"Is My Project Research?" Flowchart

START: Investigator with idea

Is it research?

yes

Does it involve human participants?

yes

Use flowchart to determine if IRB review is required

1. Will participation involve more than minimal risk?
"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 performance of routine physical or psychological examinations or texts. Such risks include not only risk of physical harm, but also the possibility of mental harm or discomfort, or damage to an individual's reputation, legal or financial standing, employability, or personal or business relationships.

yes → **Submit Application Cover Page, Non-Exempt Research Checklist** and **Project Details to IRB for Review**

no

2. Can and do participants give free and informed consent?
"Informed consent" means that participants have been provided sufficient information about the research and the consequences of their participation to be able to decide, free of coercion, whether they are willing to participate. At a minimum, participants need to know that this is a research activity; need to know what the project's objectives, procedures, potential risks (including protection of confidential material), and benefits are; and must understand that they are free to withdraw at any time without prejudice to their legitimate interests. Special attention must be given if participants are individuals with limited capacity to consent. Minors, for instance, cannot give informed consent.

no → **Submit Application Cover Page, Non-Exempt Research Checklist** and **Project Details to IRB for Review**

yes

3. Could release of data be potentially harmful to participants?
If identifiable date were inadvertently released or subpoenaed, or if participants' identities could be deduced, would this place them at legal or financial risk, or be damaging to their reputation, employability, or personal or business relationships?

yes → **Submit Application Cover Page, Non-Exempt Research Checklist** and **Project Details to IRB for Review**

no

4. Does research involve deception likely to be significant to participants?
If a participant knew – before agreeing to be in the study – all the details of what participation would entail, would this affect his or her decision about whether to participate?

yes → **Submit Application Cover Page, Non-Exempt Research Checklist** and **Project Details to IRB for Review**

no

5. Does research recruitment or participation involve coercion or undue influence or deprivation of accustomed or necessary resources?

yes → **Submit Application Cover Page, Non-Exempt Checklist** and **Project Details to IRB for Review**

no ↓

6. Does research involve hypnosis or an unusual degree of mental stress?

yes → **Submit Application Cover Page, Non-Exempt Checklist** and **Project Details to IRB for Review**

no ↓

7. Does investigator provide professional services for participants?
Professional services may include services that the researcher provides to the participant in a contractual, educational, advisory, or therapeutic sense. Such relationships include employer/employee, teacher/student, physician/patient, lawyer/client, etc.

yes → **Consult with IRB. In case of teacher/student relationship, consult federal guidelines**

no ↓

8. Does research involve illegal activities, or activities that are likely to offend prevailing standards of morality?

yes → **Submit Application Cover Page, Non-Exempt Checklist** and **Project Details to IRB for Review**

no ↓

Research is most likely exempt from IRB requirements. Confirm by filling out Application Cover Page, Exempt Checklist and Project Details page and submit to IRB