WVU Flex Protocol Type

WVU Flex is an expeditious protocol review type. Although the federal regulations do not apply to research eligible for Flex, the research must operate within the bounds of the ethical guidelines of the Belmont Report and comply with institutional policy. If a protocol originally approved as Flex receives federal funding, incurs a change in risk, or research procedures significantly change (e.g., a retrospective review adding a prospective component, adding a vulnerable population, etc.), it is the responsibility of the Principal Investigator (PI) to notify WVU OHRP and/or create a new protocol submission.

Eligible for Flex	
✓	Non-federally funded research
✓	No more than minimal risk
✓	Research involving tissues and samples collected under standard of care procedures
✓	Otherwise permitted under Expedited Categories 2 and 3 (45 CFR 46.110)
✓	Otherwise permitted under Exempt Category 4 (45 CFR 46.101(b)(4) or Expedited Category 5 (45 CFR 46.110)
✓	Minors • Must obtain permission from a guardian and agreement to participate from the minor. • Surveys- Include a permission question for the guardian and a permission question for the minor. • In-person Activities– Verbal permission from the guardian and the minor is sufficient.
✓	Pregnant Women, Neonates, and Fetuses – Flex eligibility is risk-based (see definition below).
✓	Deception – Must have a de-briefing plan and an option to opt-out.

Only Minimal Risk - The regulations state that "minimal risk means that 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. (45 CFR 46.102(i))

Not Eligible for Flex	
✗	Federally funded research
✗	Research supported/funded by WV CTSI, WV-INBRE, or CoBRE
✗	Research with FDA regulated elements: • Otherwise permitted under Expedited Category 1 (45 CFR 46.110). For example, drugs and devices used according to approved labeling. • Investigational New Drug (IND) or Investigational Device Exemption (IDE).
✗	Research involving sensitive topics: Suicide/suicide ideation; Sexual behavior or practices; Illegal activities or ethically questionable behaviors; Racism, ageism, classism, discrimination, and sexism; Involving experiences of grief and loss, trauma, or violence; Job performance or competency; Mental Health/Alcohol and Drug Treatment; Criminal history or past arrests
✗	Research with an NIH Certificate of Confidentiality
✗	Researching involving international research sites
✗	Research involving the following target populations: • Prisoners, Tribal Members, Military Personnel, Wards of the State, Cognitively Impaired, **some** research involving Pregnant Women, fetuses, and neonates (based on risk)
✗	Some research involving minors
✗	Research involving genetic testing
✗	Research requiring a reliance agreement
✗	International research
✗	Clinical trials