Revisions to Common Rule, effective 01/21/2019
Impacts to social, behavioral and education research at UMBC

Category	Current Definition	Revised Definition
What is research?	An activity where an investigator is: • engaged in a research project that is • designed to test a hypothesis or assess a theory by • proposing or intending to explore a particular research topic that is "about" a living individual • by obtaining information or biospecimens from that person through an intervention or interaction • which will then develop or contribute to generalizable knowledge by drawing general conclusions (e.g., knowledge gained from a study may be applied to populations outside of the specific study population), or inform policy and then • either publish (e.g., in a journal) or present at a professional conference	An activity where an investigator is: • engaged in a research project that is • designed to test a hypothesis or assess a theory by • proposing or intending to explore a particular research topic that is "about" a living individual • by obtaining ***private*** information or ***identifiable*** biospecimens from that person through an intervention or interaction • ***that is used, studied or analyzed which generates identifiable private information or identifiable biospecimens*** • which will then develop or contribute to generalizable knowledge by drawing general conclusions (e.g., knowledge gained from a study may be applied to populations outside of the specific study population), or inform policy and then • either publish (e.g., in a journal) or present at a professional conference
Who are human subjects?	Living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.	Living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information ***or identifiable biospecimens***.

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What is NOT research?	• Internal management projects, such as program evaluation, quality assurance, quality improvement, or marketing studies • Projects that only document or report on events, situations, policies, institutions or systems without the intent to form hypotheses • Projects which collect information about policies, practices or procedures • Interviews or surveys which do not collect information about a person, such as interviews on government or corporate policies on government or corporate policies • Production of creative arts, e.g., writing poetry and prose, painting, taking artistic photographs • Journalistic activities • Reporting of current events, trends, newsworthy issues or stories about people or events, such as those presented in the news, magazines and on-scholarly periodicals • Secondary data from publicly available sources	• Internal management projects, such as program evaluation, quality assurance, quality improvement, or marketing studies • Projects that only document or report on events, situations, policies, institutions or systems without the intent to form hypotheses • Projects which collect information about policies, practices or procedures • Interviews or surveys which do not collect information about a person, such as interviews on government or corporate policies • Production of creative arts, e.g., writing poetry and prose, painting, taking artistic photographs • ***Oral history, journalism, biography, and historical scholarship or*** journalistic activities • Reporting of current events, trends, newsworthy issues or stories about people or events, such as those presented in the news, magazines and on-scholarly periodicals • Secondary data from publicly available sources • ***Classroom projects conducted for educational purposes and not as research (as defined above)***

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Exempt research categories		
#1	Research conducted in established or commonly accepted educational settings involving normal educational practices	Research conducted in established or commonly accepted educational settings involving normal educational practices ***that is not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction***
#2	Research involving educational tests, survey procedures, interview procedures, or observation of public behavior	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. ***Research cannot readily identify subjects and responses outside of the research cannot reasonably place subjects at risk.***
#3	N/A	***Benign behavioral interventions with collection of information (verbal, written, audiovisual recording) from adult subjects who prospectively agree. Interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact nor with subjects find them interventions offensive or embarrassing. Deception allowed only if subject proactively agrees.***
#4	Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.	Research ***with identifiable private information (data, documents, records,) or identifiable biospecimens where no consent is required and at least one of the following criteria is met:*** • information or biospecimens are publicly available; • recorded information cannot readily be identified ***(directly or indirectly/linked);*** • ***investigator does not contact subjects and will not re-identify the subjects;*** • ***information collection and analysis involving identifiable health information when used is regulated by HIPAA "health***

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		care operations" or "research" or "public health activities and purposes"
#6	Taste and food quality evaluation and consumer acceptance studies	N/A
#7	N/A	***Storage of identifiable private information or identifiable biospecemens for secondary research for which broad consent is required. Applies only if identifiable data or biospecimens are saved for future unspecified research. NOTE: UMBC will not implement procedures for the category at this time***
#8	N/A	***Use of identifiable private information or identifiable biospecemens for secondary research for which broad consent is required. NOTE: UMBC will not implement procedures for the category at this time***

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Informed Consent		
Regular consent	Using the basic elements of consent found in the templates, documents are formatted to: • present informed consent information in a way that helps with participant comprehension, not just running down a list of risks and procedures; • provide a copy of the consent form to the participant and/or legal representative; • seek consent only if the potential participant has the decisional capacity to give consent; if not, consent must be obtained by a legal representative; • obtain parental permission for minor participants; • provide sufficient opportunity to the potential participant or legal representative to consider whether or not to participate; • ensure that the possibility of coercion or undue influence is absent; • enhance each participant's comprehension of the information; and • use a consent form appropriate to the age level.	Using the basic elements of consent found in the templates, documents are formatted to: • ***provide "key information" to participants essential to decision making*** • present informed consent information in ***sufficient detail and in*** a way that helps with participant comprehension, not just running down a list of risks and procedures; • provide a copy of the consent form to the participant and/or legal representative; • seek consent only if the potential participant has the decisional capacity to give consent; if not, consent must be obtained by a legal representative; • obtain parental permission for minor participants; • provide sufficient opportunity to the potential participant or legal representative to consider whether or not to participate; • ensure that the possibility of coercion or undue influence is absent; • enhance each participant's comprehension of the information; and • use a consent form appropriate to the age level.

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Broad Consent	N/A	***Documents use of basic elements of consent found in the templates. Additional consent elements involves the collection of identifiable private information or identifiable biospecimens will include a statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent. NOTE: UMBC will not implement procedures for broad consent at this time***
Waivers of Consent	Three criteria in use at UMBC: • Waivers of Documentation of Signed Informed Consent • Waivers or Alteration of Elements of Informed Consent • Waivers of the Informed Consent Process	No change, except under "Waivers of Documentation of Signed Informed Consent", an ***allowable criteria is when signing is not a cultural norm and research is minimal risk***
Cooperative Research	An IRB Authorization Agreement (IAA) is used to document the IRB of record when IRB approval is needed from all of the institutions who are "engaged" in research	***IAA's can continue in use. There is an NIH requirement for single IRBs for certain multi-site studies (clinical trials). If UMBC is involved in such studies, investigators will comply with the NIH requirements***
Screening to determine eligibility	The IRB can approves screening activities with potential participants to determine further eligibility performed *after* an investigator obtains consent to ensure participants are qualified for the study.	The IRB can approve screening activities ***without requiring an investigator to obtain informed consent if:*** • ***The investigator obtains information by communicating with the subject or LAR*** • ***The investigator is accessing records or stored biospecimens***

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		This is an exception obtaining consent, not a waiver. The IRB will review and approve the entire research protocol.
Vulnerable persons	Participant population who are considered vulnerable include children, cognitively impaired, etc.	Participant population who are considered vulnerable include "***subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons***"**. Pregnant women are no longer included in the definition of vulnerable women**

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Expedited Research	No changes to current federal expedited categories. ***However, the expedited protocol application is revised to request more details to allow the IRB to assess research projects on uses of informed consent, screening measures, vulnerable person, etc.***	N/A
Expedited Research	Annual review during the term of the approved protocol period	***Annual review no longer required for expedited research unless:*** • ***the original expedited reviewer determines and documents that the study involves review on more of a regular basis*** ***OR*** • ***Research has progressed to data analysis, including analysis of identifiable private information or identifiable biospecimens*** ***The ORPC will forward "Status Checks" at least annually to assess approved research. The ORPC may increase its use of Protocol Monitoring and Review to assess approved research.*** ***Investigators are required to document any changes to approved expedited research protocols using the current Modification Request process. Investigators are required to document any Protocol Deviations and Adverse Events in current IRB procedures***