Use this packet to determine the following:

- Does my project qualify for exempt review? If yes, which category or categories?
- Does my project qualify for expedited review? If yes, which category or categories?
- Does my project require full review?

**Unsure if your project requires IRB review and approval?**
Please complete the Determination of MU IRB Submission Form and send it to the Office of Research Compliance for review. All forms, as well as additional guidance and policy information, can be found on the ORC website: www.mu.edu/orc/irb

**Note about special/vulnerable populations**: special regulations and/or policies may apply to research with vulnerable populations and some specific groups of potential research participants. For research involving **minors**, see guide in this packet. For research involving **prisoners or prisoner data**, and non-survey/interview research with **pregnant women, fetuses or neonates**, please contact the ORC.

**Contents:**

**Decision Tree** for the following types of research activities:
- Interview, Focus Group, Survey, Questionnaire, Educational Tests

**Decision Tree** for the following types of research activities:
- Analyzing a data set, specimens, record review, chart review

**Decision Tree** for the following types of research activities:
- Educational Research, Program Evaluation, Quality Improvement/Accuracy

**Research Interventions A to Z**

**Research Involving Minors** (age 17 or under)

This document is designed to aid researchers in determining the appropriate level of review and category of review to select when submitting human subjects research projects. Please keep in mind that the final decision regarding level of review is made by the Office of Research Compliance and/or the Institutional Review Board.

**Can’t find what you are looking for?**
**Contact the ORC for assistance determining the appropriate level of review for your project.**

**Questions or Comments - Please let us know**
Marquette University Office of Research Compliance
560 N. 16th Street – Schroeder Complex, Room 102
Phone: (414) 288-7570
Email: orc@marquette.edu
Web: www.mu.edu/orc/irb
Marquette University Office of Research Compliance
Decision Tree for the following types of research activities:
Interview, Focus Group, Survey, Questionnaire, Educational Tests

START HERE

Does your project only involve research subjects that are age 18 or over?

- YES
  - Your project qualifies for Exemption under Category 2: Educational Tests, Surveys, Interviews or Observations – Complete the Exempt Review Form

- NO
  - See Research Involving Minors

Is your project anonymous? This means that no identifying information will be collected (includes information like name, date of birth, medical record number, audio/video recording, or other unique factors that could identify an individual).

- YES
  - Your project qualifies for Expedited Review under Category 7: 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. Complete the Expedited and Full Review Form

- NO
  - Will you be collecting any “sensitive” information? Information is considered sensitive if any disclosure outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation or be stigmatizing.
    - YES
      - Is it possible, and will reasonable and appropriate protections be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?
        - YES
          - Full IRB Review Required Contact the ORC and complete the Expedited and Full Review Form
        - NO
          - Will your project involve audio or video recording? If yes, Expedited Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes, also applies.

- NO
  - See Research Involving Minors
Select Level of Identification for records/specimens that will be ACCESSED

IDENTIFIABLE
Records or specimens identified by name, medical record number, or any other unique characteristic that could identify the subject

Are all of the records/specimens currently in existence (as of the day the research protocol is submitted)?

YES

NO

CODED
Records or specimens can be linked to an identifier through a code (even if the investigator does not have access to the code)

Is there a written agreement that prohibits the Marquette researcher and his/her research team from having access to the key for the code, or can justification be made that the likelihood of the Marquette researcher having access to the key or information that could re-identify the records/specimens extremely unlikely?

YES

Complete MU Determination of IRB Submission Form

NO

DEIDENTIFIED
No identifying information exists that could link a subject to the record/specimen

Will information be recorded in such a manner that subjects cannot be identified directly or through linked identifiers OR is the information publicly available?

YES

Project qualifies for Exemption under Category 4: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. Complete the Exempt Review Form

NO

PROJECT QUALIFIES FOR EXPEDITED REVIEW UNDER:

Category 3: Prospective collection of biological specimens for research purposes by noninvasive* means.

OR

Expedited Review under Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). May also include materials collected under a previously IRB approved research study.

Complete the Expedited and Full Review Form

*Specimens collected for research purposes by invasive means will require full IRB review

IMPORTANT INFORMATION
Other regulations/policies may apply to data/specimen research. For example:
- HIPAA – Health Records
- FERPA – Educational Records
- Biosafety, OSHA - Specimens
Marquette University Office of Research Compliance
Decision Tree for the following types of research activities:
Educational Research, Program Evaluation, Quality Improvement/Assurance

START HERE

Select Research Type Below

YES

Have you reviewed the Marquette Determination of MU IRB Submission Form to verify that IRB review and approval is needed?

NO

Review the form to verify that IRB review and approval is required

EDUCATIONAL RESEARCH

Does the project involve ONLY evaluation of normal educational practices that take place in an educational institution?

NO

YES

Your project qualifies for Exemption under Category 1: Normal Educational Practices – Complete the Exempt Review Form

YES

Your project qualifies for Expedited Review under Category 7: 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.

Complete the Expedited and Full Review Form

PROGRAM EVALUATION

QUALITY IMPROVEMENT/ASSURANCE

Is the program being conducted for research purposes?

And/Or

Is the quality improvement/assurance activity being done for research purposes?

If the program and/or quality improvement activities would take place regardless of the research, answer NO.

YES

NO

If the research exclusively involves data or specimens – use the Decision Tree for Analyzing a data set, specimens, record review, chart review

If the research involves an interview, focus group, survey, questionnaire, educational tests, etc. use the Decision Tree for Interview, Focus Group, Survey, Questionnaire, Educational Tests
<table>
<thead>
<tr>
<th>Intervention/Interaction</th>
<th>Level of Review*</th>
<th>Category</th>
<th>Additional Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Audio Recording</td>
<td>Varies - Could be exempt Category 2, Expedited Categories 6 &amp; 7, or full review depending on the information collected and risk level</td>
<td></td>
<td>Healthy nonpregnant adults weighing at least 110 lbs - amount not to exceed 550ml in 8-wk period and collection not more than 2x/week - OR - for other adults and children considering age/weight/health, lesser of 50ml or 3ml per kg in an 8wk period and collection no more than 2x/week</td>
</tr>
<tr>
<td>Blood Draw - Finger stick, heel stick, ear stick, venipuncture</td>
<td>Expedited</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Body composition (not DXA)</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Cortisol (saliva)</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>CT Scan</td>
<td>Full Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dental x-ray (for research purposes)</td>
<td>Full Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device testing (FDA regulated medical device)</td>
<td>Full Review</td>
<td></td>
<td>May qualify for Expedited Category 1 if NSR and minimal risk</td>
</tr>
<tr>
<td>Doppler blood flow</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Drug administration</td>
<td>Full Review</td>
<td></td>
<td>Unless minimal risk, then Expedited Category 1 may apply</td>
</tr>
<tr>
<td>DXA Scan</td>
<td>Full Review</td>
<td></td>
<td>Involves small amount of radiation exposure</td>
</tr>
<tr>
<td>EEG</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>EKG/ECG</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Electoretinopathy</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>EMG (electrodes only)</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>EMG (intramuscular)</td>
<td>Full Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exercise</td>
<td>Expedited</td>
<td>4</td>
<td>Unless the activity presents more than minimal risk because of the population, level of exertion, etc.</td>
</tr>
<tr>
<td>Flexibility testing</td>
<td>Expedited</td>
<td>4</td>
<td>Evaluated based on age, weight and health of study participant</td>
</tr>
<tr>
<td>fMRI</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Force plate</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Genetic testing</td>
<td>Full Review</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Memory testing</td>
<td>Varies - Could be exempt Category 2, Expedited Category 7, or full review depending on the information collected and risk level</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Mobile application (development/testing)</td>
<td>Varies - Could be exempt Category 2, Expedited Category 6 and/or 7, or full review depending on the information collected and risk level. Health related apps may also require review under FDA regulations.</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Motion tracking/analysis</td>
<td>Expedited</td>
<td>4 and/or 6</td>
<td></td>
</tr>
<tr>
<td>MRI</td>
<td>Expedited</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Observation of Subjects - Other than Public Behavior</td>
<td>Expedited</td>
<td>7</td>
<td>Only exempt if either no minors are involved or, if minors are present, the researcher will not participate in the activites being observed (otherwise Expedited Category 7)</td>
</tr>
</tbody>
</table>
## Research Interventions/Interactions A to Z

### Level of Review, Category, and Special Considerations

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Level of Review</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photographs</td>
<td>Varies - Could be exempt Category 2, Expedited Category 7, or full review depending on the information collected and risk level</td>
<td></td>
</tr>
<tr>
<td>Saliva collection</td>
<td>Expedited 3</td>
<td></td>
</tr>
<tr>
<td>Social/Behavioral intervention</td>
<td>Varies - Could be exempt Category 2, Expedited Categories 6 and/or 7, or full review depending on the intervention, risk level, and any use of deception</td>
<td></td>
</tr>
<tr>
<td>Strength Testing</td>
<td>Expedited 4</td>
<td></td>
</tr>
<tr>
<td>Sweat collection</td>
<td>Expedited 3</td>
<td></td>
</tr>
<tr>
<td>Tendon tapping</td>
<td>Expedited 4</td>
<td></td>
</tr>
<tr>
<td>Ultrasound</td>
<td>Expedited 4</td>
<td></td>
</tr>
<tr>
<td>Video Recording</td>
<td>Varies - Could be exempt Category 2, Expedited Categories 6 &amp; 7, or full review depending on the information collected and risk level</td>
<td></td>
</tr>
<tr>
<td>Vision testing/evaluation</td>
<td>Expedited 4</td>
<td></td>
</tr>
<tr>
<td>Vital signs (blood pressure, heart rate, respirations, etc.)</td>
<td>Expedited 4</td>
<td>Use of x-rays taken for research purposes requires full review</td>
</tr>
<tr>
<td>X-ray (any type)</td>
<td>Full Review</td>
<td>Use of x-rays taken for research purposes requires full review</td>
</tr>
</tbody>
</table>

*For interventions marked "Expedited" or "Exempt" - The ORC/IRB makes the final determination and may require more rigorous review depending on risk level of the research, vulnerability of study subjects, or other factors.

Looking for an intervention that is not listed? Have you checked the Decision Trees? If you still can't find what you need contact the ORC at orc@mu.edu.
Research involving Minors

In the State of Wisconsin, minors are considered those age 17 or under. The age of majority may vary by state and other factors may influence whether or not an individual is considered a minor.

Minors can be considered a “vulnerable population” and thus have special protections under human subject research regulations/Marquette IRB policies.

In general, participation of minors in a research study will require assent of the child (if age 6 or above) and permission from one or both parents. Templates for consent documents can be found on the ORC web site. Assent documents should be appropriate for the level of understanding of the subject population.

If you are conducting research involving minors, please review the types of research below to see how your project may be impacted:

**Observation of Public Behavior** – This type of research qualifies for Exempt Category 2 if the researcher does not participate in the activities being observed, otherwise Expedited Category 7 and parent permission is required unless justification for a waiver of parent permission can be made and is approved by the IRB.

**Survey, Focus Group, Interview, etc.** – Expedited Category 7 – parent permission required unless justification for a waiver of parent permission can be made and is approved by the IRB. Exempt Category 2 does not apply to minors for these types of research activities.

**Educational Research** – There is no regulatory restriction on participation of minors in educational research (Exempt Category 1), however, it is strongly recommended that parents and children be informed about the research project when appropriate.

For all categories of research, the Office of Research Compliance and/or the IRB make the final determination.