Dear Researcher,
Malone University's Institutional Review Board/Human Research Committee (HRC/IRB) is part of the Research Participants Protection Program (RPPP) at our institution. As such, it performs a review of proposed research to assure that the research conforms to the ethical standards of the university and the requirements set forth in 45 CFR part 46. The committee reviews all proposals involving human subjects to assure that ethical standards are met in the conduct of the work. Your proposal will be reviewed and you must have HRC/IRB approval before soliciting and/or gathering any data. The committee wants to assure that your work is not hindered by the review process. You can use the following checklist to assure that your research proposal obtains a timely response.

Definitions: HRC/IRB is part of the Malone University Research Participants Protection Program (RPPP).

Student Researcher Checklist

□ Complete the IRB Training Module (Section I)
□ Submit your completed Investigator Certification from Section I3
□ Submit completed Sections A, B, and C (signing in all locations where requested)

• Supply an email address for each researcher, including students and faculty.

□ Submit a copy of your survey or interview questionnaire
□ Submit a copy of all consent forms:

1. Informed Consent forms for participants,

2. If applicable, a copy of a guardian's Informed Consent form

□ Submit a copy of all letters of cooperation/permission. This includes:

1. Letters of cooperation from collaborating/cooperating institutions
from students' supervisors who may be off campus.

2. Letters of cooperation/permission from cooperating institution (should be on letterhead, signed, and dated)

□ Submit a copy of all instructions to participants.

□ Submit a copy of the debriefing script if applicable

□ Make sure all applicable signatures are affixed before submitting. Student researchers must have signature from faculty advisor.

 Keep a copy of your forms. Do not turn in pages beyond Section C. Keep the other sections so that you have them when you need them.

 Print the entire packet. Obtain signatures/dates. Scan the whole packet to .pdf and then email it to the HRC/IRB Research Participants Protection Program Chair & Coordinator, Dr. Seifert at LSEIFERT@malone.edu

 Do not email files larger than 7MB

 If opting to send a hard copy of forms through campus mail or US Mail, then be sure that all pages are ONE-SIDED with NO STAPLES, NO PAPER CLIPS, and NO FASTENERS or TAPE on them.

Dear Faculty Instructor / Research Supervisor,
Malone University's Institutional Review Board/Human Research Committee (HRC/IRB) is patrt of our Research Participants Protection Program and will review your student's research to assure that the research conforms to the ethical standards of the university and the requirements set forth in 45 CFR part 46. One of the roles of the Faculty Instructor / Research Supervisor is to supervise students' preparation of materials for the HRC/IRB on behalf of Malone University. To assure that the student's research conforms to these requirements please use the following checklist to assure that your student's research obtains a timely response.

Definitions: HRC/IRB is part of the Malone University Research Participants Protection Program (RPPP).

Faculty Instructor / Research Supervisor Checklist

□ Assure that the student has completed the Investigator Certification from Module – Section I

□ Review the student's Sections A, B, and C and all Consent Forms

□ Sign-off on the forms where indicated (Section A)

□ Make sure the student provides letters of cooperation from collaborating/cooperating institutions and from any students' supervisors who are off campus. If a student researcher is being supervised off campus, the letter should include a statement that the other institution accepts responsibility for the study and releases Malone University from liability associated with the study.

□ Make sure the student identifies researcher names, department/school, and project topic (and protocol number, if known) with a contact phone or e-mail on each message, form, or e-mail sent to the Malone HRC/IRB. An email address should be supplied FOR EACH PERSON associated with the study.

□ Please do not leave students (especially undergraduates) to prepare documents and communicate with the HRC/IRB on their own.

□ Please do not send incomplete or unsigned forms to the HRC/IRB.

□ Please do not expect quick reviews or demand same-day approvals. HRC/IRB reviewers give time and energy to read and understand each project and its intersections with numerous laws (e.g., FERPA, HIPAA, 45 CFR 46, and 21 CFR 50). Our goal is to help you follow laws that guide human research.

Make sure all applicable signatures are affixed before submitting. Student researchers must have a signature from a faculty supervisor.

□ Keep a copy of your forms. Do not turn in pages beyond Section C. Keep the other sections so that you have them when you need them.

□ Print the entire packet with signatures/dates. Scan the whole packet to .pdf and then email it to the HRC/IRB Research Participants Protection Program Chair & Coordinator, Dr. Seifert at LSEIFERT@malone.edu

□ Do not email files larger than 7MB

□ If opting to send a hard copy of forms through campus mail or US Mail, then be sure that all pages are ONE-SIDED with NO STAPLES, NO PAPER CLIPS, and NO FASTENERS or TAPE on them.

□ Thank you. Please, contact the HRC/IRB Research Participants Protection Program Chair & Coordinator, Dr. Lauren Seifert at LSEIFERT@malone.edu or at 330-471-8558, if you have questions about any of the above forms. Thank you for your consideration and may the Lord bless your work.Malone University's HRC/IRB

Human Research Committee/IRB
Malone University

Definitions: HRC/IRB is part of the Malone University Research Participants Protection Program (RPPP).

Request for Review of Faculty, Staff, or Student Research Project Involving Human Subjects

All faculty, staff, and student research projects involving human subjects must undergo a review process for human subjects protection. The typical proposal will be exempt from additional reviews, or will require only expedited review (e.g., with one reviewer). In order to make the initial review possible, please complete this application and send it with any additional materials. Proposals should be submitted via email to LSEIFERT@malone.edu
An alternative method of submission is campus mail, or US Mail, to: Dr. Lauren S. Seifert, Chair & Coordinator, Research Participants Protection Program-IRB, Malone University, 2600 Cleveland Ave., NW, Canton, Ohio 44709.

If you have any questions, please, feel free to contact Professor Lauren Seifert at LSEIFERT@malone.edu or at 330-471-8558.

IRB OFFICE USE ONLY

Project

Date Received:

Actions:

Date Approved:

According to the policies of Malone University, all researchers, including students, must be certified to conduct research with human subjects. Also, it is important that the faculty or staff supervisor of the project should be certified. Certification indicates that appropriate training in human subjects protection has been received. Certification can be obtained individually through the Human Research Committee (by contacting Dr. Seifert), via the website (www.malone.edu, click on "Academics", click on "Institutional Review Board", click on handbook/training document), or through a classroom presentation on the principles underlying human subjects research, OR **see Section I, Training.**

➢ Section A: Applicant Information and Assurances

* ***Instructions:*** Please, complete the following. For the purposes of HRC/IRB review: "Researchers" are all persons who will have direct contact with research participants, with research records that list participants' identities, and/or with research data during analysis and writing of research reports. All fields of this table (below) must be completed.

*Researcher Name(s)					
Title of Proposed Research					
Anticipated Start Date of Project		Anticipated End Date of Project			
Primary contact:		Box #		Phone # and Email	
*Faculty/Staff Supervisor (write N/A, if not applicable)			Faculty Phone # and Email		

Course # and Name (if applicable)	

- THIS PAGE: Reviewer Comments: For Use by the Human Research Committee only

Researchers, please, go on to the next page and leave this one blank and in the packet with your completed forms.

Name of Reviewer (print) _____

Signature of Reviewer _____

Date _____ Phone _____ Box # _____

IRB Office Use Only

_____ This research project **is exempt** from IRB review based on 45 CFR 46.101(b)

_____ This project **is approved** as submitted.

_____ This project **is approved contingent** on the changes listed below.

_____ A **waiver** of written informed consent is granted.

Other:

- **Section A: Applicant Information and Assurances (continued)**

Additional information: US Mail addresses and any additional contact information for primary researchers should be supplied here (e.g., cell phone; continued from p. 1).

All persons having direct contact with participants and/or research data should sign below. All faculty/staff supervisors for student researchers should sign below, too. If you are a faculty member or staff member doing research without student assistance, then skip the student signature space immediately below and sign as the primary researcher in the Faculty/Staff signature location.

Student Researcher Assurance: Please, read each item and <u>check each box</u>.

____ I/we agree that the proposed research includes only the instruments, behaviors, and activities described in this application;

____ I/we agree that I/we have received appropriate training in human subjects protection to conduct this research in accordance with the principles outlined in the Belmont Report, 45 CFR 46, and additional federal, state, and local regulations that apply to this research project;

____ I/we agree that Training Module – Section I(or an approved substitute) has been completed and signed documentation submitted; and

____ I/we agree that the research will not be initiated until written approval is given by the Human Research Committee of Malone University.

Student(s): _____
(sign) Date

Faculty/Staff Researcher Assurance:
I have participated in the construction of this proposal and I take responsibility for supervision of this research project. I agree to report any significant changes in the research proposal to the Human Research Committee of Malone University. I agree that I have received certification for human subjects research and that the student(s) named above has/have done so also: With Training Module – Section I (or approved substitute) completed and signed documentation submitted to the HRC/IRB at Malone University.

Faculty/Staff Researcher(s): _____
(sign) Date

- **Please, go on to the next page...**

➢ Section B: Criteria for Determination of Review Level

***Instructions*:** Please answer ALL questions. Select the appropriate answer: No, Yes, or NA (not applicable)

1. Does application involve human subjects participating in biomedical procedures? ..... YES NO

2. If biomedical procedures are involved:

   a. are provisions for emergency medical care necessary? ..... YES NA NO
   (If answer is yes, give details in Section C.)

   b. has a qualified/licensed medical professional participated in planning the project? ..... YES NA NO
   (If answer is yes, attach a signed letter from the professional which indicates his/her level of involvement with the project)

   c. will this study involve drugs or chemical agents (dosages), ionizing radiation, nonionizing radiation (microwaves, lasers), or high intensity sound? ..... YES NA NO

3. Does this project involve the use or collection of human tissue, human blood, and/or other human body fluids? ..... YES NO

4. Does this study involve giving false or misleading information to subjects or withholding information from them such that their "informed" consent is in question? ..... YES NO

5. Are the procedures to be used new or innovative (not established and accepted)? ..... YES NO

6. Will the procedures:

   a. cause any degree of discomfort, harassment, invasion of privacy, risk of physical injury, or threat to the dignity of subjects, or be otherwise potentially harmful to subjects? ..... YES NO

   b. if answer to 6a is yes, have specific provisions been made to correct any harmful or adverse conditions that may arise? ..... YES NA NO
   (Give details in Section C.)

7. Will any type of electrical equipment be used that will be connected to subjects? (If the answer is yes, provide with Section C the name and qualifications of the individual who will check for electrical safety and attach a signed letter from that person which indicates his/her level of involvement with the project.) ..... YES NO

8. Will subjects receive any payment for participating (money, course credit, etc.)? (If answer is yes, give details in Section C.) ..... YES NO

➢ **Please, go on to the next page...**

➢ Section B: Criteria for Determination of Review Level (continued)

9. Will the *targeted* subject population consist of persons with/who are:
   - minors (less than 18 years of age)? ..... YES NO
   - pregnant women? ..... YES NO
   - prisoners? ..... YES NO
   - developmental disability? ..... YES NO
   - neurocognitive disability/impairment (e.g., brain-damage, psychiatric diagnosis, etc.)? ..... YES NO
   - physical challenged (e.g., using wheelchair, walker, etc.)? ..... YES NO
   - in institutional care (e.g., persons in residential care who have an identified disability)? ..... YES NO
   - members of specific ethnic or cultural groups? ..... YES NO
   - citizens of other countries? ..... YES NO

10. Will the targeted subject population be Malone University students? ..... YES NO
    a. If yes and course credit is offered, does Section C (below) address an alternate means of earning the extra credit? ..... YES NO

11. Do procedures include *obtaining parental/guardian consent and/or institutional authorization for access to subjects* if minors, persons with developmental disability, persons with neurocognitive disability, or persons in institutional care? ..... YES NA NO

12. Are procedures for maintaining confidentiality of all subjects' data fully described in Section C (below)? ..... YES NO

13. Are procedures for obtaining informed consent fully described in Section C (below)? ..... YES NO

14. Will a copy of the informed consent document be provided to each subject? ..... YES NO

15. If applicable, have copies of the following documents been submitted with Sections A, B, & C?
    - •Instrument(s) (e.g., surveys, interview outlines, etc.) ..... YES NA NO
    - •Consent document ..... YES NA NO
    - •Debriefing statement ..... YES NA NO
    - •Letter of agreement from cooperating institution(s) ..... YES NA NO
    - •Letter(s) from cooperating individuals (e.g., secondary data, individual responsible for electrical safety, physicians, etc.) ..... YES NA NO
    - •Emergency Procedures ..... YES NA NO

16. Average amount of time required for subject's participation (in hours) ..... _____

    How many different questionnaires, tests, surveys, etc., per subject, are to be involved? ..... _____

    Number of subjects to be involved in this study ..... _____

17. Earliest possible date when research subjects will first be involved. ..... _____
    (This date must **not** be prior to the date of approval by the IRB)

18. Approximate ending date of involvement of research subjects. ..... _____

- **Please, go on to the next page...**

Section C: Explanation of the Proposed Research Project

Instructions: Please, respond to EACH of the following items or questions. Provide enough detail so that the IRB will be able to judge how well your study protects human subjects. Please type your responses to Section C or print clearly, and number them to correspond to the items on this form (if a separate page is used). NOTE: Write/type NA whenever an item is not applicable to your study. Then, provide a sentence to explain why the NA response has been given.

1. Provide a brief description of **the issue under investigation** in the study.

This is a study about

2. **Who will your subjects/participants be?** What are the *requirements for and characteristics of the participants* (e.g., what gender, age range, health or medical status, prisoners, in institutional care, with developmental or neurocognitive disability)?

3. **How will you get subjects/participants?** How will people be sampled, recruited, or otherwise enlisted as participants in the study (e.g., at random, via particular classes, by convenience as they wander out of the Library, etc.)?

4. Describe, in detail, the **methodology of your study**. (e.g., How will the study be conducted from start to finish, as far as human subjects are concerned? Be specific about the methods, instrumentation, types of data collected, etc.) Any parts of the study which are not yet fully developed should be outlined. Revisions/final methods should be submitted upon completion with a "letter of modification" (i.e., forms Section F). If the study requires coding of participants' identities, the purpose of the coding should be fully explained and the ways in which confidentiality will be maintained should be described.

5. Describe the **personnel, materials/equipment**, or other resource requirements for your study. (Identify all personnel involved in the study including their roles, qualifications, and access to confidential data.) PROVIDE A LETTER OF AGREEMENT FROM ALL COOPERATING INSTITUTIONS.

6. If you are not using a written informed consent form, describe the procedure for obtaining informed consent from the participants (e.g., how, when, and where the study will be explained to participants). How will participants indicate their consent? (If you are using a written informed consent form, simply include it with your proposal.)

7. What are the **potential risks to the participants**, and **what is the likelihood and seriousness of these risks**? (Risks could be physical, psychological, social, legal, etc. Risks may result from your experimental procedures or from your methods of obtaining, handling, or reporting data.). As applicable, **describe how you will minimize or protect against potential risks to participants throughout the study. (**Describe emergency procedures, confidentiality safeguards, debriefing procedures, security measures for storing data, etc.)

➢ Section C: Explanation of the Proposed Research Project (continued)

8. What are the **potential benefits** to the individual participants and/or society of the proposed research?

9. **Debriefing**: Provide a script for verbal debriefing or the text of the debriefing that will be provided and explain how it will be disseminated.

10. **Will participants be provided opportunities to ask questions** and to be debriefed about the purpose of your study? If so, when and how? (If not, provide a brief justification of omitting debriefing.)

11. Please**, describe the steps that will be taken to minimize risk** to research participants. (If your study is "minimal risk" in nature, your response may be that this review embodies the steps taken to ensure appropriate risk minimization is in place.)

➢ Section C: Explanation of the Proposed Research Project (continued)

12. **Resource persons:** Have you consulted other scientists, professors, researchers to obtain affirmation about the safety and appropriateness of your methods? If so, list their names and contact information below:

13. Published Resources: Are there published articles/books/materials that affirm the safety and appropriateness of your methods? If so, list them below:

➢ **ONLY COMPLETE Sections D and beyond when appropriate (e.g., to apply for renewal, to register an off-campus researcher). <u>DO NOT TURN IN SECTION D and BEYOND with an initial proposal.</u>**

Section D: Report of Project Status (for completions and for renewals *without method changes*)

Instructions: **Please, submit this page when all subject testing has been completed, *or* when a renewal/continuing review of the project is requested. Most approvals are effective for one year. Renewal should be requested *before* the date of the approval's expiration.**

Please, send this report as a .pdf file to the chair & coordinator, Research Participants Protection Program-IRB via email at LSEIFERT@malone.edu

An alternative method of submission is via mail to: Professor Lauren S. Seifert, Chair & Coordinator, RPPP/IRB at Malone University, 2600 Cleveland Ave., NW, Canton, Ohio 44709. If you would like to contact her directly, please feel free to call 330-471-8558 or email LSEIFERT@malone.edu

*Researcher Name(s)					
Title of Proposed Research					
Anticipated Start Date of Project		Anticipated End Date of Project			
Primary contact:		Box #		Phone # and Email	
*Faculty/Staff Supervisor (write N/A, if not applicable)			Faculty Phone # and Email		
Course # and Name (if applicable)					

The Protocol designation is: Letters_____ #_____.

Status of the Project: The primary researcher (if staff/faculty), or the faculty advisor (if study is a student project), should complete this section. Please, check one.

____ All testing has been completed and no adverse events have been observed by researcher. This project is complete. (Use this page, alone: Section D).

____ All testing *has not* been completed, and a renewal of the approval is requested with *no changes in method*. (Use this page, alone: Section D.)

____ All testing has been completed and one or more adverse events has occurred (Use this page, Section D., along with Section F).

____ All testing *has not* been completed, and a renewal of the approval is requested *with one or more changes in method* (Use Section E., alone, without Section D.).

□ **Other, please, describe:**

Person submitting the report: _____ Date: _____

(sign)

- **Please, go on to the next page when appropriate...**

- **Section E: Request for Renewal/Continuing Review of a Human Research Protocol *with Method Changes***
- **Note: This form is also used for Request of an Addendum to an Existing (i.e., unexpired) Approved Research Protocol.**

Please, send this report as a .pdf file to the chair & coordinator, Research Participants Protection Program-IRB via email at LSEIFERT@malone.edu

An alternative method of submission is via mail to: Professor Lauren S. Seifert, Chair & Coordinator, RPPP/IRB at Malone University, 2600 Cleveland Ave., NW, Canton, Ohio 44709. If you would like to contact her directly, please feel free to call 330-471-8558 or email LSEIFERT@malone.edu

Protocol designation: Letters_____ and #_____

Names of all researchers continuing on the project:

Person requesting the renewal: _____

Printed name

Signature: _____ Date: _____

Contact information:

Description of method changes (attach additional pages as needed):

➢ Section F: Form for Report of Unanticipated Events that increase risk to one or more research subjects and/or Adverse Events in Human Research

Instructions: **Please, provide a description of the alleged adverse event(s) with date, day, and time of occurrence.**

Please, send this report as a .pdf file to the chair & coordinator, Research Participants Protection Program-IRB via email at LSEIFERT@malone.edu

An alternative method of submission is via mail to: Professor Lauren S. Seifert, Chair & Coordinator, RPPP/IRB at Malone University, 2600 Cleveland Ave., NW, Canton, Ohio 44709. If you would like to contact her directly, please feel free to call 330-471-8558 or email LSEIFERT@malone.edu

Person reporting the event: _____ _____

Printed name Date of report

Contact information:

Description of the event (s):

Section G: Noncompliance Allegation Report

Form for the Report of Alleged Non-Compliance, Continuing Non-Compliance, and/or Similar Violation of federal regulations for human research and/or oversight of human research

- In the event of suspected non-compliance, continuing non-compliance, and/or similar violation of federal regulations related to human research and/or oversight of human research, the complainant should immediately complete and sign this form.

Instructions: **Please, send this report as a .pdf file to the chair & coordinator, Research Participants Protection Program-IRB via email at LSEIFERT@malone.edu**

An alternative method of submission is via mail to: Professor Lauren S. Seifert, Chair & Coordinator, RPPP/IRB at Malone University, 2600 Cleveland Ave., NW, Canton, Ohio 44709. If you would like to contact her directly, please feel free to call 330-471-8558 or email LSEIFERT@malone.edu

In the event that alleged non-compliance involves one or more members of the Malone University Human Research Protections program – IRB,please, submit copies to: (1) the Provost of Malone University, and (2) the Chair & Coordinator of the Malone University RPPP-IRB. Thank you.

In the event that alleged noncompliance involves the HRC/IRB Research Participants Protection Program Chair & Coordinator, please, submit this report to the Provost of Malone University. Thank you.

(If known) Protocol designation: Letters_____ and #_____

Name of person/persons involved:

Description of the complaint (using additional pages when needed and providing the date of the event):

Complainant's Statement (Please, check the items that apply):

____ I/we certify that all statements contained herein are true, to the best of my/our knowledge.

____ I/we request investigation of the aforementioned claim(s) by the Malone University HRC/IRB.

____ I/we request investigation of the aforementioned claim(s) by the Malone University Provost.

____ I/we request follow-up with me/us.

Print name(s) of complainant(s):

Person submitting the report: _____ Date: _____

(sign)

Section H: Individual Investigator Agreement (Page 1 of 2)

➢ **for persons who are conducting research under a federal grant, contract, or cooperative agreement, and who are not otherwise affiliated with Malone University**

- **Please, send this report as a .pdf file to the chair & coordinator, Research Participants Protection Program-IRB via email at LSEIFERT@malone.edu**
- **An alternative method of submission is via mail to: Professor Lauren S. Seifert, Chair & Coordinator, RPPP/IRB at Malone University, 2600 Cleveland Ave., NW, Canton, Ohio 44709. If you would like to contact her directly, please feel free to call 330-471-8558 or email LSEIFERT@malone.edu**

➢

- ➢
- **Names of all institutions involved in the research project:**
- **Protocol designation: Letters_____ and #_____**
- **Name of Primary Investigator and his/her contact information:**
- **Name of Individual Investigator making this application:_____**

(Please, note that the text, below, follows recommendations made by the OHRP of HHS for Individual Investigator Agreements, as accessed online at http://www.hhs.gov/ohrp/humansubjects/ on May 15, 2009.)

(1) The above-named Individual Investigator (hereafter referred to as the "Investigator") has reviewed: 1) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (or other internationally recognized equivalent; see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions); 2) the U.S. Department of Health and Human Services (HHS) regulations for the protection of human subjects at 45 CFR part 46 (or other procedural standards; see section B.3. of the Terms of the FWA for International (Non-U.S.) Institutions); 3) the FWA and applicable Terms of the FWA for the institution referenced above; and 4) the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this agreement.

(4) The Investigator will abide by all determinations of the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) designated under the above FWA and will accept the final authority and decisions of the HRC/IRB AT MALONE UNIVERSITY, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any educational training required by the Institution and/or the HRC/IRB AT MALONE UNIVERSITY prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the HRC/IRB AT MALONE UNIVERSITY any proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior HRC/IRB AT MALONE UNIVERSITY review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the HRC/IRB AT MALONE UNIVERSITY any unanticipated problems involving risks to subjects or others in research covered under this Agreement.

(8) The Investigator, when responsible for enrolling subjects, will obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected on the FWA for the institution referenced above) as stipulated by the HRC/IRB AT MALONE UNIVERSITY.

(9) The Investigator acknowledges and agrees to cooperate in the HRC/IRB AT MALONE UNIVERSITY's responsibility for initial and continuing review, record keeping, reporting, and certification for the research referenced above. The Investigator will provide all information requested by the HRC/IRB AT MALONE UNIVERSITY in a timely fashion.

(10) The Investigator will not enroll subjects in research under this Agreement prior to its review and approval by the HRC/IRB AT MALONE UNIVERSITY.

(11) Emergency medical care may be delivered without HRC/IRB AT MALONE UNIVERSITY review and approval to the extent permitted under applicable federal regulations and state law.

(12) This Agreement does not preclude the Investigator from taking part in research not covered by this Agreement.

(13) The Investigator acknowledges that he/she is primarily responsible for safeguarding the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.

Investigator : _____Date _____
(sign)

Full Name: _____ Degrees: _____

Address: _____ phone #: _____

_____
(City) (*State/Province*) (*Zip/Country*)

FWA Institutional Official (or Designee): _____ Date _____
(sign)

Name: _____Institutional Title: _____

Address: _____ phone #: _____

Section I: Researcher Training and Certification

Certification of Training Module Completion

Definitions: HRC/IRB is part of the Malone University Research Participants Protection Program (RPPP). Please, detach this page, complete it, and return it to the address below in order to receive your certification as a researcher at Malone University. Students, faculty, and staff who wish to submit research protocols to the Research Participants Protection Program/IRB at Malone University must verify their certification at least once per year through the chair & coordinator of Malone's RPPP/IRB. This form can be submitted at the same time as a research proposal. Thank you.

Applicant's full name (printed): _____

Applicant's address: _____

Applicant's phone: _____ Applicant's email: _____

Using the training module that follows, please, respond to the following items.

1) In the USA and in many other nations, human research protections evolved during the _____ trials that followed World War II.

2) In the USA, the _____ Report was issued in 1979, as an important step in establishing basic principles of human protection in research.

3) The Report mentioned in Item #2 (above) named three basic standards of subject protection in human research. Circle the item that lists those standards.

a. vanity, humanity, and integrity
b. beneficence, justice, and respect for persons
c. volatility, lability, and perspicacity
d. economy, advantage, and risk

4) Federal guidelines for protection of subjects in human research include the "Common Rule" which is Title ___ Part ___ of the federal code.

5) The Human Research Committee/IRB at Malone University recognizes a stewardship responsibility in line with the mission of the institution. Specifically, we cite Matthew 19:19, Christ's mandate to, "...love ____ _____ as _____."

Applicant's Statement:
I verify that I have completed this form and have read the training module for human researchers at Malone University.

SIGNED: _____ DATED: _____
Submit via campus mail or US mail to: Dr. Lauren S. Seifert, Chair, HRC/IRB, Malone University, 2600 Cleveland Ave. NW, Canton, Ohio 44709

What most people don't know about Human Research Committees…

Human Research Committees exist around the world, because of resolutions that were made by nations that participated in the **Nuremberg trials after World War II**. Those countries resolved to convict scientists who had participated in Nazi war-time experiments. They also wanted to help prevent such atrocities in the future by putting in place committees to help protect the rights of individuals who might participate in research studies. Many people are not aware that Adolf Hitler endorsed the testing of humans without their prior knowledge or consent—
in schools, in labor camps, and in factories that he controlled during WWII. Nations that participated in the Nuremberg trials, did not want similar experiments to occur in their own countries after the war. Thus, in many countries, laws that created "institutional review boards" or "institutional ethics committees" were created.

****

In the U.S., across college/university campuses and at hospitals and private institutions, the protection of human subjects is not by the whim of a particular set of committee members or chairpersons. It is mandated by federal law.

When the **Belmont Report** was issued by the Dept. of Health, Education, & Welfare in 1979, it set human research standards of *beneficence, justice,* and *respect for persons* (e.g., individual autonomy and protections for those with reduced autonomy) in human research in the USA.

Under the Federal Code, Title 45, Part 46 (called the "Common Rule"; Revised June 18, 1991) the OPRR (i.e., the Office for Protection from Research Risks) described how it is that human research committees should conduct themselves. Today, the OHRP (i.e., Office of Human Research Protections of the Dept. of Health & Human Services) oversees human research protections that were established in the **45 CFR 46 guidelines**.

At Malone University, our Human Research Committee views the task of protection of human research participants as an issue of stewardship…in relationship to His command in Matthew 19:19 to "…love your neighbor as yourself."

Additional laws may apply to human research, and the Food & Drug Administration (FDA) oversees and enforces regulations that relate to clinical investigations, such as studies of new medications, medical interventions, cosmetics, and foods. The **FDA's guidelines, like 21 CFR 50-56**, help researchers as they conduct those types of studies.

The additional benefits to research participants are protection from harm and the potential for increasing their own knowledge and scientific knowledge in areas that may directly benefit or that may eventually benefit them. For researchers, the potential for benefit from IRB's/IEC's/Human Research Committees is to help protect them from harming their research participants, to help protect them from harming themselves. This is big responsibility. Our committee can only help. Ultimately, each researcher must take responsibility for his/her own conduct.

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Why does Malone's committee seem to have two names: the "IRB" and the "Human Research Committee"?

The Human Research Committee at Malone University has a fundamental obligation to uphold the Christian mission of our institution. It also has a mandate to help Malone University uphold its obligations to research participants under the federal law. The federal code refers to a committee of our variety as an "Institutional Review Board"[Title 45, Part 46.102g], but does not disallow alternative labels—as long as we identify ourselves to federal officials as the institutional review board for Malone University.

In view of our missions to uphold both the law and our institutional values, it seemed as if a "more gentle" name might work. It helps to identify the committee's functions, without making its role to seem one of solely upholding the law. Indeed, we view our roles as Christian stewards very seriously, and our aim is to "love our neighbor as we love ourselves" (Matthew 19:19; Luke 10:27; Mark 12: 30-31)

Section J: For those conducting research with non-human animals.

For those working non-human animals, AWA (the Animal Welfare Act) may apply. Complete the following form and provide a detailed description of your research methods with materials and procedures.

Title of your project:

Researcher information:

Full name	Email address	Phone	Signature/Date

Genus and species with which you are working:

Strain or breed (if specified):

How many animals will be involved? _____

Where will the animals be housed (be specific- building and room)?

What are the exact dates when the animals will be housed at Malone University?

Will the animals be housd in separate enclosures (circle one)?
YES NO

Describe the feeding schedule:

Describe the watering schedule:

Describe the schedule for cleaning the housing room and enclosures:

Describe enrichments (if applicable):

Attach a description of your detailed research protocol.

Submit forms as pdf files to the RPPP Chair & Coordinator, Dr. Lauren Seifert, at LSEIFERT@malone.edu or call 330-471-8558 for additional assistance.