In order to approve research covered by these regulations (45 CFR 46.111 and 21 CFR 56.111) the IRB shall determine that all of the following requirements are satisfied:

1. **Risks to subjects are minimized** by using procedures which are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (Beneficence).

2. **Risks to subjects are reasonable in relation to anticipated benefits**, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research (Beneficence).

3. **Selection of subjects is equitable**. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of 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 (Justice).

4. **Informed consent** will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by the Federal regulations (Respect for Persons).

5. Informed consent will be appropriately documented (or appropriately waived) in accordance with, and to the extent required by the Federal regulations (Respect for Persons).

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to assure the safety of subjects (Beneficence).

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (Respect for Persons and Beneficence).

b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects (Respect for Persons and Beneficence).

Revised January 2019

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1 January 21, 2019: The 2018 Common Rule removes pregnant women as ‘vulnerable’ however Subpart B still applies.
2 OHRP 45 CFR 46. 111 / FDA will allow waivers or alterations of consent for research no more than minimal risk as per FDA guidance document dated July 2017.
3 Per FDA 21 CFR 56.111 pregnant women are listed as part of vulnerable populations and individuals with impaired decision-making capacity are listed as mentally disabled persons.