جامعة نيويورك أبوظبي

NYU | ABU DHABI

IRB Revised Exemption Categories

Cat.	Exemption Category Description	Conditions/Allowances/ Limitations	Review Process
1	***Research in established or commonly accepted education settings that involves normal educational practices***	• Not likely to adversely Impact Students' opportunity to learn or assessment of educators	IRB member (usually staff) will review protocol only in so far as to make the determination. Investigators required to complete the CITI course for exempt research
2	***Research only includes educational tests, surveys, interviews, public observation if at least ONE of the following criteria is met***: a. Recorded information cannot readily identify the subject (directly or indirectly/linked) b. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, education advancement, reputation) c. Identifiable info is recorded and there is risk of harm if results are disclosed but the IRB conducts a limited review.	• Surveys & Interview: No Children • Educational Tests or observation of Public Behavior: Can only include children when investigators do not participate in activities being observed	If **a.** or **b.**: IRB member (usually staff) will review protocol only in so far as to make the determination. Investigators required to complete the CITI course for exempt research If **c.**: IRB member (usually staff) will conduct a limited review to ensure that informed consent, privacy and confidentiality safeguards are in place. Investigators required to complete the CITI course for exempt research

3	***Research involved Benign Behavioral Interventions (BBI) through verbal, written responses (including data entry or audiovisual recording) from adult subjects who prospectively agree and one of the following are met:*** a. Recorded information cannot readily identify the subject (directly or indirectly/linked) b. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, education advancement, reputation) c. Identifiable info is recorded and there is risk of harm if results are disclosed but the IRB conducts a limited review.	● No Children; ● May not include medical interventions; ● Subject prospectively agrees Must be: ● Brief in duration ● Painless/harmless ● Not physically invasive ● Not Likely to have a significant adverse last impact on subjects ● Unlikely that subjects will find interventions offensive or embarrassing ● Without deception, unless participant prospectively agrees (i.e. informed consent language references incomplete disclosure)	If **a.** or **b.**: IRB member (usually staff) will review protocol only in so far as to make the determination. Investigators required to complete the CITI course for exempt research If **c.**: IRB member (usually staff) will conduct a limited review to ensure that informed consent, privacy and confidentiality safeguards are in place. Investigators required to complete the CITI course for exempt research

4	***Secondary research for which consent is not required: Use of Identifiable Information or Identifiable Biospecimen that have been or will be collected for some other 'primary' or 'initial' activity, if ONE of the following criteria is met:*** a. Biospecimens or Information is publically available b. Information record so subject cannot readily be identified (directly or indirectly/linked); investigator does not contact subjects and will not re-identify the subjects c. Collection and analysis involving use of identifiable health information when use is regulated by HIPAA "health care operations: or "research" or "public health activities and purposes" d. Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities.	• No Primary collection from subjects for the research. • Both retrospective and prospective secondary use • For (a): must be publically available • For (c): HIPAA still applies	IRB member (usually staff) will review protocol only in so far as to make the determination. Investigators required to complete the CITI course for exempt research
5	***Research and demonstration projects supported by a Federal Agency/Dept. AND Designed to study, public benefit or service programs.***	• Must be posted on a Federal website	IRB member (usually staff) will review protocol only in so far as to make the determination. Investigators required to complete the CITI course for exempt research

6	***Taste and Food Quality***		IRB member (usually staff) will review protocol only in so far as to make the determination. Investigators required to complete the CITI course for exempt research
Categories 7 and 8 will not be applied at NYUAD			
7	***(Creating a repository, biobank, archive) Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for secondary research <u>for which broad consent is required</u>.***	● Broad consent for storage of IPI or IB in repository must be obtained and all requirements met. ● Documented or documentation waived ● Must track refusals as the IRB may not waive consent for use of identifiable material for an individual who refuses	If there is a change made for research purposes in the way material stored or maintained, Privacy and confidentiality review must be conducted Investigators required to complete the CITI course for exempt research
8	***Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens <u>for which broad consent was required</u>.***	● Broad consent was obtained ● Documented or documentation waived ● No plan to return research results ● Must track refusals as the IRB may not waive consent for use of identifiable material for an individual who refuses ● Research is within the scope of the broad consent	Privacy and confidentiality review must be conducted. Investigators required to complete the CITI course for exempt research