How Do You Identify Your Project As Human Subject Research?

Review these questions and check any of these boxes to clarify. If more than one is checked, your project may require IRB review

Is it Research?	Are Human Subjects Involved?
☐ A systematic investigation (the gathering and analysis of information) designed to develop or contribute to generalizable knowledge	A living individual about whom an investigator (whether professional or student) conducting research obtains: data through intervention or interaction with the individual, or identifiable private information.
☐ Are the project activities systematic? Do they gather and analyze of information following a specific research design?	☐ Are the data being collected about living Individuals?
☐ What is the Intent? Does the project be conducted as proposed if you knew that you would never receive any form of professional recognition	☐ Do the project activities involve intervention or interaction?
for the project, including publication of results or presentation at a professional meeting?	☐ Is the information individually identifiable?
☐ Does this project contribute to generalizable knowledge? Are the data generalizable within the Institution? Outside the institution? Presented in publication or presentations?	☐ Is the information private? (can the individual reasonably expect that no observation or recording is taking place, or information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public).
	☐ Can the PI or research team "readily ascertain" the subject's Identity?
	☐ Is a specific population involved (such as persons under 18 years, decisionally impaired, non-English speaking, institutionalized individuals, substance abusers)?

If you check yes to any of the above, the following IRB review process applies:

Exempt Review if -

- the project is of low or less than minimal risk
- the project fits into one or more of the exempt categories
- the project involves anonymous surveys if information recorded where participants cannot be identified

Expedited Review if -

- the project is of minimal risk (beyond what a person would normally be encounter in everyday life)
- the project fits into one or more of the expedited categories
- the project involves potential vulnerable populations and address procedures for consent, protecting identities, safeguards from harm

Full Board Review if -

- the project is more than minimal risk
- the project does not fit into one or more of the expedited categories
- the project involves potential vulnerable populations and address procedures for consent, protecting identities, safeguards from harm and may deal with sensitive topics, such sexual orientation, illegal/underage drugs and alcohol use, suicide.

Select either Classroom Projects or Students as Researchers for additional information

Contact the OPRC at 410-455-2737 or compliance@umbc.edu with any questions

Adapted from a presentation from Patricia MacCubbin, MS, Executive Director, Office of Research Conduct, CUNY and Ada Sue Selwitz, MA, Director, Office of Research Integrity, University of Kentucky, September 11, 2009

www.cityuniversity of newyork.org/research/human-subjects research/...Research.../C3Selwitz and MacCubbin.pdf