LEVELS OF IRB REVIEW

Exempt Research (1-2 weeks to process)

The Exempt review process is much less rigorous than full IRB review. Although the category is called "Exempt," this type of research does require IRB approval. To qualify for an Exempt review, research must be “less than minimal risk” to the study participants. Research must fall into at least one of six (6) federally-defined Exempt categories. These categories present the lowest amount of risk to potential subjects because, generally speaking, they involve either collection of anonymous or publicly-available data, or conduct of the least potentially-harmful research experiments. **PER GONZAGA POLICY, ONLY THE IRB CAN MAKE AN EXEMPT DETERMINATION.**

Examples:
- Anonymous surveys or interviews
- Passive observation of public behavior without collection of identifiers
- Retrospective chart reviews with no recording of identifiers
- Analyses of discarded pathological specimens without identifiers

Non-Exempt, Expedited Research (2-3 weeks to process)

To qualify for an expedited review, research must be “no more than minimal risk” and fall into at least one of nine (9) federally-defined expedited categories. These categories involve collection of samples and data in a manner that is not anonymous and that involves no more than minimal risk to subjects. For additional information see OHRPP Expedited Guidance.

Examples:
- Surveys and interviews with collection of identifiers
- Collection of biological specimens (e.g., hair, saliva) for research by noninvasive means
- Collection of blood samples from healthy volunteers
- Studies of existing pathological specimens with identifiers

Full Board Review (4-5 weeks to process)

Use the Non-Exempt, Expedited form for a Full Board review. This will involve research that involves “greater than minimal risk” and pediatric research. The IRB can use this method at its discretion for any protocol. The majority of biomedical protocols submitted to the IRB require full IRB review. For additional information see OHRPP Full Board Guidance.

Examples:
- Clinical investigations of drugs and devices
- Studies involving invasive medical procedures or diagnostics
- Longitudinal interviews about illegal behavior or drug abuse
- Treatment interventions for suicidal ideation and behavior

Regulations and References

- DHHS 45 CFR 46.110
- DHHS 45 CFR 46.111(a)(1-2)
- OHRP IRB Guidebook, Chapter 3: Basic IRB Review, Section A, Risk/Benefit Analysis
- FDA 21 CFR 56.110
- FDA 21 CFR 56.111(a)(1-2)