**Appendix II: Evaluation Guidelines**

Reviewers are expected to evaluate protocol adherence to these core requirements, commensurate with the category of anticipated risks of potential harm in the proposed research. This document provides a compendium of recommended evaluation criteria for each core requirement, mapped to risk category

**Definitions**

**Risk Category:** A risk is a potential harm associated with the research that a reasonable person would likely consider injurious or uncomfortable. Under the federal regulations, research is categorized as either “greater than minimal risk” or minimal risk.”

**Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[[1]](#footnote-1)

**Greater than Minimal Risk:** The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests.

**Human Subject:** A living individual about whom an investigator conducting research obtains

Data through intervention or interaction with the individual (Intervention and interaction are subsequently defined, as well); or

Identifiable private information.[[2]](#footnote-2)

**Subject Engagement:** Data are acquired through intervention or interaction with the human subject.

**No Subject Engagement:** Identifiable private information is acquired without intervention or interaction with the human subject.

**Requirements**

1. **Scientific Merit**
2. Background supports the proposed study

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | * Justification for research cites existing literature |
| Minimal Risk with Subject Engagement | As above |
| Greater than Minimal Risk Studies with Subject Engagement | As above plus:   * Primary data from the literature or preliminary findings from the investigator’s own research are presented, in detail, and justify the proposal |

**Additional Considerations**

None identified

**Tools and References**

None identified

1. The protocol provides well-framed, testable hypotheses and / or well-framed study aims

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | Clear, unambiguous description of primary and (if any) secondary aims and/or hypotheses |
| Minimal Risk with Subject Engagement | As above |
| Greater than Minimal Risk Studies  with Subject Engagement | As above |

**Additional Considerations**

If relationships are proposed, the related concepts and the nature of the relationship is explicitly identified (e.g. predictive, causal).

**Tools and References**

None identified

1. Study design and strategies are adequate to test the hypothesis and / or to achieve study aims

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | * Sample characteristics (e.g. inclusion and exclusion criteria) are identified and appropriate to study aims * All concepts of interest (variables/domains of inquiry) have been defined, as appropriate for quantitative / qualitative approach * Plan for obtaining information on these variables/domains of inquiry is feasible (data are available from the proposed sources) |
| Minimal Risk with Subject Engagement | As above plus:   * Sample characteristics are justified: * inclusion/exclusion of vulnerable populations or healthy volunteers * Inclusion/exclusion based on demographic characteristics (e.g. age, race, gender) * Sample size is adequate to achieve study aims * Study procedures / tests / measures appear adequate to capture data on concepts of interest * Plan for recruitment, retention and follow up with subject is feasible\* |

**Continued**

1. Study design and strategies are adequate to test the hypothesis and / or to achieve study aims (**continued**)

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| --- | --- |
| Risk Category | Criteria |
| Greater than Minimal Risk Studies  with Subject Engagement | As above plus:   * Study protocol containing details as specified in pp. 29-31 of RSRB investigator guidance is accurate and adequate to achieve study aims * Barriers to completion are anticipated and presented in the protocol * Reasonable strategies to overcome anticipated barriers are incorporated in the protocol * Proposed interventions are consistent with standard care or are reasonable alternatives * For clinical trials, strategies to reduce bias are appropriate (e.g. randomization strategy, “blinding”) * Methods to acquire data are reliable and valid * Protocol is supplemented with detailed operations manual and/or site-specific management plan, when appropriate * Plan for continuing supervision of study activities is available (e.g. regularly scheduled team meetings, study coordinator, site visits for multi-site or sponsored research) and appears adequate for the complexity of the study |

**Additional Considerations**

* Are clinical services present to address anticipated complications?
* Feasible includes reasonable timeframe

**Tools and References**

* <http://www.rochester.edu/rsrb/documents/pdf/invguidance.pdf> (pp 29-31)
* <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf>
* <http://www.rochester.edu/rsrb/documents/pdf/PlaceboControlled.pdf>

1. The analysis plan and methods are adequate to test the hypothesis and / or achieve study aims

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | General description of proposed analytic strategy is appropriate to study aims |
| Minimal Risk with Subject Engagement | As above plus:   * For quantitative studies, power calculations have informed sample size * Specific analytic strategies proposed are appropriate for the nature of the data (e.g. level of measurement, interview transcript) |
| Greater than Minimal Risk Studies with Subject Engagement | As above plus:   * Statistician input on analytic plan has been obtained for complex analyses (e.g. stopping rules for safety in clinical trials) |

**Additional Considerations**

The reviewer is encouraged to consider the benefit of asking for additional review by a statistician.

**Tools and References**

None identified

1. The proposed research may provide societal benefits

|  |  |
| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | NA |
| Minimal Risk with Subject Engagement | * Research fills knowledge gap in discipline |
| Greater than Minimal Risk Studies with Subject Engagement | As above plus:   * Research has potential to make direct or indirect contribution to solution of a societal problem |

**Additional Considerations**

Investigator’s plan for dissemination of results

**Tools and References**

“On Being a Scientist” (<http://www.nap.edu/openbook.php?record_id=4917>)

1. **Risk Identification and Management**
2. Foreseeable risks to research participants have been identified and described

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | * All foreseeable risks from study procedures have been identified and described in the protocol. (including information to support probability of occurrence and degree of severity) |
| Minimal Risk with Subject Engagement | As above |
| Greater than Minimal Risk Studies with Subject Engagement | As above |

**Additional Considerations**

* Review the package insert and/or the investigator brochure when a drug, device or biologic is the research focus.
* Assess the necessity of proposed tests / measures (i.e. study procedures).
* Note: study procedures include all activities of the study. For example, a plan to mail blood samples to an outside lab for testing, with the subject’s name on the label, would constitute a foreseeable risk to patient privacy. Study procedures might also include subject recruitment activities, e.g. studies seeking to recruit victims of intimate partner violence.
* Subject privacy and confidentiality risks, including data management and security, are adequately identified.
* Possible negative community impact has been identified.

**Tools and References**

None identified

1. Reasonable means to mitigate risks have been employed;

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | * The plan for risk mitigation is commensurate with the level of risk and feasible      * Confidential data management (risk) is applicable to all levels |
| Minimal Risk with Subject Engagement | As above plus:   * Means to minimize risk are consistent with those employed in clinical practice (e.g. sterile technique for blood draw, metal screening for MRI) * Investigator has access to medical or psychological resources that participants might require as a consequence of the research * Sample inclusion/exclusion criteria are appropriate to protect persons at greater risk of harm from study procedures than the target population from which they are being enrolled |
| Greater than Minimal Risk Studies with Subject Engagement | As above plus:   * Planned study activities/treatments are commensurate with standard clinical care or represent a reasonable experimental alternative, or * For research with no expected direct benefit to the subject, reasonable strategies (e.g. appropriate animal studies, least injurious agents) to mitigate known risk have been employed |

**Additional Considerations**

When applicable, reviewer agrees that the plan is also consistent with University / Department policies and procedures.

**Tools and References**

<http://intranet.urmc-sh.rochester.edu/policy/hipaa/Security/S8.pdf>

1. Data and safety monitoring procedures are appropriate to the design, specific risks and risk level of the study, and are adequate to safeguard the rights and welfare of study subjects

|  |  |
| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | * The procedures for maintaining data confidentiality are feasible and consistent with university policy |
| Minimal Risk with Subject Engagement | As above plus:   * Data safety and monitoring procedures address specific foreseeable risks of the study and are adequate to mitigate them |
| Greater than Minimal Risk Studies with Subject Engagement | As above |

**Additional Considerations**

None identified

**Tools and References**

Investigator guidance

* 1. **Investigator Qualifications / Resources**

Note: The phrase “reviewer agrees” implies that a prior assessment has been done (by department or others) and the reviewer is agreeing with that assessment.

1. The investigative team has the necessary skills and experience to bring the research project to a successful conclusion

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | * Reviewer agrees that the data management skills are appropriate for the specifics of the project. |
| Minimal Risk with Subject Engagement | As above plus:  Qualifications of the team include:   * Analytic/statistical skills required for study * Experience with or adequate training in (minimal risk) study procedures required for the study (e.g. physical assessment skills, focus group leadership skills, blood draws) |
| Greater than Minimal Risk Studies with Subject Engagement | As above plus:   * Training/qualification to perform GTMR procedures for research purposes * Demonstrated prior success with managing a research study * Ability to monitor for and recognize adverse/unexpected events in study |

**Additional Considerations**

* Resource availability is complementary to the scientific review and essential, and also must precede the IRB review.
* Data collection skills appropriate for the specifics of the study (e.g. ability to abstract data by reading x-rays, interpreting lab values)
* Consider reviewing CV, Biosketch or other relevant evidence of qualifications (e.g. departmental attestation).

**Tools and References**

Department attestation that the faculty member(s) are qualified to perform the research, created prior to the scientific review

1. The Investigator has time and resources to conduct the research, including study treatments

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | Reviewer agrees that:   * The research team has access to sources of data * Necessary resources are identified. |
| Minimal Risk with Subject Engagement | As above plus   * Resources, including human subjects, will be available and support the overall feasibility for this study |
| Greater than Minimal Risk Studies with Subject Engagement | As above plus   * Protocol provides information about successful experience with recruitment and (where applicable ) retention and follow-up of subjects in similar studies |

**Additional Considerations**

* For a proposed student project, a plan for consultation with a mentor(s) is present and reasonable.
* Investigator’s other duties are compatible with the engagement needed for successful conduct of this study.
* Assess whether successful experience with recruitment, retention and follow-up of subjects was local and with the same study team, particularly in high-risk studies.

**Tools and References**

None identified

1. The Investigator has a process to ensure adequate training and supervision of the study team

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| --- | --- |
| Risk Category | Criteria |
| Minimal Risk - No Subject Engagement | * Reviewer agrees that the details of the process are contained in the protocol and are feasible and appropriate |
| Minimal Risk with Subject Engagement | As above |
| Greater than Minimal Risk Studies with Subject Engagement | As above |

**Additional Considerations**

* Scientific reviewer concurs with departmental determinations.
* All persons assisting with the research are adequately informed about the protocol and are adequately performing their research-related duties and functions throughout the life cycle of the study.

**Tools and References**

None identified

1. <http://www.rochester.edu/rsrb/documents/pdf/invguidance.pdf> [↑](#footnote-ref-1)
2. <http://ohsr.od.nih.gov/guidelines/45cfr46.html#46.102> [↑](#footnote-ref-2)