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| | IRB-030 | Human Subjects Determination | January 2019 | 1 of 1 |

1. PURPOSE

1.1. To determine whether a project meets the regulatory definition of human subjects research, and therefore, subject to MU IRB review.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. It is the responsibility of the investigator for the initial determination whether an activity constitutes human subject research. Investigators may request to confirmation that an activity does not constitute human subject research from the ORC. The request can be made by completing and submitting the “Determination of MU IRB Submission Form” found at <https://www.marquette.edu/orc/irb/>.

3.2. Determinations are made according to the definitions in IRB-020. Determinations are made by the IRB staff. However, additional input such as the IRB Chair, IRB members, the Vice President for Research and Innovation may be sought.

3.3. Documentation of determinations using the Determination of MU IRB Submission Form will be recorded in a determination folder.