FLEXibility

Limiting the scope of the FWA to federally funded research allows for an appropriate level of flexibility without compromising protections.

Flexible policies and procedures provide protections equivalent to those found in the common rule, while also reducing administrative workload and regulatory excess.

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Order of Oversight Questions

Initial	Revised
Research?	Research?
Human Subjects?	Human Subjects?
Exempt?	Engaged?
Engaged?	Flex?
Flex?	Exempt?
Expedited?	Expedited?
Full Board.	Full Board.

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FLEX Inclusion Criteria

Eligible studies must be determined to pose no more than minimal risk to subjects.

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FLEX Exclusion Criteria

1. Federal funding
2. FDA-regulated components
3. Certificate of confidentiality
4. Prisoners or parolees as subjects
5. Contractual obligations that invoke the Common Rule
6. Federally classified research
7. Clinical interventions
8. Requirement to register with clinicaltrials.gov

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Change in Eligibility for FLEX

PI is responsible for submitting project revisions in advance of initiating any changes related eligibility

HRPP will send an annual reminder of the criteria to researchers

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Flexibility can be applied to anything.

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Level	Risk	Categories
FLEX	Minimal	None
Exempt	Minimal	1 - 6
Expedited	Minimal	1 - 9
Full Board	Greater than Minimal	None

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Review Levels	Primary Reviewer
FLEX	Voting member of the IRB
Exempt	Chair or non-voting designee
Expedited	Voting member of the IRB
Full Board	Voting member of the IRB

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Period of Approval

5-year non-renewable FLEX approvals
New application to extend beyond that date

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Project Revisions

No review required when revisions are limited to:

Minor edits to survey/interview questions
Changes to personnel who meet certain criteria
Changes to recruitment materials

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Waivers: Consent & Documentation

Consent: Waive if research involves no more than minimal risk to the subjects; and the waiver or alteration will not adversely affect the rights and welfare of the subjects

Documentation: No IRB-related requirement for the researcher to obtain signed consent forms from participants. Other laws or regulations may require signature.

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Waivers: Parental Permission

Subpart D §46.408(c) will not be applied to studies meeting all of the criteria for **FLEX**.

Notification with reasonable opt-out is expected.

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Subpart B Modification

Subpart B will not be applied to studies meeting all of the criteria for **FLEX**.

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.111 Criteria

Majority of .111 criteria apply with a couple of exceptions…

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.111 Criteria

MODIFIED: Informed consent will be sought from each prospective subject or the subject's legally authorized representative~~, in accordance with, and to the extent required by §46.116~~.

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.111 Criteria

ELIMINATED: ~~Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.~~

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Acknowledgements

OSU FLEX policies and procedures exist because of the generosity demonstrated by other HRPP professionals.

These policies are built on ideas freely shared between institutions and enthusiastically promoted by Susan Rose and the Flexibility Coalition.

The success of these initiatives is a result of the continued willingness, creativity, and expertise of the OSU HRPP Staff.

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