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 for non-Exempt human research studies.

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 informed consent in 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 practically be carried out without using such information or biospecimens in an identifiable format (this criterion is not applicable for FDA regulated studies);
   4.1.4 The research could not practically 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 practically 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.
4.4 **Minimal risk:** the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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 regarding 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 In determining whether the waiver or alteration will adversely affect the rights and welfare of the participants, the UMCIRB/UMCIRB Chairperson will consider the following based on the investigator’s IRB application:
6.1.2.1 Whether there are other federal, state, or local laws that provide rights to potential subjects to require informed consent.
6.1.2.2 Whether the subject population, in general, would object if they knew of the waiver and its intent in facilitating research.
6.1.2.3 Whether the subject population, in general, would consider that the waiver has the potential to cause adverse consequences for their welfare or general well-being.

6.1.3 In determining whether the research could not practicably be carried out without the waiver or alteration, the UMCIRB/UMCIRB Chairperson will consider the following based on the investigator’s IRB application:
6.1.3.1 Pragmatic reasons: Too many sites, time of patient visits (for example, budget may not allow study team coverage for recruiting patients in an ED where they could arrive at any time of day/night, 7 days a week), inability to identify subjects ahead of time, too many subjects.
6.1.3.2 Scientific validity would be compromised if consent was required. Examples of this might include the following:
6.1.3.2.1 The sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed.
6.1.3.2.2 The subjects for whom records would be reviewed are no longer
followed and may be lost to follow-up. For example, the proportion of individuals likely to have relocated or died may be a significant percentage of the subject population and the research results may not be meaningful and lose statistical power.

6.1.3.2.3 The disclosure of the study purpose as part of the consent process would bias the research subjects so that the results will not be meaningful.

6.1.3.3 Ethical concerns would be raised if consent were required. For example:
6.1.3.3.1 There is a risk of creating additional threats to privacy by having to link otherwise de-identified data with nominal identifiers in order to contact individuals to seek consent.
6.1.3.3.2 There is a risk of inflicting psychological, social or other harm by contacting individuals or families.

6.1.3.4 There is a scientifically and ethically justifiable rationale why the research could not be conducted with a population from whom consent can be obtained.

6.1.4 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>
<tr>
<td>12.1.2019</td>
<td>Updated Procedures section to include further guidance about waiver criteria assessment.</td>
<td>Section 6.0</td>
</tr>
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References:

