Instructions for Applicants [Updated Spring-2021]

All persons wishing to conduct human subjects research must submit a proposal to the MVC-IRB for review. Human subjects research includes anytime data is collected from people (associated with MVC or not) by members of the MVC Faculty, Staff, or Students. Exceptions include in-class projects (where the only data that is collected is from registered students) and institutional record keeping or other institutional level surveys (e.g. NSSE: National Survey of Student Engagement).

- Applicants should determine which type of review they are requesting. The options are: EXEMPT, EXPEDITED REVIEW, and FULL REVIEW. Additional criteria are listed in Appendix 1.

- If you believe that your project is EXEMPT from IRB review, then do the following:
  - Write a 1-paragraph summary of your project and send it to irb@moval.edu.
  - The IRB will examine the summary to see if further information is needed.
  - The IRB will report back either EXEMPT or NOT EXEMPT.
  - EXEMPT = IRB agrees that this project does not need a review.
  - NOT EXEMPT = IRB feels that an EXPEDITED REVIEW or FULL REVIEW is needed.

- If you believe (or have been told) that your project needs an EXPEDITED REVIEW OR FULL REVIEW, then do the following:
  - Fill out the Application-Checklist Form for the correct type of review.
  - Submit an IRB proposal that includes the following information:
    - Title: Indicate the title of the study (this is what participants will see when they volunteer)
    - Name and Role: Indicate Primary Investigator(s) (P.I.) and their role(s) at MVC (Students, Faculty, etc.)
    - Faculty Sponsor: Indicate the faculty sponsor(s) (for student primary investigators)
    - Purpose: Statement of purpose, goal, and/or research question of the study.
    - Subjects: A description of the intended subjects, including any specific inclusion or exclusion criteria, and approximate number of participants. Be sure to indicate if any vulnerable populations will be included (children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged people). Subject must be at least 18 years old, otherwise a FULL REVIEW is required.
    - Recruitment: A description of how subjects will be recruited, any compensations or incentives provided.
    - Protecting Subjects' Rights: A detailed description of procedures for obtaining and documenting voluntary informed consent, and specific strategies intended to maintain anonymity and/or confidentiality of participant information (be sure to specify which, anonymous or confidential).
    - Time Frame: Indicate when you intend to start and for how many months do you expect to collect data.
    - Methods/Procedures: A detailed description of how the study will be conducted from start to finish, including the data collection procedures. Be sure to highlight the real or potential risk that may be present to subjects including physical, psychological, economic and/or social risks. Be sure to address procedures for minimizing and managing any risks.
    - Informed Consent Document: Include the informed consent statement that will be given to subjects (This may be included as a separate document). An example of a

generic informed consent document is included in Appendix 2 below. Appropriate methods for obtaining consent include one of the following:

- A signed document from the subject that is kept separate from the data (prefered method).
- Procedures where a consent statement is read out-loud to participants.
- Provide a box to check YES or NO that they have read the informed consent statement and agree to continue. For an online survey this must be a required item.

- Other Documents: If you are doing a survey, include a copy of the entire survey as participants will see it. Additionally, include any other documents that are relevant for your study.

- FOR FULL REVIEW ONLY: Include a description of specific procedures for obtaining and documenting informed consent from any identified vulnerable population, specific provisions to maintain the confidentiality of participant information, and specify how the rights, dignity, and interests of any vulnerable subjects have been fully and adequately considered. Address specifically if subjects are capable (legally or otherwise) of giving voluntary informed consent for the study (e.g. child subjects).

- WHEN YOU ARE READY TO SUBMIT:
  - The Principal Investigator and the Faculty Sponsor shall digitally sign the Checklist Form.
  - Note: when using a fillable PDF form, make sure to do the following
    - Download the form first
    - Fill it out
    - Digitally Sign it
    - Save it
    - Upload it to the Google Folder
  - Create a Google Folder with the Primary Investigator's last name in the title of the folder that contains the following items.
    - Checklist Form
    - IRB Proposal document
    - Informed consent statement
    - Other documents as needed (e.g. list of survey questions)
  - The folder is then shared with irb@moval.edu making sure that all items have “can edit” privileges.

- The Chair of the IRB Committee will respond to acknowledge the receipt of the proposal. IRB members will review the proposal. The Chair of the IRB will then reply with one of 3 responses:
  - Approved: you are free to begin collecting data.
  - Approved pending Revisions: some minor adjustments are needed, then sent back to the IRB for approval.
  - Not Approved: you may re-apply, but significant changes may be necessary to gain approval.

APPENDIX 1:

EXEMPT CRITERIA

A study qualifies for an EXEMPT review if items 1 and 2 are true.

1. Subjects DO NOT include protected groups such as children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged persons.
2. Any ONE or more of the following are true.
    a. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
    b. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, only if these sources are publicly available and personal identifying information is not included.
    c. Polls for consumer acceptance studies, or taste and food quality evaluation.

EXPEDITED REVIEW [Minimal Risk]

A study qualifies for an EXPEDITED review if items 1 and 2 are true.

1. The study does not qualify for an EXEMPT review.
2. Any ONE or more of the following are true.
    a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.
    b. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
    c. Collection of data from voice, video, digital, or image recordings made for research purposes.
    d. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
    e. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
    f. Clinical studies of medical devices when the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
    g. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (limits exist).
    h. Prospective collection of biological specimens for research purposes by noninvasive means (i.e., hair and nail clippings, excreta and external secretions (including sweat), mucosal and skin cells collected by buccal scraping or swab, or skin swab).

FULL REVIEW [Greater than Minimal Risk]

A study REQUIRES a FULL REVIEW if any of the items 1 through 4 are true.

1. The study does not qualify for an EXEMPT or EXPEDITED review.
2. The study presents subjects with greater than minimal risk.
3. Subjects DO include protected groups such as children, prisoners, pregnant women, mentally disabled, or economically or educationally disadvantaged persons.

4. Any ONE of the following are true.
    a. Projects for which the level of risk is determined by the IRB Chair to be greater than minimal.
    b. Projects that involve the intentional deception of subjects, such that misleading or untruthful information will be provided to participants.
    c. Projects that involve sensitive or protected populations (see item #3).
    d. Projects that plan to use procedures that are personally intrusive, stressful, or potentially traumatic (stress can be physical, psychological, social, financial, or legal).

APPENDIX 2A: Example of a Generic Informed Consent Document [in-person study]

Informed Consent

[If you use this template, but sure that you modify all portions of it so that it makes sense flows well for the purposes of your study.]

Title: (insert title of study here)

- You have been asked to participate in this study as part of a research project. This study examines (insert topic here or other explanation of purpose).
- To be eligible for the study, you must be a volunteer and must be at least 18 years old (if you are including minors in your study, you must go through the more complicated and involved FULL REVIEW process).
- During this study, the researcher will ask you to (insert a brief description of methods that a reasonable person would want to know about your project).
- Possible benefits from participating in this study are (insert possible DIRECT benefits, such as getting credit in a class, etc.). [and/or] There are no specific benefits to you as an individual for participating in this study. Possible benefits to society are (describe how the study expands our understanding of the topic, etc.).
- Possible risks from participating in this study are (insert possible risks). [or you say...] The risks to participants are not beyond those of normal daily activity.
- Your decision to participate in this study will have no effect on your relationship with the researcher, or Missouri Valley College. You may withdraw at any time without penalty.
- You will not be identified in the reporting of results. Your individual identity will remain confidential or anonymous (It can't be both, be sure to specify which one, anonymous or confidential).
- Your participation in the study indicates your understanding of the study and agreement to participate to the best of your ability. Please ask the researcher any questions you may have. If you choose to participate, follow the instructions below. If you choose not to participate, you may leave now without continuing.
- If you have any concerns or complaints about this study or the researchers conducting it, you should address it with the Principal Investigator, or the Faculty Sponsor, or by contacting the IRB directly at irb@moval.edu.

- Principal Investigator: (Name, email, contact number, role at MVC)
- Faculty Sponsor: (Name, email, contact number, role at MVC)

_____ _____ _____

(Signature of Subject) (Printed Name of Subject) (Date)

NOTE: If you do not collect signatures, then you need to establish a procedure to verify that subjects have been informed of their rights (such as reading a consent statement out-loud to the participants).

APPENDIX 2B: Example of a Generic Informed Consent [online survey using Google docs]

NOTE: this is the same as the previous example except that the following things need to be addressed...

1.) The informed consent statement needs to be a required item.
2.) The informed consent should be in it's own section so that the participant cannot continue without answering this required question.
3.) If it is anonymous, make sure that the "limit to 1 response" setting is turned off so that it does not collect the email address of the respondent.
4.) If it is confidential, then using the "limit to one response" option will automatically collect the email address. This allows tracking of who took the survey. In this case you need to explain how the identity is is being protected.