If research is funded, supported by or otherwise subject to certain federal agencies or agreements, it could be subject to additional requirements to those in the Common Rule. Investigators are encouraged to seek additional guidance from the Human Subjects Protection Program Office when needed.

This guidance addresses requirements for research supported by or otherwise subject to, the following federal departments and agencies:

- Department of Defense (DoD), 32 CFR 219; DoD Directive 3216.02; 10 USC 980
- Department of Education (ED), 34 CFR 99 [FERPA]; 34 CFR 98

All human subjects research carried out at the University or under its auspices must be reviewed and approved by an IRB prior to the start of the research. The IRBs are guided by the principles of The Belmont Report and the regulations and policies set forth by the DHHS and its subordinate agencies and offices in reviewing all human subjects’ protocols.

University of Louisville IRBs review human subject’s research projects when:

1. the research is sponsored by the institution or one of its affiliated institutions,
2. the research is conducted by or under the direction of any employee or agent of the institution in connection with his or her institutional responsibilities,
3. the research is conducted by or under the direction of any employee or agent of the institution using any property or facility of the institution,
4. the research involves the use of the institution’s non-public information to identify or contact human subjects, or
5. any research determined by the Institutional Official (IO).

**Department of Defense [DoD]**

Investigators should review the requirements of 3216.02 “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research” prior to submitting an application for funding support from DoD. DoD policies and links to the DoD Components policies may be found at: [http://www.dtic.mil/whs/directives/](http://www.dtic.mil/whs/directives/).

**International Research**

Research performed in a foreign country involving participants who are not US citizens or DoD personnel requires permission of the host country.

- DoD Directive 3216.02, 4.c.(2)(e)
- [AAHRPP standard I-3](#)

**Required Reporting – by Researchers, Institution**

**DoD:** Promptly (within 30 days) notify the DoD Human Research Protection Officer (HRPO) as follows:

- **Researcher** notifies:
  - When significant changes to the research protocol are approved by the IRB.
  - The results of the IRB continuing review.
  - If the IRB used to review and approve the research changes to a different IRB.

- **The institution** notifies:
  - Any unanticipated problems involving risks to participants or others (UPIRTSOs) for any DoD-supported research.
  - Any determinations of serious or continuing noncompliance of DoD supported research.
Federal Agencies - Additional Requirements for Research

- When the institution is notified by any Federal dept or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol.
- Any suspension or termination of DoD supported research.
- DoD Directive 3216.02, para. 4.b.4

Monitors
For research involving more than minimal risk the IRB shall approve an independent research monitor by name. The monitor may be an ombudsman or member of the DSMB.

The research monitor has the authority to:
- Stop a research study in progress.
- Remove individuals from the study.
- Take any steps to protect the safety and well-being of participants until the IRB can assess.

OSD (Office of the Secretary of Defense) and DoD Component heads may waive the research monitor requirement on a case-by-case basis when inclusion of a monitor is not necessary to provide additional protections for human subjects.
- DoD Directive 3216.02, para. 8
- [AAHRPP Element II.3.B]

DoD Personnel as participants
U.S. military personnel - minimizing undue influence: Officers and senior noncommissioned officers (NCOs) shall not influence the decisions of their subordinates to participate or not, and shall not be present at the time of research recruitment sessions and consent involving members of units under their command. The IRB shall appoint an ombudsman for research involving Service Members as human subjects that is greater than minimal risk and when recruitment occurs in a group setting.

For surveys performed on Department of Defense personnel, they must be submitted, reviewed, and approved by the DoD after the research protocol has been reviewed and approved by the IRB.
- DoD Directive 3216.02, 7.e.(1)(b), (d), (2)(d)
- [AAHRPP Element II.3.C]

Compensation to Participants (Payment and Limits)
Limitations on dual compensation prohibit US military personnel from receiving payment for research during duty hours, but the participant may be paid for participation during off duty hours. However, federal employees while on duty and non-federal persons may be compensated for research blood draws up to $50 for each blood draw. Non-federal employees may be compensated for research other than blood draws in a reasonable amount as approved by the IRB.
- DoD Directive 3216.02, 11
- Dual Compensation Act (Title 5 USC Section 5533), 24 U.S.C 30
- [AAHRPP Element II.3.C]

Research Involving a Human Being as an Experimental Subject (subset of research involving human subjects.)
An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f)).
- DoD Directive 3216.02, Glossary Part II: Definitions
- [AAHRPP element II.3.G]

Risk Evaluation; Definition of Minimal Risk
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The phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” in the definition of minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life.

For example, risks imposed in research focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

- DoD Directive 216.02, 6.b.
- [AAHRPP element II.3.A]

**Vulnerable subjects**

Additional safeguards shall be provided for subjects who may be considered vulnerable to coercion or undue influence because of their age, health, employment, financial status, or other circumstances. Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D. Research involving children cannot be exempted.

**Pregnant women, fetuses and neonates:**

- DHHS 45 CFR 46 Subpart B applies, replacing the phrase “biomedical knowledge” with “generalizable knowledge”.
- The applicability of Subpart B is limited to research that is more than minimal risk and includes interventions or invasive procedures to the woman or fetus; or research involving fetuses/neonates as human subjects.
- Human subjects research using fetal tissue shall comply with U.S.C. title 42 (289g-289g-2).

**Prisoners:** DHHS 45 CFR 46 Subpart C applies:

All prisoner research must be reviewed and approved at a convened IRB meeting, including research which meets the criteria for exemption. Research involving prisoners cannot be reviewed by expedited procedures. When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.

Epidemiological research is allowable, if the research:

1. Describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor associations for a disease;
2. Presents no more than minimal risk;
3. Presents no more than an inconvenience to the human subject;
4. Does not focus particularly on prisoners.

If a participant becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the institutional official and DoD Component office review the IRB’s approval to change the research protocol.

Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy.
The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-participant’s confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-participant to continue to participate in the research. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.

**Detainees and POWs:**

The IRB is aware of the definition of “prisoner of war” for the DoD component granting the addendum. Research involving prisoners of war is prohibited. Research involving any person captured, detained, held, or otherwise under the control of DoD personnel is prohibited.

The prohibition does not apply to detainee research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.

- DoD Directive 3216.02, 7
- [AAHRPP element II.4.A]

**Limitations on research where consent by legally authorized representatives is proposed**

In such cases, the determination that research is intended to be beneficial to the subject must be made by the IRB.

- DoD Directive 3216.02, para. 4.2.1
- [AAHRPP element II.4.A]

**Waivers of Informed Consent**

**DoD:** For research involving a human being as an experimental subject, waivers of the consent process are prohibited unless granted by Assistant Secretary of Defense for Research and Engineering.

- DoD Directive 3216.02, 9

**Other DoD and DON Requirements**

**Training**

Initial and continuing research ethics education is required for all University of Louisville personnel who conduct, review, approve, oversee, support, or manage human participant’s research.

a. Initial and continuing education and training shall be commensurate with the duties and responsibilities of the University of Louisville personnel working on DoD-funded research.

b. All training and education of University of Louisville personnel shall be documented.

c. Professional certification in the field of human research protection is encouraged for all personnel involved in review and oversight of research involving human subjects.

d. When assessing whether to support or collaborate with an external institution on DoD funded research involving human subjects, the institution should evaluate the external institution’s education and training policies to ensure the personnel are qualified to perform the research. The rigor of the evaluation should be appropriate for the complexity and risk of the research.

Information on required training for Human Subjects Research is available through the HSPPO website and in the HRPP Policy Manual Chapter 4.
IRB staff, chair/vice chairs, members, and researchers/research staff become aware of specific requirements contained in the DoD regulations and become educated about these requirements through reviewing this Guidance Document, reviewing DoD Directive 3216.02, and by contacting the HSPPO office for consultation, guidance, or for further information on specific DoD regulations.

In addition, there may be additional training requirements imposed by the DoD for all University of Louisville researchers working on DoD-funded research based on the complexity and risk of the research. Please consult the IRB office for additional questions on training requirements.

- DoD Directive 3216.02, 5.d
- [AAHRPP element I.1.E.]

Scientific Review
- DoD Directive 3216.02, 4.b.2
- [AAHRPP element I.1.F.]

Definition: Human Subject Research
- DoD Directive 3216.02, Glossary Part II: Definitions
- [AAHRPP element II.3.G]

Children: DHHS 45 CFR 46 Subpart D applies
  DoD Directive 3216.02, 7b.(3), 32 CFR 219.101(i) footnote #1
  [AAHRPP element II.4.A]

When a subject becomes a prisoner see:
- DoD Directive 3216.02, 7d.
- [AAHRPP element II.4.A]

Record Keeping and Retention
Records maintained that document compliance or non-compliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

- DoD Directive 3216.02, 15.a., d.
- [AAHRPP element II.5.A, II.5.B]

Transnational Research

All transnational research conducted by UofL researchers will follow federal guidelines, be reviewed by the UofL IRBs, and follow requirements (including local laws, regulations, and customs) of the location where the research is conducted. All UofL policies and procedures which are applied to research conducted domestically will be applied to research conducted in other countries, as appropriate.

The UofL IRB will not take action to approve an application without either written documentation that local review and approval has been granted in the host country, or the consult requested by the IRB has been received and accepted. The protocol will be submitted following the same procedures utilized to submit any other protocol. Refer to HRPP Policy Chapter 13.
(including National Institute on Disability and Rehabilitation Research (NIDRR))

School officials and/or teachers do not have the authority to give consent for the participation of children in research. Only a parent or legally authorized representative may allow a child, with the child’s assent, to participate in research.

The IRB requires documentation of approval of the school prior to allowing investigators to contact, recruit, or enroll children into a study. Investigators should contact the appropriate school officials in the district in which the wish to conduct the research regarding the procedures for obtaining permission to conduct the research in individual schools.

Under FERPA, Generally, schools must have written permission from the parent or eligible student in order to release any information from a student's education record. However, FERPA allows schools to disclose those records, without consent, to the following parties or under the following conditions (34 CFR § 99.31):

- School officials with legitimate educational interest;
- Other schools to which a student is transferring;
- Specified officials for audit or evaluation purposes;
- Appropriate parties in connection with financial aid to a student;
- Organizations conducting certain studies for or on behalf of the school;
- Accrediting organizations;
- To comply with a judicial order or lawfully issued subpoena;
- Appropriate officials in cases of health and safety emergencies; and
- State and local authorities, within a juvenile justice system, pursuant to specific State law.

Schools may disclose, without consent, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. However, schools must tell parents and eligible students about directory information and allow parents and eligible students a reasonable amount of time to request that the school not disclose directory information about them.

Kentucky Revised Statutes (KRS) mirror the requirements of the federal regulations and are applicable to all Kentucky public schools.

Jefferson County Public Schools (JCPS) utilize their Code of Acceptable Behavior and Discipline which includes their Student Bill of Rights (p.29) (Attachment 1) to notify parents and guardians of their and their children’s rights.

PPRA, as amended, has two sets of requirements for surveys:

- Requirements that apply to “protected information” surveys that are funded in whole or in part by the U.S. Department of Education.
- Requirements that apply to "protected information" surveys that are funded by sources other than the U.S. Department of Education and that are administered or distributed by education institutions that receive funds from any Department of Education program (i.e. public elementary and secondary schools and some private schools).

PPRA, updated by NCLB in 2001, lists 8 categories of protected information for survey responses. If a student or parent is surveyed and the survey contains questions related to any one of the following eight categories, provisions must be made to solicit the active consent of the parent or guardian and the assent of the student:

1. political affiliations or beliefs of the student or the student's parent;
2. mental or psychological problems of the student or the student's family;
3. sex behavior or attitudes;
4. illegal, anti-social, self-incriminating, or demeaning behavior;
5. critical appraisals of other individuals with whom respondents have close family relationships;
6. legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
7. religious practices, affiliations, or beliefs of the student or student's parent; or
8. income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

PPRA has implications for IRBs in applying the Common Rule criteria for waiving informed consent (in section 116(d) of the Common Rule). Specifically the second IRB criterion: "research does not adversely affect the rights and welfare of subjects" is impacted because of the "rights" that PPRA gives parents.

Practical Implications in Applying the Common Rule Waiver Requirement pertaining to rights and welfare:

First Set of Requirements: US Department of Education Funded Protected Information Surveys
- Does the research involve "protected information" surveys?
- Are the surveys U.S. Department of Education- funded in whole or part?
- Are the surveys “required”?
If the answer is yes to the three questions, PPRA affords parents the right to provide active consent.

Under the circumstances, it would be difficult for an IRB to determine that the "rights and welfare" criterion for waiving informed consent entirely could be met; therefore, prior written parental consent would be required, even if the IRB determined that some of the basic elements of informed consent specified in section 116(a) could be waived as inappropriate to the activity.

Second Set of Requirements: Surveys that are funded by sources other than the U.S. Department of Education and that are administered or distributed by education institutions that receive funds from any U.S. Department of Education administered program (i.e., public schools and some private schools)
- Do the surveys include protected information?
- Are the surveys being administered or distributed by schools that receive any U.S. Department Education funds?
If the answer is yes to both questions, PPRA affords parents the right to inspect the surveys before they are administered or distributed and to opt the student out of the surveys.

PPRA requires schools to develop and adopt policies, in conjunction with parents, regarding 6 areas, some of which are relevant to surveys:
- Right to inspect a survey before administered or distributed;
- Arrangements to protect student privacy in the administration of a survey;
- Right to inspect any instructional material used as part of educational curriculum;
- Administration of physical examinations or screenings;
- Collection, disclosure or use of personal information for purposes of marketing or selling;
- Right to inspect any instrument in the collection of information for marketing or selling the surveys.

PPRA also requires schools to notify parents of the policies and to offer parents the opportunity to opt out of (remove child from) participation in third-party surveys involving protected information.
Exception (Exemption) from Written Informed Consent

When using the exception of informed consent, the following is required to comply with the Family Educational Rights and Privacy Act (FERPA).

A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the university or investigator conducting the research that specifies:

- The determination of the exception.
- The purpose, scope, and duration of the study.
- The information to be disclosed.
- That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
- That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the institution with legitimate interests.
- That the institution is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
- The time period during which the institution must either destroy or return the information.

The University of Louisville has in policies and procedures, a process to grant exceptions to parental/student consent to release student records for research. This responsibility is delegated to the Chair and Vice-Chairs of the IRB.

Under FERPA, the following information must be removed to release education records without consent:

- Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
- Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

- Develop, validate, or administer predictive tests.
- Administer student aid programs.
- Improve instruction.

Obtaining Student Records or Personal Education Information

When researchers obtain student records or personal education information from an education program (as defined in 34 CFR 99.3), such activity is subject to the Family Educational Rights and Privacy Act (FERPA).

- 34 CFR 99.3 [FERPA Definitions]
- [AAHRPP element II.3.G.]

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Releasing Records Without Consent

An educational institution may disclose personally identifiable information from an education record of a student without consent under certain conditions as listed in FERPA.

- 34 CFR 99 [FERPA]
- [AAHRPP element II.3.G.]

Protection of Students

No student shall be required, as part of any program specified in §98.1 (a) or (b), to submit without prior consent to psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning certain topics.

- 34 CFR 98.4
- [AAHRPP element II.4.B.]

Protection Of Pupil Rights

Inspection of instructional materials by parents or guardians; Limits on survey, analysis, or evaluations;

Local policies concerning student privacy, parental access to information, and administration of certain physical examinations to minors.

- 20 U.S.C. Ch.31, Subchapter III, Part 4, § 1232h especially (a),(b),(c)(1) (as was amended by PUBLIC LAW 107–110—JAN. 8, 2002 115 STAT. 2083)
- [AAHRPP element II.4.B.]

Access to Instructional Material Used In Research or Experimentation Program:

All instructional material—including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project shall be available for inspection by the parents or guardians of the children engaged in such program or project.

- Research or experimentation program and children or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
- Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

- 34 CFR 98.3
- [AAHRPP element III.2.C.]

Representation for Vulnerable Subjects on the IRB

When an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.

- 34 CFR 356.3
- [AAHRPP element II.1.E.]