate if they will receive any direct benefit for participating in the project. Typically, participants do not receive any direct personal benefit. However, one benefit to participants may be the awareness they will be contributing to an effort aimed to help the organization, improve patient care, or advance the profession. |

1. **RISKS**

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| **Research** | **Evidence Based Practice Project/****Action Research/Performance Improvement** |
| Describe risks to the subject and precautions that will be taken to minimize them. The concept of risk goes beyond physical risk and includes risks to the subject’s dignity and self-respect, as well as financial, psychological, emotional, legal, or behavioral risk. If data are collected which could prove harmful or embarrassing to the subject and/or to someone associated with him or her, then describe the methods to minimize the discomfort and any potential debriefing procedures. Describe methods used to ensure the confidentiality and anonymity of data obtained, including plans for final disposition or destruction of data. Should be consistent with consent form. Proposals that indicate “There is no risk” will be returned without further review. For further direction related to Risk, refer to the CITI modules focused on assessing risk. | State up front who the project participants are. The concept of risk goes beyond physical risk and includes risks to the participants dignity and self-respect, as well as financial, psychological, emotional, legal, or behavioral risks. If data are collected which could prove harmful or embarrassing to the participant and/or to someone associated with him or her, then describe the methods to minimize the discomfort and any potential debriefing procedures. Describe methods used to ensure confidentiality and anonymity of data obtained.Identify the risks the project participant may experience (e.g. stress associated with change in normal routine, unfamiliarity with expectations). Because EBP Projects are typically an employer initiated strategy, choice of participation is not typically an option. Therefore, this section should also include what risk there may be if the participants refuses to participate in the EBP Project (e.g., disciplinary action, loss of employment).Risk is minimized when secondary data is used without identifiers. How the project leader plans to de-identify data and report findings in aggregate must be included. If a confidentiality statement with the organization has been signed by students, it should be reported in this section. |

1. **USE OF DATA**

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| **Research** | **Evidence Based Practice Project/****Action Research/Performance Improvement** |
| Describe how the data will be used, who will use it, where it will be kept and by whom, and how and when it will be destroyed. Describe the method for subjects to obtain results and potential for presentation or publication of study findings.  | Describe how will project data be used (analyzed), where will it be kept and by whom, and plans for final disposition or destruction of data. Describe the method for project stakeholders to obtain results and potential for presentation or publication of project findings. |

1. **INFORMED CONSENT**

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| **Research** | **Evidence Based Practice Project/****Action Research/Performance Improvement** |
| Describe when and how informed consent will be obtained from eligible subjects. Describe where signed CONSENT FORMS will be kept and for what period of time.  | An EBP project generally will not have a consent form. Two examples of common statements utilized for this purpose may be as follows:“Because this is an organizational initiative directed by (enter project setting) leadership, employees who will be affected by the recommendations and implementation of this project are expected to participate. Consequently, informed consent is unable to be obtained from individual project participants.”“For the sake of the proposed project, no consent form can be collected. The organization’s leadership fully support and welcome the implementation of the (insert project topic). Participation is an expectation; therefore obtaining an informed consent is not possible.” |

**D. Tips for Completing the Human Subjects Informed Consent Form**

The informed consent is only applicable to Primary Research studies. Project settings implementing an Evidence Based Practice Project/Action Research/Performance Improvement project expect employees to participate, removing their option to consent to participation. The following table outlines how the Informed Consent portion of the IRB application is to be completed for Primary Research and for Evidence Based Practice Project/Action Research/Performance Improvement projects.

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| **Research** | **Evidence Based Practice Project/****Action Research/Performance Improvement** |
| The informed consent form will be attached as a separate document to the IRB application. As part of the primary research process, the researcher will distribute the informed consent to the potential research participant, who will then determine their consent to participate in the research or to abstain from participation in the research.  The entire consent form must be written in a clear, concise language that an average person with no experience in science or scientific terminology can understand. Informed consent must be obtained under circumstances that provide the subject (or legally authorized representative) sufficient opportunity to consider whether or not to participate and that minimize the possibility of subject coercion or undue influence. No informed consent, whether verbal or written, may include any exculpatory language through which the subject or a legally authorized representative is made to waive, or appear to waive, the subject’s legal rights, including any release of the University or its agents from liability for negligence.If a minor (age 7 or above) or vulnerable adult will be a participant in the study, the informed consent will be signed by the parent or guardian. An *additional* informed “Assent” form must also be provided to and signed by the minor or vulnerable subject in language understood by that individual. Researchers who need more information about informed consent should consult the CITI modules related to Informed Consent or visit the FAQ page on Informed Consent on the HHS website (link provided on IRB website).The informed consent must include each of the following numbered headings with descriptive narrative:1. **Explanation**: An explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any treatments or procedures which are experimental.
2. **Risks and Discomforts**: All research has some risk. The concept of risk goes beyond physical risk and includes risks to the subject’s dignity and self-respect, as well as financial, psychological, emotional or behavioral risk. This must be described, with an explanation of methods to minimize this risk. A description of any reasonable predictive risk or discomfort to the subject including possible results if the experimental treatment or intervention should prove ineffective when the subject is a recipient of treatment for an illness or dysfunction.
3. **New Information**: A disclosure of new appropriate alternative procedures or courses of treatment that become available during the course of the study and that may be advantageous to the subject’s condition or well-being.
4. **Benefits to Be Expected**: A description of direct benefits to the subject or to others which may be reasonably expected from the research, including compensation (if any) offered to the subject.
5. **Confidentiality**: A description of the extent to which confidentiality of records identifying the subject will be maintained.
6. **Contacts**: A description of whom to contact for answers to any questions the subjects may have about the research, the subject’s rights, or other matters. A 24 hour phone number is preferable. Include contact information for primary investigator(s), advisor, and IRB Office. Include contact person in the event of research-related injury.
7. **Freedom of Consent and Approval**: A description that participation is voluntary, and that refusal to participate will not result in a penalty or loss of benefits to which the subject is otherwise entitled. Also, included is a statement that the subject may discontinue participation at any time.
8. **Voluntary Participation/Medical Treatment**: For all studies involving human subjects the following statement **must** be included:

My signature below acknowledges my voluntary participation in this research project. Such participation does not release the researcher, the University of Mary, or other agencies from their professional and ethical responsibilities to me. Potential risks from participation in this research project have been disclosed to me. I acknowledge that unforeseeable and/or unknown risks or discomforts may occur. In the event that medical treatment occurs as a result of normal participation in this research project, the University of Mary, or other agencies will not be responsible for my medical costs or other damages incurred in the absence of fault on their behalf. 9. Lines for signature and date of the subject and/or the legally authorized representative who is providing consent and the witness to the consent.If appropriate, the following content must also be provided on the Informed Consent Form:1. A statement that the specific intervention or treatment may involve unforeseeable risks to the subject or embryo or fetus, if the subject is or may become pregnant.
2. Foreseeable circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.
3. Additional costs the subject may incur as a result of participation in the research project.
4. Important consequences of a subject’s decision to withdraw from the research and procedures for organized termination of participation by the subject.
5. A statement that significant new findings will be provided to the subject.
6. Approximate number of subjects involved in the study.

 The Institutional Review Board may approve an informed consent procedure that alters some or all of the elements of informed consent provided that the Board finds and documents all of the following:1. The research protocol involves no more than minimal risk to the subjects.
2. Sufficient information will be disclosed to inform the subject fairly to decide whether or not to participate in the research project.
3. Withholding or altering part of the description of the procedures will not materially affect the ability of the subject to evaluate the harm or discomfort caused by the research.
4. The project cannot practically be carried out without the withholding or alteration of the information, but with the assurance that the study’s design ensures protection of the rights and safety of each individual subject with the alteration.
5. The information is not altered or withheld for the goal of eliciting participation of the subjects.

A copy of the CONSENT FORM to be signed by the subject [if applicable] and/or a STATEMENT to be read to the subject should be attached to the application. If no CONSENT FORM is to be used, document the procedures to be used to assure that infringement upon the subject’s rights will not occur. | As there will be no Informed Consent or Assent form to upload, simply answer “Yes” to the question stating that “No consent form can be submitted” on the Human Subjects Informed Consent page of the application. |