Introduction
The Institutional Review Board for the Protection of Human Subjects (IRB) at the University of Wisconsin – River Falls (UWRF) was established to provide ongoing protection for the rights and welfare of human subjects participating in research projects and activities. The IRB reviews each human subjects research project conducted by UWRF faculty, staff, administration, or students to ensure the safe, fair, and ethical treatment of research subjects, ensuring that these projects adhere to federally accepted standards of ethical research conduct. The IRB also reviews all human subjects research done by individuals not affiliated with the university when the human subjects are UWRF faculty, staff, administration, or students. UWRF uses the proprietary software known as CayuseIRB to submit, review, and manage all IRB protocols and activities.

Authority
Title 45 of the Code of Federal Regulations, Part 46 (hereafter referred to as 45 CFR 46), which was revised 15 January 2009, requires that all institutions engaged in research involving human subjects are to establish an IRB. The statutory authority for the HHS regulations derives from 5 U.S.C. 301; 42 U.S.C. 300v-1(b); and 42 U.S.C. 289 (enacted in 1985).

In order to protect the rights of all human subjects involved in research at UWRF, the university operates its human subjects research activities under a Federalwide Assurance (FWA; FWA #00022589) with the Office of Human Research Protection (OHRP) within the Department of Health and Human Services. The FWA represents a fundamental commitment to the protection of human subjects and applies to all research involving human subjects in which UWRF’s administration, faculty, staff, and/or students are involved. The Provost and Vice Chancellor for Academic Affairs, as the chief academic officer of the university, serves as the Institutional Official for the FWA. The Provost has oversight responsibility for all UWRF human subjects research, including ensuring that the UWRF IRB operates in accordance with the FWA and all applicable laws, monitoring the operation of the IRB, and appointing its membership in accordance with federal law.

Specifically, 45 CFR 46.107(a) mandates the following criteria:
(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.
(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(d) No IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

UWRF IRB Policy
To protect the rights of human subjects, the IRB shall establish policies and procedures for the review of human subjects research prior to the initiation of research activities. The IRB review process is based on the federally recognized principles contained within The Belmont Report, specifically the rights of persons, beneficence, and justice. The IRB will adhere to the review process and procedures identified in the Appendix.

Without exception, all human subjects research involving UWRF faculty, staff, administration, or students must receive prior approval from UWRF’s IRB. The IRB has the authority to review approve, disapprove, or require changes in research or related activities involving human subjects. All researchers, whether affiliated with UWRF or with other entities, must obtain written approval from this committee before beginning research activities.

The IRB has the final determination as to what constitutes research and the use of human subjects and thereby, what activities must be reviewed and/or approved by the IRB. Investigators cannot independently determine that their human subjects research is excused from review by the IRB. Any questions regarding whether IRB approval is needed should be addressed to the current IRB Chairperson. The approval by the IRB must occur before the collection of research data.

IRB policies and procedures will be widely available to all faculty, staff, and students at the university. The IRB shall issue, and update as needed, documentation that addresses required review procedures, review forms, and appropriate additional documentation.

Definitions
A. Exempt level review: A type of review for research in which the only types of human subjects participation are covered by §46.101(b). The six exemption categories are the following:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity
to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or
demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

B. Expedited level review: A type of review for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

The Chairperson of the IRB or designee will determine if a protocol qualifies under §46.110 for expedited review. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be
disapproved only after review in accordance with the non-expedited procedure set forth in §46.108(b).

**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.

C. **Full board review:** A type of review for human subjects research that is not eligible for exempt or expedited level review.

Full board review is required for research that contains more than minimal risk and/or involves the use of vulnerable (protected) populations of human subjects and/or involves the use of deception. The IRB will convene a meeting to review the protocol in order to determine whether the project will be rejected, need amendment, or will be accepted. The Principal Investigator and other project staff will be requested to attend this meeting.

D. **Human subject:** “a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) data through intervention, interaction with, or observation of the individual; or
(2) identifiable private information.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

**Interaction** includes communication or interpersonal contact between investigator and subject.

**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.” (§46.102f)

E. **Institution:** “any public or private entity or agency (including federal, state, and other agencies).” (§46.102b)

F. **Investigator:** the individual(s) designated to have the appropriate level of authority and responsibility to direct and/or make decisions about the research project and/or activity.
G. **IRB**: “an institutional review board established in accord with and for the purposes expressed in this policy [45 CFR 46].” (§46.102g)

H. **IRB approval**: “the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.” (§46.102h)

I. **Research**: “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.” (§46.102d)

**Membership**

Regular, Full-Voting Members: The University of Wisconsin – River Falls IRB will consist of no fewer than five (5) and no more than ten (10) full voting members who are appointed by the Provost and Vice Chancellor for Academic Affairs. All full-voting members of the IRB must be members of the faculty and/or academic staff at UWRF, with the exception of the aforementioned required community member. The membership of the IRB will adhere to the federal requirements presented above and it is preferred that the membership will include at least one (1) full voting member from each of the following units of UWRF: College of Arts and Sciences; College of Education and Professional Studies; and College of Business and Economics, College of Agriculture, Food and Environmental Sciences.

Each full voting member of the IRB will serve for a three (3) year term. It is preferred that appointments to the IRB will be staggered in rotation, such that no more than one-third of the IRB should be appointed in a single calendar year. The Provost and Vice Chancellor for Academic Affairs may reappoint any member for a second term. However, under extenuating circumstances, the Provost and Vice Chancellor for Academic Affairs may allow extensions beyond the limit on consecutive years of service.

Chairperson: The Chairperson of the IRB will be appointed by and will report directly to the Provost and Vice Chancellor for Academic Affairs for a three (3) year period. A person who would qualify as a regular, full-voting member would be eligible for the Chairperson position. The Chair appointment will supersede an existing term on the IRB, permitting the three-year appointment to be served in full. Upon completion of the Chairperson’s term, continuity through a minimum of two additional years of service as an IRB member is expected. At official IRB meetings the Chairperson will be a full voting member but will only vote in the event of a tied decision. The term as Chairperson can be renewed for an additional three (3) year period based on the agreement of the Chairperson and the Provost and Vice Chancellor for Academic Affairs.

*Ex officio members and ad hoc consultants*: *Ex officio* members and *ad hoc* consultants to the IRB can participate in IRB meetings and activities but do not have a vote in any decision.

The Director of Grants and Research serves as an *ex officio*, non-voting member of the IRB, reporting directly to the Provost and Vice Chancellor for Academic Affairs.
In accordance with 45 CFR 46.107(f) “The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.” These individuals serve the IRB on an ad hoc basis and serve as non-voting consultants during IRB proceedings.

**Training**

As of January 2018 all IRB members, the IRB Chairperson, the Institutional Official, and human subjects researchers will be required to have completed a specified training in human subjects research. As of November 1, 2016 this training has been provided through the on-line Collaborative Institutional Training Initiative (CITI) program.

**Meetings and Records**

The Chairperson of the IRB is responsible for arranging a regular schedule for IRB meetings that provides researchers with an opportunity to have their projects reviewed in a timely manner. The full membership of the IRB shall meet at least one (1) time during the academic year. A majority (greater than 50%) of the full voting membership of the IRB constitutes a quorum for the purpose of holding an official meeting if at least one member whose primary concerns are in nonscientific areas is present (§46.108b). This quorum is sufficient for holding an official meeting, issuing official verdicts, actions, and judgements. All meetings shall be conducted in accordance with the state of Wisconsin’s Open Meeting Laws and any other appropriate state and/or federal regulation governing the operation of the IRB. Public notice of the date and time of these meetings will be provided through outlets identified as appropriate by the university.

UWRF will maintain appropriate documentation of IRB activities, in accordance with the federal guidelines provided within 45 CFR 46. The IRB Chairperson will manage the retention of all IRB documentation including a list of the IRB membership, written procedures for the IRB, statements provided to research subjects regarding significant new findings, copies of all correspondence between the IRB and researchers, CITI training documentation, records of continuing review activities, records related to conducted research, approved protocols, and meeting minutes of the IRB. All records will be retained for a minimum of three years. (§46.115).

The minutes of IRB meetings will be maintained in Cayuse and will contain the following information: “attendance at the meetings; actions taken by the IRB; the vote on these actions including number of members voting for, against, and abstaining; the basis for changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution” (§46.115(a)(2)).

Records related to conducted research include, at a minimum “copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects” (§46.115(a)(1)).

The IRB will review and assess its policies and procedures at least every three years. Appropriate changes will be made to ensure that the IRB is in adherence with the regulations of UWRF, the University of Wisconsin System, and the Department of Health and Human Services.
HHS-OHRP Registration Updates and Renewals
Updates to the HHS-OHRP IRB registration (HHS IRB# IRB00009964; IORG# IORG0008314) will be made within 90 days after changes regarding the contact person who provided the IRB registration information (generally the Director of Grants and Research) or the IRB Chairperson. Updates to the IRB registration will also be made in a timely manner after a change in the membership roster. Renewal of the IRB registration will be made every 3 years following a renewal or update.

Updates to the FWA (FWA #00022589) will be made following changes in the institution's name, human protections administrator, or signatory official. Renewal of the FWA will be made every 5 years.

Procedures for Conflicts of Interest
No member of the IRB may participate in the initial or continuing review of a research project if an actual or apparent conflict of interest exists. Said IRB member may not participate in the IRB's deliberations or votes on the project but may provide information requested by the IRB.

It is the responsibility of IRB members to identify the existence of an actual or apparent conflict of interest and voluntarily remove himself/herself by informing the IRB Chairperson. A member who voluntarily recuses himself/herself does not have to identify the specific nature of the conflict of interest. Preference is that IRB members do not review protocols form their department.

If an IRB member does not voluntarily recuse himself/herself from the proceedings, a challenge may be raised by either members of the IRB or by the researcher(s) whose project is under review. A conflict of interest challenge must be raised prior to action taken by the IRB on the project. The conflict of interest challenge takes immediate precedence as a point of order during an official meeting. After a motion to recuse said IRB member, discussion of the cause for recusal, and vote by the full committee about the recusal, the committee may return to their prior point of order.

The minutes of the IRB meeting must clearly identify that one or more members were recused from deliberations and votes for the given protocol due to the conflict of interest.

Institutional Review
Research reviewed by the IRB may also be subject to other conditions and/or restrictions by officials at UWRF. In cases where the IRB has denied approval for a research project, this decision stands until such time that the project has been modified to meet all guidelines for approval of human subjects' research. University officials are not allowed to approve research that has not been approved by the IRB (§46.112).

Suspension or Termination of IRB Approval of Research
Under normal circumstances an IRB protocol can be approved for a period of up to one year; however in accordance with 45 CFR 46, the IRB shall “suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects” (§46.113).

The IRB requires that a researcher suspend research activity if there is unexpected harm to subjects. The researcher must then notify the Chairperson of the IRB via Cayuse of the suspension of the research and
the events that led to this decision. The IRB’s subsequent review of the situation will include evaluation of the risks and safety procedures identified in the approved protocol.

Suspension of a protocol, whether initiated by the IRB or the researcher, shall be followed by a statement of the reasons for the action. This statement will be provided to the investigators listed on the protocol, the head of the department the investigators are affiliated with, and to the Provost and Vice Chancellor for Academic Affairs at URF.


Provost and Vice Chancellor
For Academic Affairs

UW – River Falls Chancellor
Appendix: Institutional Review Board Research Review Process

1. The Principal Investigator(s) (PI), or their designee, fully completes the IRB protocol form in Cayuse, not leaving any item of the protocol form blank. Once completed, all investigators certify the protocol submission via Cayuse.

2. The PI ensures that all investigators on the research project, including graduate and undergraduate students, have completed the appropriate online CITI human subjects training modules. Certificates of completion for every investigator are required to be provided as attachments to an IRB protocol submitted for review.

3. The IRB protocol form and all appropriate attachments, hereafter referred to as the “protocol,” are submitted via Cayuse. Attachments may include, but are not limited to CITI training certificates of completion, instruments used for data collection, sample consent forms, letters of support from agencies providing access to human research subjects, samples of correspondence intended for human research subjects, and advertising intended to be used for recruitment of subjects. Failure to provide all required documentation will delay the review of the protocol.

4. The IRB Chairperson, or designee, confirms that all appropriate files and documentation are provided. Protocols are reviewed according to the order in which they are received by the IRB Chairperson, not by the intended start date indicated by the PI on the protocol form. PIs may share compelling extenuating circumstances for consideration by the IRB Chairperson.

5. The IRB Chairperson will determine the level of review required. In the case of exempt level review, the exemption category will be specified. The volume of protocols will determine the length of time it takes for a protocol to be reviewed. It is generally expected that exempt level and expedited level reviews will occur within a two to three-week time period. Any protocol requiring a full board review will be reviewed when the full IRB convenes a meeting for this purpose. The PI(s) and other project staff will be requested to attend the meeting where the review of the protocol will occur. The committee typically meets at least once or twice each semester depending on need. The IRB chair will communicate a specific review time for full board reviews typically within 2 weeks of receipt of the protocol initial submission.

6. Feedback from the initial review of the protocol will be communicated to the PI by the IRB Chairperson via Cayuse. The feedback will provide instructions on how the PI needs to proceed, which typically entails a request for revisions and resubmission of the revised protocol materials to the IRB Chairperson via Cayuse. A protocol must meet all of the criteria identified in §46.111 to be eligible for approval.

7. When the final version of the protocol is approved by the IRB Chairperson, the IRB Chairperson or designee will notify the PI via Cayuse. PI(s) will be permitted to begin conducting the research upon receipt of the IRB protocol approval letter.
8. A copy of the final approved protocol will be saved on Cayuse. Any changes to the protocol or further communication will also happen via Cayuse submission approval. The IRB Chairperson, the Director of Grants and Research, the Provost and Vice Chancellor for Academic Affairs, and their designees will have access to all current protocols, as well as all aforementioned IRB records.

All records will be retained for a minimum of three years. (§46.115).

9. Questions about the status of pending protocols or information about current protocols may be sent to IRB@UWRF.edu.

10. Reportable events (including an occurrence of unexpected harm or deviations from approved protocols) should be immediately reported to the IRB Chairperson via Cayuse. The IRB Chairperson will notify the IRB and the Provost and Vice Chancellor for Academic Affairs. A review will be conducted. The review will be determined whether or not the mandatory reporting requirements from 45 CFR 46.103(a) and (b)(5) are met and corrective actions that will be required. The IRB Chairperson will communicate this information to the PI.