



CATEGORIES OF RESEARCH EXEMPT FROM OHIO STATE IRB REVIEW

Category 1

Research conducted in established or **commonly accepted educational settings**, involving **normal educational practices**, so long as the research is not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, such as:

- Research on regular and special education instructional strategies
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2

Research involving the use of **educational tests** (cognitive, diagnostic, aptitude, achievement), **survey procedures**, **interview procedures** or **observation of public behavior** (including visual or auditory recording) uninfluenced by the investigator if at least one of the three criteria is met:

- The information is recorded without direct or indirect identifiers;
- Disclosure outside of the research would not reasonably place the subjects at risk of harm (e.g., legal, financial, reputational, employability); or
- The information is recorded with either direct or indirect identifiers, and there are adequate protections in place for protecting privacy and maintaining confidentiality (requires limited IRB review).

Note: *The exemption under category 2 does not apply when individuals under the age of 18 are subjects of the activity except for research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*



Category 2
tip sheet

Category 3

Research involving **benign behavioral interventions** (brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think that the participants will find the interventions offensive or embarrassing) 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 is met:

- The information is recorded without direct or indirect identifiers;
- Disclosure outside of the research would not reasonably place the subjects at risk of harm (e.g., legal, financial, reputational, employability); or
- The information is recorded with either direct or indirect identifiers, and there are adequate protections in place for protecting privacy and maintaining confidentiality (requires limited IRB review).

Note: *If the research involves **deceiving subjects** regarding the nature or purposes of the research, this exemption is not applicable unless the subject is informed in advance that he or she will be unaware of or misled regarding the nature or purposes of the research.*



Category 3
tip sheet

EXEMPT CATEGORIES, CONT'D

Category 4 Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- The identifiable private information or identifiable biospecimens are publicly available;
- The information, which may include information about biospecimens, is recorded by the investigator in such a way that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects or try to re-identify subjects;
- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated by the HIPAA Privacy Rule (**Not available at Ohio State**); or
- The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, provided that the original collection was subject to specific federal privacy protections and continues to be protected.

Category 5 Research and demonstration projects which are conducted by or subject to the approval of **federal department or agency heads**, and which are designed to study, evaluate, or otherwise examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, possible changes in methods or levels of payment for benefits or services under those programs.

Note: Projects eligible for exemption under this category will be posted on the applicable federal agency's website.

Category 6 Taste and food quality evaluation and consumer acceptance studies, if:

- Wholesome foods without additives are consumed; or
- 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.

Category 7 Storage or maintenance of identifiable data and/or biospecimens obtained with "broad consent"

Not available at Ohio State.

Category 8 Use of identifiable data and/or biospecimens obtained with "broad consent"

Not available at Ohio State.

Additional Notes

- These exemptions do not apply when the proposed activity(ies) might expose the human subjects to **discomfort or harassment** beyond levels encountered in daily life.
- These exemptions do not apply when individuals **involuntarily confined or detained** in penal institutions are subjects of the activity.
- Exempt determinations are made by designated ORRP staff and/or IRB members; investigators are not permitted to make their own determinations of exemption. Requests for exempt determinations should be submitted in Buck-IRB.
- For more information, see HRPP policy [Exempt Research](#).

Tip Sheet: Overview of IRB Submissions (medical focus)

	NOT HUMAN SUBJECTS RESEARCH	EXEMPT	EXPEDITED	CONVENED
Risk/criteria	Not applicable	Fits exemption category(ies), <i>presumed low risk</i>	1. Fits expedited category(ies) AND 2. Minimal risk (if FDA-regulated)	<ul style="list-style-type: none"> Greater than minimal risk OR Does not fit expedited categories
Type of review	Not applicable	ORRP staff review	Review by one IRB member	Review by full Board
Initial submission requirements	Not applicable <i>A NHSR determination can be requested by emailing ORRPdeterminations@osu.edu</i>	Buck-IRB: exempt application (abbreviated)	Buck-IRB: initial submission application	Buck-IRB: initial submission application
Review time (median) https://orpp.osu.edu/irb/timeline-to-approval/	Not applicable	5 calendar days	30 calendar days	70 calendar days
Examples	<ul style="list-style-type: none"> Analysis of de-identified data from Information Warehouse (Honest Broker)* Quality improvement project without the intent to generalize results Physician's off-label use of approved drug for treatment <p><i>* If study does not involve FDA-regulated device</i></p>	<ul style="list-style-type: none"> Use of existing data/specimens without identifiers* Survey of staff on medical practices Patient surveys that do not elicit sensitive info <p><i>* If study does not involve FDA-regulated device</i></p>	<ul style="list-style-type: none"> Secondary use (prospective or retrospective) of identifiable data/specimens Blood draws, dental scrapings, etc. Non-invasive medical procedures (ultrasound, mild exercise, MRI) Observational studies Some drug/medical device studies that do not require INDs/IDEs 	<ul style="list-style-type: none"> Most FDA-regulated clinical trials involving drugs, devices, tobacco products, etc. Medical procedures posing greater than minimal risk Studies involving greater than minimal levels of non-physical risks (psychological, social, economic, legal) Repository/banking protocols
Annual review requirements	Not applicable	None; active for 3 years in Buck-IRB	Buck-IRB: Annual Status Report (most studies)	Buck-IRB: Continuing Review application (most studies)
Report changes?	Not applicable	Yes: New exempt application	Yes: Buck-IRB Amendment	Yes: Buck-IRB Amendment
Report problems?	Not applicable	Yes: exemptinfo@osu.edu	Yes: Buck-IRB Event Report	Yes: Buck-IRB Event Report



Additional Resources

General ORRP Resources

- Investigator Guidance: <https://orrrp.osu.edu/irb/investigator-guidance/>
- HRPP Policies: <http://orrrp.osu.edu/irb/osuirbpolicies/hrpppolicies/>
- Human Subjects FAQs: <http://orrrp.osu.edu/article-categories/human-subjects/>
- Educational Offerings (upcoming & archived):
<https://orrrp.osu.edu/irb/workshopsseminars/>

IRB & Review Information

- IRB rosters: <https://orrrp.osu.edu/irb/about-irb/>
- Convened meeting dates: <https://orrrp.osu.edu/irb/irbmeetings/>
- Time to approval: <http://orrrp.osu.edu/irb/time-to-approval/>

Buck-IRB Resources

- Buck-IRB access: <http://go.osu.edu/Buck-IRB>
- General information: <https://orrrp.osu.edu/irb/buck-irb/>
- Buck-IRB application forms (for reference only): <https://orrrp.osu.edu/irb/buck-irb/buck-irb-offline-printable-forms/>
- Recorded education session – “Buck-IRB and Initial IRB Submissions – medical focus” (March 2019): <http://orrrp.osu.edu/irb/workshopsseminars/orrrpeducation/>

Collaborative Research

- Collaborative research inbox: IRBAgreements@osu.edu
- FAQs: <http://orrrp.osu.edu/article-categories/collaborative-research-and-agreements/>
- Engagement determination tool: <http://go.osu.edu/hsengagement>
- Collaborative research tools – decision trees & Buck-IRB guidance:
https://orrrp.osu.edu/files/2019/09/Packet_Collaborative-Research-Tools.pdf
- Recorded education sessions: <http://orrrp.osu.edu/irb/workshopsseminars/orrrpeducation/>
 - “Let’s Work Together: IRB Oversight of Collaborative Research – Part 1” (August 2019)
 - “Let’s Work Together: IRB Oversight of Collaborative Research – Part 2” (September 2019)
 - “Advarra Review of Human Subjects Research” (January 2020)
 - “Submission to Western IRB under the Revised Common Rule” (April 2019)

Exempt Research

- Investigator guidance: <http://orpp.osu.edu/irb/investigator-guidance/exempt/>
- Exempt FAQs: <https://orpp.osu.edu/article-categories/exempt-research/>
- Exempt inbox: exemptinfo@osu.edu
- Recorded education session – “Exempt Research under the Revised Common Rule” (January 2019): <http://orpp.osu.edu/irb/workshopsseminars/orppeducation/>

Informed Consent Process & HIPAA Research Authorization

- Consent templates & guidance: <http://orpp.osu.edu/irb/investigator-guidance/consent/>
- HIPAA authorization template & guidance: <http://orpp.osu.edu/irb/investigator-guidance/hipaa/>
- Recorded education sessions: <http://orpp.osu.edu/irb/workshopsseminars/orppeducation/>
 - “Troubleshooting Informed Consent” (June 2019)
 - “Electronic Informed Consent: Processes, Platforms, and Participants” (April 2019)
 - “Waivers of Informed Consent and HIPAA Research Authorization” (July 2019)

Research involving Data and Specimens

- Recorded education session – “Secondary Analysis of Data & Biospecimens” (August 2018): <http://orpp.osu.edu/irb/workshopsseminars/orppeducation/>
- FAQs: <http://orpp.osu.edu/article-categories/research-involving-secondary-use-of-data-and-or-specimens/>
- dbGaP and other genomic data sharing guidance: <http://orpp.osu.edu/irb/investigator-guidance/submission-of-data-to-dbgap-and-other-requests-for-genomic-data-sharing/>

Resources for Ongoing Research

- Continuing Review & Annual Status Report Decision Tree: https://orpp.osu.edu/files/2019/11/Tip_Sheet_ASR_vs_CR_chart.pdf
- Event reporting guidance: <http://orpp.osu.edu/irb/investigator-guidance/event/>
- Recorded education sessions: <http://orpp.osu.edu/irb/workshopsseminars/orppeducation/>
 - “Amendments and Buck-IRB” (December 2019)
 - “Continuing Review under the Revised Common Rule” (February 2019)
 - “Event Reporting in Human Subjects Research” (May 2019)