MWU Guidance: IRB Review

When IRB or Dual IRB Review is Required

MIDWESTERN UNIVERSITY

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When IRB or Dual IRB Review is Required

Overview

Midwestern University (MWU) requires that all activities meeting the United States Department of Health and Human Services (HHS) definition of “research” involving human subjects conducted by faculty, staff, residents, and/or students affiliated with the university, be reviewed and approved by the Institutional Review Board (IRB) prior to initiation, regardless of the source of funding and regardless of its federal status as an exempt, an expedited, or a full board review protocol. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB. Only MWU faculty members, on their own behalf or serving as an advisor for a student or resident, may serve as a principal investigator (PI) on a study involving human subjects.

Most Common Errors

Some of the most common errors that the Downers Grove and Glendale IRBs receive are avoidable if researchers remember the following:

<table>
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<th>Ways to Avoid Common Errors</th>
<th>Comments</th>
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<td>IRB approval must be obtained BEFORE soliciting subjects or collecting data.</td>
<td>Federal regulations DO NOT allow for any flexibility for the IRB to approve a completed research study. If a researcher does so, the IRB is REQUIRED by Federal regulations to deny it.</td>
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<td>The Principle Investigator (PI) MUST be an MWU faculty member</td>
<td>No students or residents are allowed to serve as the PI.</td>
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<td>Loss of confidential information IS A RISK and needs to be recognized as such.</td>
<td>Many IRB applications claim that there are no risks associated with the study. What is ignored by the PI is that there is always a risk of loss of confidential information and this needs to be explicit in the informed consent and the measures that will be taken to minimize the risk.</td>
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<td>Case reports do, UNDER CERTAIN CIRCUMSTANCES, require IRB review</td>
<td>There is an assumption by many PIs that a case report, particularly a retrospective case report, will not require IRB review. For a number of circumstances, a case report DOES REQUIRE IRB review before soliciting the first subject. Please see the Case Report/Case Study/Case Series section below.</td>
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Definitions

Federal law and the MWU IRBs define “research” as a “systematic investigation designed to develop or contribute to generalizable knowledge” [45 CFR 46.102(d)]. If the activity is research, it is considered to involve human subjects if it involves “obtaining information about living individuals” and “intervention or interaction with the individuals” [45 CFR 46.102(f)]. If the research does not involve intervention or interaction with the individuals, but provides information that is “individually identifiable” and “private” [45 CFR 46.102(f)(2)], it would also be considered “research involving human subjects” which may require IRB review. MWU’s IRB Committees recognize that interpretation of what activities require IRB review involves interpretation of these definitions, and the Chairs of these committees are available to help you determine whether IRB review is required.

Surveys for assessment data, marketing and accreditation

MWU has many surveys conducted to collect assessment data that is needed for marketing, accreditation purposes, or to ensure compliance with the Department of Education requirements. Such data is used in self-studies, internal reports, marketing studies, reports to accreditation agencies, or for the Fast Facts sections of the University website. Such surveys issued or completed by university personnel for the intent and purposes of improving University services/programs or for developing new services or programs for MWU students, employees, or alumni, may not meet the definition of human subject research as long as the privacy of the subject is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. However, if the survey is being conducted to produce generalizable knowledge or the survey data is used in the future for a new study producing generalizable knowledge, then IRB review may be required. If you have any question whether your activity requires IRB review, please contact MWU’s IRB Chair on your campus in advance of survey distribution to make that determination.

Case reports/case studies/case series

Many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case. The MWU IRBs offer the following guidance on cases:
Case Report/Case Study/Case Series Checklist

This guidance is intended to assist in determining whether a case report, case study, or case series may not require review by the MWU IRB. If all items below are satisfied, please check off all items, sign, and send to the appropriate IRB Coordinator for your campus:

- Ms. Barbara Le Breton on the Downers Grove, IL campus
  - Email: blebre@midwestern.edu; Phone: 630-515-6394; Fax: 630-515-6430
- Ms. Lindsay Goboly on the Glendale, AZ campus
  - Email: igobol@midwestern.edu; Phone: 623-572-3728

If you have any questions relating to this checklist, please contact the IRB chair for your campus before beginning your project. Please check off as many of the following as are accurate for your study:

[ ] The project is examining 3 patients or less;

[ ] The project is a case report, case study, case series, or multi chart review reporting patient condition, treatment, outcome, or presentation that draws conclusions only about that participant or group and only in that specific context;

[ ] The project does not involve the investigation of a United States Food and Drug Administration (FDA) regulated product;

[ ] The project does not involve confidential information, identifiers that could place a participant at risk if disclosed, or sensitive topics (e.g. surveys about sexually transmitted diseases, mental illness, risk taking behavior, developmental disorders, or disorders of childhood or adolescence);

[ ] The project does not involve persons from vulnerable populations (e.g. pregnant women, human fetuses, neonates, prisoners, homeless people, or children);

[ ] The project does not include data manipulation to include use of statistical methods such as subgroup comparison or compilation of observations in such a manner that might allow for generalization to a larger population;

[ ] The project does not involve experimental intervention or a case series that incorporates statistics;

[ ] The project does not offer incentives to participants (e.g., compensation, free treatments, or diagnostic work);

[ ] The project does not include any added interventions to enhance the case study (additional treatments beyond the standard of care, diagnostic work, etc.);

I ____________________________, a faculty PI or advisor at MWU, am fully aware of all

[Print MWU Faculty PI or Advisor Name Above]
aspects of this scholarly activity and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of these activities. To the best of my knowledge, I believe that all criteria checked and unchecked above are true.

____________________________________  ______________________
Signature of MWU Faculty Member  Date

Case Title: _____________________________________________________________

________________________________________________

Student(s)/Resident(s): __________________________________________________

Cases that meet ALL Criteria in the checklist

When a case report, case study, or case series meets **ALL** criteria in the preceding checklist, it does not meet the HHS definition of “research” and therefore, IRB review **IS NOT** required for this scholarly activity. When the MWU IRB Coordinator receives a properly checked, filled out, and signed Checklist for a qualifying project, the PI will be sent a letter that should meet the IRB requirements of any journal. The statement shall read:

“The Midwestern University IRB received your request (dated ‘X’), concerning a case report, case study, or case series that you wish to publish. The information that you provided informed us that:

- The project is examining 3 patients or less;
- The project is a case report, case study, case series, or multi chart review reporting patient condition, treatment, outcome, or presentation that draws conclusions only about that participant or group and only in that specific context;
- The project does **not** involve the investigation of a United States Food and Drug Administration (FDA) regulated product;
- The project does **not** involve confidential information, identifiers that could place a participant at risk if disclosed, or sensitive topics;
- The project does **not** involve persons from vulnerable populations;
- The project does **not** include data manipulation to include use of statistical methods such as subgroup comparison or compilation of observations in such a manner that might allow for generalization to a larger population;
- The project does **not** involve experimental intervention or a case series that incorporates statistics;
- The project does **not** offer incentives to participants; and
- The project does **not** include any added interventions to enhance the case study.
Since this scholarly activity meets all of the above criteria, it does not meet the HHS definition of research and therefore IRB review is not required for this activity.”

**Cases that do not meet all criteria in the checklist**

When a case report, case study, or case series **DOES NOT** meet all criteria in the preceding checklist, **it requires** IRB review. Please fill out Form A and submit it to the IRB Coordinator on your campus.

**When is Dual IRB Review not required**

An MWU IRB will not perform a dual review provided that another IRB is reviewing the project and all of the following conditions are met:

1. the research is conducted at an institution with an Office for Protection of Research Risks (OPRR) approved Multiple Project Assurance (MPA) or Federal Wide Assurance (FWA);
2. the primary appointment of the principal investigator (PI) is with the other institution;
3. MWU is not the primary recipient of funding; and
4. the research is conducted entirely at the other site

If any of these conditions are not met, the research proposal must be submitted to MWU’s IRB for review and approval, unless it meets all criteria in the case report/case study/case series checklist.