GUIDELINE FOR SCIENTIFIC AND RESOURCE REVIEW OF HUMAN SUBJECT RESEARCH

According to Policy 505 Departmental Scientific and Resource Review, department scientific and resource review is expected to occur and documentation provided to the RSRB prior to review of the protocol. The following elements must be evaluated and documented:

1) Scientific Merit,
2) Risk Identification and Management, and
3) Investigator Qualifications and Resources.

This review should be commensurate with the level of risk and potential harm to subjects in the proposed research. This guideline provides the recommended evaluation considerations associated with each element. The Scientific and Resource Review Checklist template may be used to ensure adequate assessment and documentation of all core elements in the scientific and resource review.

Definitions

Minimal Risk (MR) – The probability and magnitude of harm or discomfort anticipated in the research are **not greater**, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Greater Than Minimal Risk (GTMR) – 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.

Elements for Evaluation

1) Scientific Merit

A. Background supports the proposed study

Risk Level	Considerations
Minimal Risk	✓ Justification for research cites existing literature
Greater than Minimal Risk	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

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

Risk Level	Considerations
Minimal Risk	✓ Clear, unambiguous description of primary and (if any) secondary aims and/or hypotheses
Greater than Minimal Risk	As above

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

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

Risk Category	Considerations
Minimal Risk	✓ Sample characteristics (e.g. inclusion and exclusion considerations) 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) ✓ 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*
Greater than Minimal Risk	As above plus: ✓ Study protocol containing details as specified in the RSRB Protocol Template is accurate and adequate to achieve study aims ✓ 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

* Feasible includes reasonable timeframe

Additional Considerations

- Are clinical services available to address anticipated complications?

Tools and References

- RSRB Protocol Templates
- OHSP Policy 605 Research Involving FDA Regulated Drugs, Biologics and Supplements
- OHSP Policy 606 Research Involving FDA Regulated Devices
- Guideline for the Use of Placebo in Clinical Research

D. The statistical analysis plan is adequate to test the hypothesis and / or achieve study aims

Risk Category	Considerations
Minimal Risk	✓ General description of proposed analytic strategy is appropriate to study aims ✓ 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	As above plus: ✓ Analytic plan is included 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.

E. The proposed research may provide societal benefits

Risk Category	Considerations
Minimal Risk	✓ Research fills knowledge gap in discipline
Greater than Minimal Risk	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)

2) Risk Identification and Management

A. Foreseeable risks to research subjects are identified and described

Risk Category	Considerations
Minimal Risk	✓ 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)
Greater than Minimal Risk	As above

Additional Considerations
- When a **drug, device or biologic** is the research focus, review additional related materials included with the application (e.g., package insert, investigator brochure).
- Assess the necessity of proposed tests / measures (i.e., study procedures). *In order to accomplish the research aims, consider whether it is necessary to expose the subject to any risk associated with that test/measure/study procedure.*

- 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 is a study activity and would constitute a foreseeable risk to patient privacy. Study procedures also include subject recruitment activities and these too can carry risk, 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. That is, beyond the direct risk to subjects participating in the research, consider whether this study carries a likelihood of harming individuals or groups in the community, reducing community trust, or other negative impacts to our community.

B. Reasonable means to mitigate risks are described;

Risk Category	Considerations
Minimal Risk	✓ The plan for risk mitigation is commensurate with the level of risk and feasible ✓ Confidential data management (risk) is applicable to all levels ✓ 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 considerations 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	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

- URMC Policy 0S8 Use of Systems and Media Containing ePHI

C. 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	Considerations
Minimal Risk	✓ The procedures for maintaining data confidentiality are feasible and consistent with university policy ✓ Data safety and monitoring procedures address specific foreseeable risks of the study and are adequate to mitigate them
Greater than Minimal Risk	✓ A data and safety monitoring plan is included in the protocol or provided as a separate document, and is appropriate to the specific risks of the proposed study.

Tools and References

- OHSP Policy 506 Data & Safety Monitoring

3) ***Investigator Qualifications and Resources***

The Investigator confirms, upon submission of the protocol/application in the IRB Review System, he or she has adequate qualifications and resources to implement the study and to oversee the study team. The Scientific Reviewer for the Department may request to review a copy of the Investigator's or study team member's CV, Biosketch or other relevant evidence of qualifications. Alternatively, the reviewer may contact the Investigator directly to request additional information if there are any questions about Investigator qualifications and resources.

A. Investigator and study team member's credentials are adequate for this type of research and the study team has adequate time to conduct the study

Risk Category	Considerations
Minimal Risk	✓ The data management skills are appropriate for the specifics of the project. Qualifications of the team include: ✓ Analytic/statistical skills required for study ✓ Experience with or adequate training in the study procedures required for the study (e.g. physical assessment skills, focus group leadership skills, blood draws)
Greater than Minimal Risk	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

- Data collection skills appropriate for the specifics of the study (e.g., ability to abstract data by reading x-rays, interpreting lab values).

Tools and References

- QI Study Start Up Consultation
- Research Education Opportunities

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

Risk Category	Considerations
Minimal Risk	Reviewer agrees that: ✓ The research team has access to sources of data ✓ Necessary resources are identified ✓ Resources, including human subjects, will be available and support the overall feasibility for this study
Greater than Minimal Risk	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, consider whether a plan for consultation with a mentor(s) is necessary.
- 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

- OHSP Policy 901 Investigator Responsibilities
- Exempt Responsibility Summary Sheet
- Non-FDA Regulated Responsibility Summary Sheet
- FDA Regulated Responsibility Summary Sheet