

---

## 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.

\*\*\*\*\*

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)