# The HREB Chair emailed the SUNY New Paltz community on November 4, 2019, with HREB Updates containing information on Changes to Informed Consent.

*Dear Researcher,*

*With the new revisions to the Common Rule that went into effect in January 2019, the informed consent guidelines have changed and there are additional requirements that must be met.*

*First, you must begin your informed consent form with a brief summary that conveys key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. The summary must contain the following information:*

1. *The fact that consent is being sought for research and that participation is voluntary*
2. *The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research*
3. *The reasonably foreseeable risks or discomforts to the prospective subject*
4. *The benefits to the prospective subject or to others that may reasonably be expected from the research*
5. *Appropriate alternative procedures or courses of treatments, if any that might be advantageous to the prospective subject.*

*Second, if you are collecting **personally identifiable private information or biospecimens** you must include one of the following statements:*

*(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or*

*(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.*

*Third, you must get broad consent for the storage, maintenance, and secondary research use of **personally identifiable private information or biospecimens**. Broad consent will provide participants with a choice to say no to storage, maintenance, and secondary research. If an individual was asked to provide broad consent and refused to consent, the HREB cannot waive consent for the use of identifiable private information or identifiable biospecimens in the future. In addition to the requirements for informed consent, the requirements for broad consent include:*

1. *A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;*

2. *A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;*

3. *A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);*

4. *Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;*

5. *Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and*

6. *An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.*

*If you have any questions, please do not hesitate to contact me at HREBchair@newpaltz.edu or give me a call at 845-257-3476. You may also contact Roseann Merrill at HREBcoordinator@newpaltz.edu or by phone at 257-3282.*

*Maryalice Citera, Ph.D., Chair, Human Research Ethics Board*