1.0 Purpose: The purpose of this standard operating practice (SOP) is to outline the requirements to obtain a waiver or alteration of the informed consent process.

2.0 Persons Affected:
2.1 Principal investigators (PI) and research team members
2.2 University and Medical Center Institutional Review Board (UMCIRB) members
2.3 UMCIRB office staff members

3.0 SOP: The IRB may approve a waiver or alteration of the consent process in non-FDA regulated human research. The investigator must provide adequate justification for requesting this type of waiver.

4.0 Definitions:
4.1 Exceptions to informed consent requirements: the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent if it finds and documents
  4.1.1 The research involves no more than minimal risk to the subjects;
  4.1.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;
  4.1.3 If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
  4.1.4 The research could not practicably be carried out without the requested waiver or alteration; and
  4.1.5 Whenever appropriate, the subjects or legally authorized representative will be provided with additional pertinent information after participation.
4.2 Other exceptions to informed consent requirements: the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or may waive the requirement to obtain informed consent if it finds and documents
  4.2.1 The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    4.2.1.1 Public benefit or service programs;
    4.2.1.2 Procedures for obtaining benefits or services under those programs;
    4.2.1.3 Possible changes in or alternatives to those programs or procedures; or
    4.2.1.4 Possible changes in methods or levels of payment for benefits or services under those programs; and
  4.2.2 The research could not practicably be carried out without the waiver or alteration.
4.3 Practicable: (a) feasible; (b) capable of being effected, done or put into practice; and (c) that may be practiced or performed; capable of being done or accomplished with available means or resources.

5.0 Responsibilities:
5.1 UMCIRB office staff will
5.1.1 Perform a pre-review of the waiver request provided by the investigator.
5.1.2 Communicate with the PI or appropriate research personnel on any changes that might be needed with regard to the request for waiver.

5.2 Investigators have the responsibility to
5.2.1 Provide complete and robust justification for a waiver or alteration of the consent process.

5.3 UMCIRB/UMCIRB Chairperson (or designee)
5.3.1 Reviews each waiver request to determine whether sufficient justification is provided in order to grant approval.

6.0 Procedures:
6.1 When requesting a waiver of informed consent:
6.1.1 There should be a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.
6.1.2 Practicability should not be determined solely by considerations of convenience, cost, or speed.

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
<th>Reference Section(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.22.2015</td>
<td>Updated to stand-alone document.</td>
<td>All</td>
</tr>
<tr>
<td>1.21.2019</td>
<td>Updated definitions secondary to revised regulations.</td>
<td>Section 4.0</td>
</tr>
</tbody>
</table>

References:
DHHS, OHRP. Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

FDA. Code of Federal Regulations:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50 and