Waiver or Alteration of Informed Consent		
	Revisions Date	12.1.2019

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 practicably 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 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.

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.

Date	Change	Reference Section(s)
1.22.2015	Updated to stand-alone document.	All
1.21.2019	Updated definitions secondary to revised regulations.	Section 4.0
12.1.2019	Updated Procedures section to include further guidance about waiver criteria assessment.	Section 6.0

References:

DHHS, OHRP. Code of Federal Regulations.

FDA. Code of Federal Regulations:
Protection of Human Subjects
Institutional Review Boards

Secretary's Advisory Committee on Human Research Protections (SACHRP). SACHRP Letter to HHS Secretary. January 31, 2008.

FDA Guidance Document. IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects-Guidance for Sponsors, Investigators, and Institutional Review Boards. July 2017.

Appendix A: Guidance and Examples of Appropriate Waiver of Consent Scenarios

In order to qualify for a waiver of consent all of the following must be satisfied:

1. The research involves no more than minimal risk to the subjects.

2. The waiver or alteration will not adversely affect the rights of the subjects.

3. The research could not practicably be carried out without the requested waiver or alteration (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. Whenever appropriate, the subject or legally authorized representative will be provided with additional pertinent information after participation.

The following scenarios are examples of studies where a waiver of informed consent would appear to be appropriate based on the criteria above.

1. An Investigator wants to look at flu vaccination rates in patients presenting at ECU Physicians for routine primary care. Additionally, they want to see if there are differences in demographics or comorbidities in those that are vaccinated and those that are not. The study will look at medical records for adult patients seen for primary care between September 1, 2015 and May 1, 2016.

The following datapoints will be retrospectively abstracted from the patient's chart in June of 2016:

- Date of service
- Reason for visit
- Basic demographics including race, gender, insurance status, marital status, employment information
- If the vaccine was offered to the patient
- Flu vaccine history for the time period of the study
- Any chronic disease comorbidities such as diabetes, congestive heart failure, chronic obstructive pulmonary disease, hypertension, etc.

The Investigator notes that ECU Physicians sees several thousand patients each year and a particularly high-volume during flu season.

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2. An Investigator is working with other institutions in North Carolina to try and determine the prevalence of sickle-cell anemia in the state of North Carolina. Demographic information will also be used to describe the population. The study is prospective in nature (meaning none of the study data exists at the time of

submission to the IRB) and is intended to last for two years. Members at each institution will abstract data from patient charts and enter de-identified data in a central database. All of the charts abstracted will be from patients of the investigators and they are seen several times a year.

The following datapoints will be prospectively abstracted from each patient's chart:

- Year of Birth
- Sickle-cell anemia status
- Basic demographics including race, gender, insurance status

The Investigator notes that all of the charts abstracted will be from patients of the Investigators' and they are seen several times a year.

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3. An Investigator wants to look at the impact of the University calendar on the usage of public greenways in Greenville, NC. Specifically, are the greenways used more or less often when the University is in session and presumably more students are in the city. The study will use public observation of the entrance to several greenway spaces in the city on six consecutive Saturdays surrounding the end of classes in May.

Data to be collected is a simple count of individuals entering the greenway spaces as well as notes on whether the individuals are alone, in groups, appear to be walking, running or biking and how many children appear to be using the spaces.