

Checklist for Determining Whether a Project Involves Human Subjects Research

Please note that this application does not replace the submission of an application to determine if the research is exempt from human subjects research regulations. Federal and local UAE regulations do not provide investigators with the authority to make an independent determination that an activity meets one or more of the categories of exempt human subjects research. Investigators who intend to conduct activities that might involve human subjects research must submit a formal application to the NYUAD Institutional Review Board (IRB) for approval before the research can begin. Guidance on this issue is available in the NYUAD policies and procedures.

I. Research Title:

II. Personnel

A. Principal Investigator or Faculty Sponsor

Name (Last, First)	Degree(s)	University Status/Title
Department		College
Phone Number		E-mail Address

B. Student Investigator(s) Required for student-initiated projects

Please include Full Name, Email Address, Phone Number and NYUAD NET ID

III. Activities Determined by the NYUAD IRB Not to Represent Human Subjects Research

Indicate whether any of the below describe the activities associated with your project.

Your project is limited to accessing one or more of the following public use datasets: Inter-University Consortium for Political and Social Research (ICPSR), U.S Bureau of the Census, National Center for Health Statistics, National Center for Educational Statistics, U.S. Bureau of Labor Statistics, National Election Studies, National Crime Victimization Survey: School Crime Supplement, 2003, National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), National Survey of America's Families (NSAF), National Sample Survey of Registered Nurses (NSSRN), Federal Election Commission Website, and PRAMS.

Your project is limited to course-related activities designed specifically for educational or teaching purposes; where data is collected from and about human subjects as part of a class exercise or assignment and is not intended for use outside of the classroom.

Your activity is a case report involving the observation of a single patient whose novel condition or response to treatment was guided by the care provider's judgment regarding the best interest of the individual.

Your project involves research that is limited to death records, autopsy materials, or cadaver specimens (provided that the cadaveric tissues/cells are not used for clinical investigations).

*If you checked any of the above boxes – **STOP**. Your activity is in a category that the IRB has determined **not** to represent human subjects research. The requirement for submission to the IRB of an application for human subjects research has been waived. You can skip to page 3, Section V, sign and retain this form in your files to document this determination. The IRB strongly recommends that investigators (faculty) document this determination by placing a copy of this completed application in your files to address any future queries about the project.*

If your data set is not listed above, complete the remainder of this application or contact the IRB to determine if you must complete an application for IRB review.

IV. Criteria for Research Involving Human Subjects

A. Does the activity meet the definition of research?

Answer yes or no to the following:

B. The activity employs a systematic approach involving predetermined methods for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing a theory.

Yes No

- The activity is intended to contribute to generalized knowledge by extending the results beyond a single individual or an internal unit (e.g., publications or presentations).

Yes No

B. Does the activity involve human subjects according to the definition?

Answer yes or no to the following:

- The investigator obtains specimens or data through intervention or interaction with a living individual (e.g., interviews, surveys, physical procedures, manipulations of the subject's environment, private or limited access internet sites, or any other direct contact or communication with a subject).

Yes No

- The investigator is obtaining identifiable private information about living individuals (e.g. chart reviews, lab studies on tissues or specimens, information from data or tissue repository).

Yes No

- The data or specimens are received by or provided to the investigator with identifiable private information.

Yes No

- The data or specimens are coded and the investigator has access to a link that would allow the data or samples to be identified.

Yes No

Note: If you answered “yes” to both questions in Section IV.A **AND** “yes” to at least one question in Section IV.B. **STOP**. Your activity meets the definition of human subjects research, and either exempt, expedited, or convened review is required.

For all projects that do NOT meet the definition of human subjects research, obtain appropriate signatures in Section V below and retain for your files.

V. SIGNATURES

Signature of PI/Faculty Sponsor: _____ **Date** _____

Signature of Student: _____ **Date** _____

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