University of Wisconsin-Oshkosh
Institutional Review Board (IRB)

STANDARD OPERATING PROCEDURES (SOP)	
SOP Number: 1 Effective Date: December 15, 2016 Last Reviewed: December 15, 2016 Attachment: Page 1 of 6 Prepared By: Kelly Schill & Anca Miron	**Title: Determining Whether a Project Requires UWO IRB Review and Approval**

Determining Whether a Project Requires UWO IRB Review and Approval

I. Purpose

This standard operating procedure was developed to help faculty, staff, and students determine whether a project will require IRB review at University of Wisconsin-Oshkosh. Appendix A provides a decision tree which can also be used as an additional reference. If you need assistance in making a determination on whether IRB review and approval is required, please contact irb@uwosh.edu.

II. Foundation of Human Subjects Protections

UW Oshkosh Federalwide Assurance (FWA) includes a set of principles and guidelines that are used to protect the rights and welfare of human subjects taking part in research conducted at, or sponsored by the institution. The following principles found in the Belmont Report govern UW Oshkosh in the discharge of its responsibilities for protecting the rights and welfare of human subjects:

• Respect for persons (applied by obtaining informed consent, respecting privacy and confidentiality, and affording additional protections for vulnerable populations);

• Beneficence (applied by weighing risks and benefits);

• Justice (applied by the equitable selection of subjects)

The IRB Standard Operating Procedures represent the written procedures and guidelines provided in UW Oshkosh's Federalwide Assurance.

III. Regulations for Human Subjects Protections

A. 45 CFR 46, codifies basic human subject protection measures. This is known as the Common Rule.

B. 21 CFR 50 and 21 CFR 56 codify human research protection measures pertaining to FDA-regulated research and are largely congruent with 45 CFR 46.

The current IRB committee reviews Social, Behavioral, and Educational research protocols and conforms to the Common Rule regulations 45 CFR 46 published by Department of Health and Human Services (DHHS). UW Oshkosh does not review research protocols regulated by the FDA at this time.

IV. Charge of Institutional Review Board (IRB)

The IRB is charged with the responsibility for reviewing and monitoring human subjects research conducted under the auspices of UW Oshkosh.

Human subjects research that meets any of the following criteria will be subject to UW Oshkosh IRB review and monitoring:

- The research is sponsored by UW Oshkosh
- The research is conducted or directed by any faculty, staff member, student, or affiliated member of the University in connection with his or her UW Oshkosh responsibilities
- The research involves access to any property, equipment, or facility of UW Oshkosh other than access to open spaces on the University campus that are readily available to the public at large (Example of space readily available to public: Reeve Union)

V. Determining whether IRB Review is Required

The first question with respect to IRB review of a project is a determination of whether the project fits the definition of human subjects research. The definitions of "research" and "human subjects" for this purpose are derived from federal research regulations 45 CFR 46.102. Secondly, if the project meets the definition of human subjects research, a determination must be made on whether UW Oshkosh is engaged in the research (See V.3 for determining if UWO is engaged in the research).

1. Does the project meet the definition of **Research?**

The definition of research as defined by the Department of Health and Human Services (DHHS) regulations: "Research means a *systematic investigation*, including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*." 45 CFR 46.102 (d)

To be considered a "systematic investigation", the concept of a research project must meet all of the following:

- Attempt to answer research questions.
- Is methodologically driven, that is, it collects data or information in an organized and consistent way.
- The data or information are analyzed in some way, be it quantitative or qualitative data.
- Conclusions are drawn from the results.

"Generalizable Knowledge" would include one or more of the following concepts:

- The knowledge contributes to a theoretical framework of an established body of knowledge.
- The primary beneficiaries of the research are other researchers, scholars and practitioners in the field of study.
- Publication, presentation or other distribution of the results is intended to inform the field of study.
- The results are expected to be generalized to a larger population beyond the site of data collection or population studied.
- The results are intended to be replicated in other settings.

2. Does the project involve ***Human Subjects*****?**

DHHS regulations define a human subject as "a living individual about whom an investigator conducting research obtains (1) data through *intervention* or *interaction* with the individual, or (2) identifiable *private information*." 45 CFR 46.102(f)

"Intervention" includes:

- physical procedures by which data are gathered (for example, venipuncture, imaging, BMI)
- manipulations of the subject or the subject's physical or virtual environment that are performed for research purposes

"Interaction" includes:

- communication or interpersonal contact between investigator and subject
- includes face-to-face interviews, focus groups, surveys, mail, and online communication/ contact (i.e. interaction through computer, phones, games or experiments in physical or electronic environments, as well as any other mode of communication)

"*Private information*" includes:

- information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and
- information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).

Private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

HIPAA provides a list of 18 identifiers, the removal of which renders a data set de-identified for the purpose of determining if a human subject is involved.

Private information scenarios:

- Simple observational studies of public behavior (including television and internet chat rooms) do not involve human subjects as defined, because there is no intervention or interaction and the behavior is not private. However, if the environment is manipulated, it does involve intervention.
- Studies based on data collected for non-research purposes may not constitute human subjects research if individual identity is not identifiable (programmatic data such as service statistics, school attendance data, crime statistics, or election returns).
- Studies based on data that are individually identifiable data but also are publicly available may not constitute human subjects research [45 CFR 46.101(b)(4)]; however, the term "publicly available" is intended to refer to record sets that are readily available to the broad public. (See **IRB SOP #2: Policy on Analysis of Secondary Datasets** which has a list of public datasets that can be accessed without IRB review).

3. Is UW Oshkosh engaged in the research?

In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.

For additional guidance and examples, see the Office for Human Research Protections (OHRP) guidance on engagement.

UW Oshkosh is engaged in the research if any of the following conditions are met:

(1) research conducted by a) any faculty member of any rank (tenured, tenure track, adjunct, and emeritus), b) staff member (academic or professional), c) student (undergraduate, graduate, or post-doctoral), or d) visiting faculty/scientist drawing salary support from a UW Oshkosh sponsored project as part of their UW Oshkosh responsibilities

(2) research conducted by affiliated faculty under UW Oshkosh auspices

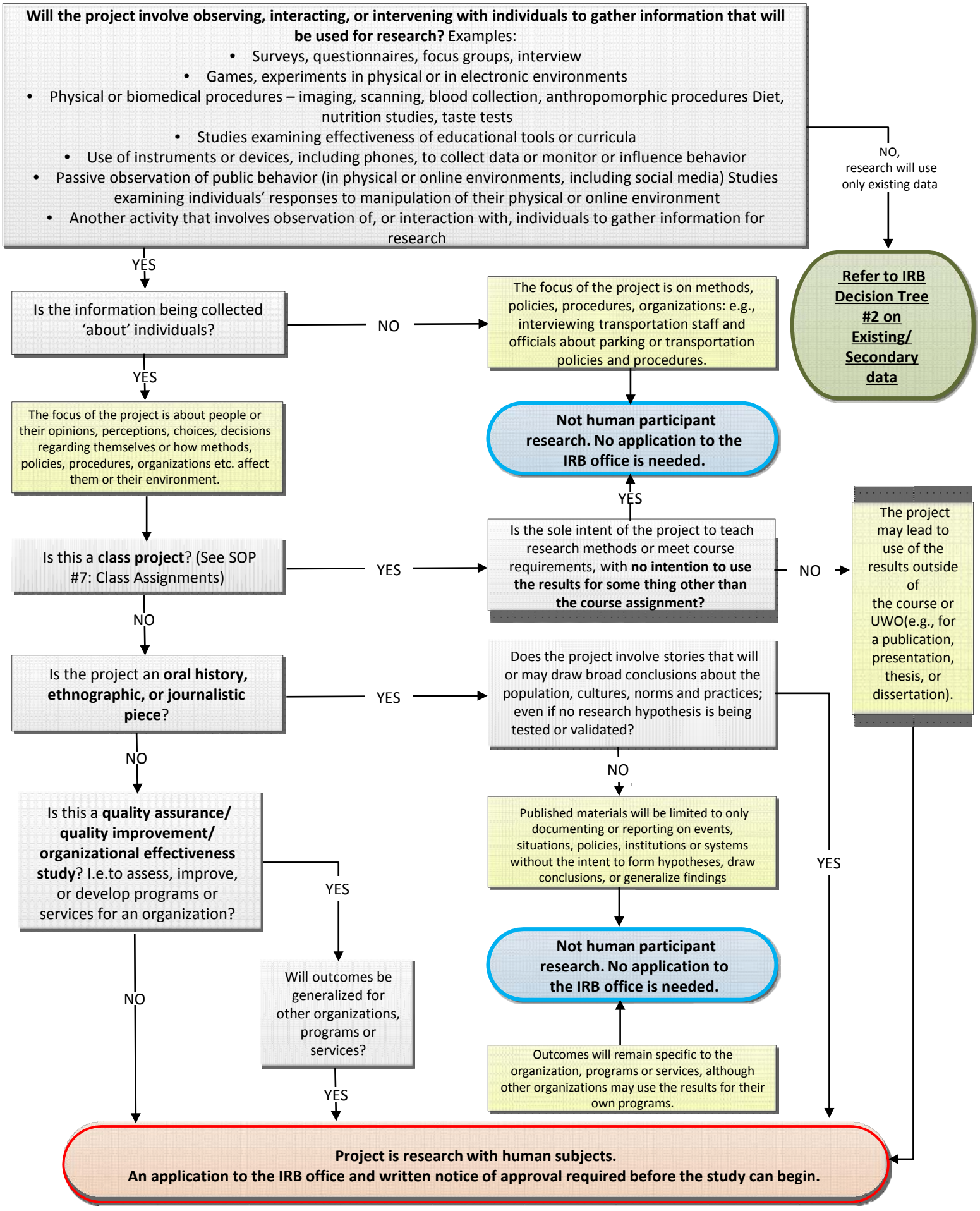
(3) non-UW Oshkosh personnel using UW Oshkosh equipment or facilities not readily available to the public at large

(4) any individual listed under (1) who obtains identifiable private information or identifiable biological specimen from a collaborator at another Institution

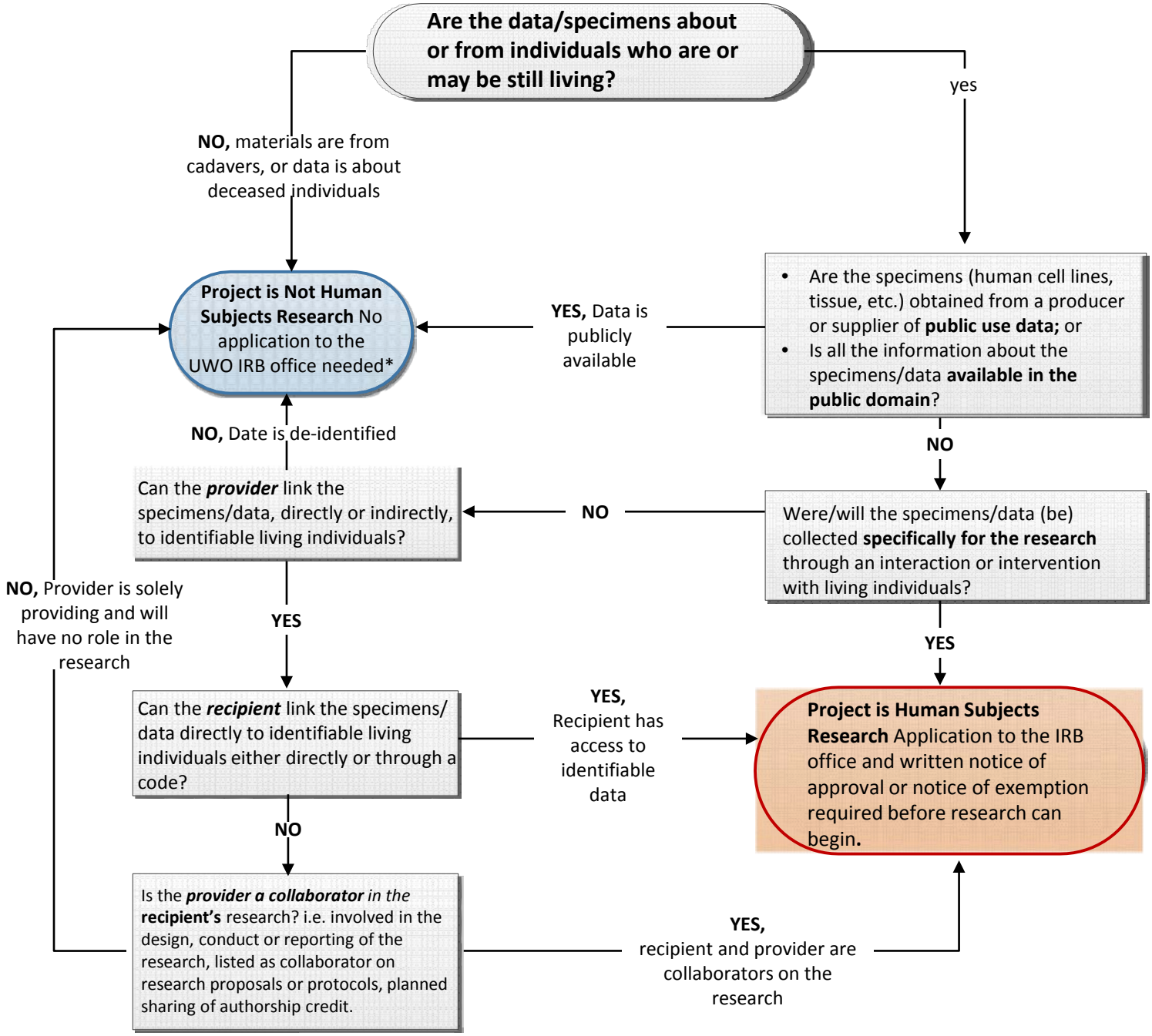
VI. Decision Chart: Is UWO IRB Review Required

UW Oshkosh IRB has developed decision trees which can be used as a reference in determining if IRB review is required (see Appendix A). For further guidance, please contact irb@uwosh.edu.

Appendix A: Does Your Project Require an Application to the UW Oshkosh IRB?
Decision Tree #1



Does Your Research Involving Secondary or Existing Data, Documents or Biological Specimens Require Review by UWO IRB? Decision Tree #2



*Contact the UWO IRB Office if acquiring the data requires a Data Use Agreement or a Materials Transfer Agreement between the provider and recipient.

Reference:

"Research Involving Private Information or Biological Specimens Flowchart", National Institute of Health (NIH), January 2006, https://grants.nih.gov/grants/policy/hs/PrivateInfoOrBioSpecimensDecisionChart.pdf

Cornell IRB Decision Tree: https://www.**irb**.**cornell**.edu/documents/**IRB**%20**Decision**%20**Tree**.pdf