UNDERSTANDING IRB REVIEW PROCESSES

This handout provides a side-by-side comparison of the different types of IRB review processes under the Common Rule (45 CFR 46). It is intended to help Councils and sub-recipients recognize what each pathway looks like, how long it typically takes, and who is involved in the review. While this tool is designed to support decision-making, it should not replace consultation with an IRB or institutional compliance office when questions arise.

DIMENSION	HUMAN SUBJECTS DETERMINATION	EXPEDITED REVIEW	FULL IRB REVIEW
Definition	Assessment of whether an activity meets the definitions of research and human subject in 45 CFR 46.102.	Review pathway for **minimal risk** projects that fall into categories listed in 45 CFR 46.110.	Required for greater than minimal risk projects or those involving vulnerable populations under 45 CFR 46.111.
What It Looks Like	• Short form (1–2 pages). • Investigator describes purpose, population, and data. • Results in a “Not Human Subjects Research” letter if exempt.	• Standard IRB application with protocol, data tools, and consent forms if applicable.	• Comprehensive application package with protocol narrative, recruitment, detailed consent, risk/benefit analysis.
Who Reviews	Compliance office or IRB staff (administrative review).	IRB chair or designated reviewer.	Full IRB committee at a scheduled meeting.
Typical Timeline	A few days to 1 week.	~2–4 weeks.	1–3 months.

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