Exempt Research

Standard

The standard applies to research that meets the criteria for exemption under 45 CFR 46.104. Research that is determined to be exempt is still considered to be human subjects research, however it is exempt from meeting the requirements of 45 CFR 46 and must meet Longwood IRB requirements for exempt human subjects research.

Human subjects research activities must be reviewed to determine whether the research meets one of more of the exemption categories and, if so, whether the research complies with applicable ethical standards. Research personnel do not have the authority to make an independent determination that research involving human subjects is exempt and must obtain determination of exemption prior to beginning the research. A determination of the exemption category must be made by the Longwood IRB. Although the research may qualify as exempt from the regulatory requirements, it must still be conducted in accordance with the ethical principles for human subjects research outlined in the Belmont Report, Longwood IRB Standards and Procedures, and other federal and applicable international regulations including but not limited to:

- Family Educational Rights and Privacy Act (FERPA) rules about student records
- Protection of Pupil Rights Amendment (PPRA) rules about giving surveys to students in schools
- HIPAA privacy rules about protected health information (e.g., medical records)

Procedures

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Exempt Determinations and Approvals

- Exempt determinations and approvals are made by the IRB Chair or a designated IRB member. Any member of the IRB may be designated to make exempt determinations.
- Research activities for projects that meet the criteria for exempt status can proceed from the date of the exempt determination and approval on the notification.
- All research activities in the project must meet the criteria for exemption for the project to receive an exempt determination.

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Multi-site and Collaborative Research

Longwood University will accept an exempt determination made by another institution. Other institutions may choose to accept Longwood's exempt determination depending on that institution's policies for exempt research. If another institution will rely on Longwood for limited IRB review, the reliance must be documented in the standard way for any reliance.

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General Exclusions from Exemption

- Studies that are greater than minimal risk do not qualify for exemption and rapid review with the exception of Exempt Category 5, which can involve greater than minimal risk. This is based on statements in the Preamble to the Revised Common Rule and communications from OHRP.
- Exemptions do not apply to research with prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners (45 CFR 46.104(b)(2)).
    - The Preamble to the Revised Common Rule states that subjects may continue their participation in exempt research if they become prisoners after beginning their participation.
    - No research involving interactions or interventions with prisoners qualifies for exempt status.
- Exemption 2(iii) and Exemption 3 do not apply to research with children. Exemption 2(i) and 2(ii) involving educational tests or the observation of public behavior may only apply to research with children if the investigator(s) do not participate in the activities being observed.
- The research is FDA regulated. Exempt status is not granted to research that is subject to regulations for the Food and Drug Administration. Exemptions other than Exemption Category 6 do not apply to FDA-regulated research.
- All Exemption categories may apply to research that targets Longwood student-athletes.
- Studies that use identifiable data may also undergo limited IRB review under 45 CFR 46.111(a)(7) as part of the criteria for exemption.

Examples of research that may or may not be exempt

- A study that involves interviews and the secondary analysis of research data recorded without identifiers **may qualify** for exempt status because the research activities are described in exempt category 2 and category 4.
- A study that involves interviews and blood draws **will not qualify** for exempt status because while interviews are described in exempt category 2, a blood draw is not an activity described in the categories of exempt research.
- The first phase of a two-phase study involves only surveys and interviews. The second phase involves surveys, interviews, chart reviews, blood draws, and MRIs. The **first phase may qualify** for exempt status because interviews are included in the categories of exempt research, but **the second phase will not**. Longwood IRB staff may review the first phase as a stand-alone project and issue a determination of exempt status. The second phase could later be submitted as an amendment, or as a separate IRB application, requiring IRB review.

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Research Involving Deception or Concealment

Research involving deception or concealment may qualify for exempt category 3 if:

- The subjects prospectively agree to be deceived;
- The deception is necessary to ensure valid results;
- The deception is not being used to get the subjects to do something that the majority of them would not do if the information was fully disclosed to them;

- The conditions pose no more than minimal risk of physical or emotional distress;
- Participants are adequately debriefed in a timely manner and provide consent for the use of their data.

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Informed Consent Requirements

Investigators will obtain prospective informed consent in a manner that is appropriate for the methodology employed and target subject population, examples:

- Informed consent material should be presented prior to survey questions and the anonymous indication of consent collected with the survey data;
- Researchers using interview techniques will deliver the consent material in writing prior to the interview.
    - The informed consent material may be delivered electronically and consent documented via a reply through the electronic method of communication. Consent will be reaffirmed verbally at the beginning of the interview and recorded as part of the interview.
    - Questions should be framed to continuously reaffirm voluntariness
- Informed consent should be collected in hard copy when research interactions are in-person.

Informed consent templates are available. Informed Consent materials should contain the following elements:

- A statement that the activity is research and that participation is voluntary;
- A brief description of the primary study procedure(s) – e.g. answering questions, time requirement;
- A statement that the research is minimal risk and any benefits or compensation to the subjects;
- How the data will be used and if the data will be shared with other researchers or used in future studies, and whether identifiable data will be de-identified for this purpose.
- How the data will be stored, used, secured, and deleted.
- The lead researcher(s) names, affiliation(s), and contact information. For student-led research, the class (if applicable) should be identified, and faculty mentor's contact information provided.
- Contact information for the Longwood IRB (irb@longwood.edu) in case of questions or concerns, including the link to anonymously report a concern.
- The opportunity for subjects to choose whether or not to participate.
- A statement that participants may withdraw at any time.

Broad Consent is a specific type of consent that participants can give allowing their **identifiable** private information or **identifiable** biospecimens to be used for future research studies beyond the initial study for which consent was obtained. **Important**: At this time, the Longwood University IRB will not mandate nor implement the institutional use of broad consent, as the tracking requirements may be burdensome. Exempt category 7 and category 8, which rely on broad consent, will not be utilized. Longwood University IRB will continue to support investigators seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through other processes including comprehensive IRB review and consent procedures as appropriate.

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Waivers of Informed Consent and/or the Documentation of Informed Consent

- Student-led research may not utilize waivers of informed consent or the documentation of informed consent.
- Faculty may apply for a waiver of informed consent under the conditions listed in 45 CFR 46.116(f)(3). The IRB must find and document that:
    - The research involves no more than minimal risk to the subjects;
    - The research could not be practicably carried out without the requested waiver;
    - If the research involves identifiable information or biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format;
    - The waiver will not adversely affect the rights and welfare of the subjects; and
    - Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- Faculty may apply for a waiver or alteration of the requirement to document a subject's informed consent in the manner that is appropriate for the study methodology.

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Criteria for Approval (45 CFR 46.111)

In order to approve human subjects research the IRB shall determine that all of the following requirements are satisfied:

- Risks to subjects are minimized.
- Study procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
- Risks are reasonable in relation to anticipated benefits realizing that most research does not directly benefit the subject.
- Subject selection and recruitment is equitable and does not involve coercion or undue influence.
- Informed consent is sought in a manner that is appropriate for the subject population and the research methodology.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- There are adequate provisions to protect the privacy of subjects and confidentiality of data.
- Adequate steps are taken to ensure data security.

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Approval Periods

- Class-related projects will be approved for three months (undergraduate) or 1 year (graduate).
- Student-led independent research will be approved for 1 year (undergraduate) or 3 years (graduate) with the option of continuing approval for additional years.
- Faculty-led independent research will be approved for 3 years with the option of continuing approval for an additional 3 years.

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Continuing Approval and Annual Check-Ins

- Investigators will complete annual check-ins to verify the status and progress of the project. Non-completion of annual check-ins may result in the suspension of approval or administrative closure of the project.
- Projects will be administratively closed one month after the expiration of approval unless continuing approval is requested.

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Amendments to Exempt Research Projects

Consider the impact of a research modification before implementing it. Researchers commonly make modifications to their research during the course of a study. Changes to the research may invalidate the exempt determination because the research no longer meets the exempt criteria described in this guidance.

Some changes always require Longwood IRB to review a modification and make re-determination of exempt status. **Many other changes do not**.

Changes that always require a re-determination of exempt status

- **New types of subjects, data, or specimens.** For example, adding: children, patients with a different disease, records (e.g., student educational records, medical records) when previously those records were not used, changes in the scope of questionnaires, surveys, interviews, focus groups.
- **New types of procedures**, when it means that the research methods no longer fit into the same exempt category.
- **Switching the method of data collection to another method within the same category** for example, from a focus group to an individual interview or an interview to a survey on the same topics.
- **Obtaining funding or other support**.
- **Obtaining or recording identifiable data or specimens** for studies that previously obtained only de-identified or anonymous data or specimens. Identifiable data may require adding a limited IRB review.
- **Increased risk** due to any change. For example, adding sensitive questions to a survey or interview process (e.g. questions regarding illegal activities; traumatic events such as childhood, sexual, or domestic abuse; suicide; or other probing questions that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation).
- **New intent to submit the research data to the Food and Drug Administration (FDA).**

Changes that do not require a re-determination of exempt status

- **Adding similar survey or interview questions that do not increase risk.** Questions must be similar in scope, content, and sensitivity level to what is already described in the IRB Protocol.
- **Revising an intervention (defined in category 3) to something similar that does not increase risk.** The new intervention must be comparable in nature, duration, and potential for harm, embarrassment, or discomfort as was already described in the IRB Protocol.

- **Increasing data security protections for a study with limited IRB review.** No additional limited IRB review is required when a more protective safeguard is put in place.
- **Adding a subject population that is similar to what is already approved.** For example, it would not require a modification to add interviews with surgeons, generally when the application describes interviewing neurosurgeons or to add Longwood graduate students when the application describes Longwood undergraduates.
- **Making changes to: number of subjects, consent and recruitment materials or methods, survey platform being used, or study instruments** so long as the changes don't fall into one of the categories that require a re-determination, as listed above.
- **Updating the study team in eProtocol** unless the changes are needed to grant access to the eProtocol application.

For all other changes, researchers should assess the proposed changes against the exemption criteria described in this guidance. If you are unsure whether a modification is needed, consult with Longwood IRB staff.

Amendments are submitted in eProtocol. Describe the changes, submit the modification and Longwood IRB staff will make a re-determination.

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Limited IRB Review

Limited IRB Review (LIRB) **i**s a type of IRB review that is required for granting exempt status, in some circumstances, for exempt category 2 and category 3 (also categories 7 & 8 which Longwood does not use).

- Longwood IRB staff identify the need for LIRB approval during review of the application materials.
- It is focused on only one criterion for IRB approval: that there are appropriate protections for subject confidentiality and privacy.
- It must be conducted by a qualified IRB member who is authorized to conduct expedited IRB review.
- It is subject to IRB records requirements.
- LIRB approval is granted simultaneously with exempt status.

LIRB is not allowed for research that is subject to the regulations of the Food and Drug Administration (FDA) or Department of Justice (DoJ).

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Exempt Research Categories Under 45 CFR 46.104

Exempt Category 1 – Educational Research

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.

Established or commonly accepted educational settings are settings where one would go to have an educational experience that is regularly offered in the location where the research will be conducted or that is commonly accepted in a specific culture or population. This could include a wide variety of traditional and nontraditional settings if they are established or commonly accepted, such as:

- Public or private schools and classrooms offering K-12 education, college degrees or technical vocational instructions and certifications
- After school clubs or programs, vocational schools, alternative education programs
- Boy or Girl Scout meetings
- Professional development seminars or programs (e.g., Toastmasters)
- Driver education programs or schools
- Education in applied settings (e.g., grocery stores that offer cooking or nutrition classes; bicycle shop that offers bicycle repair and maintenance classes; woodworking techniques instruction offered in a community "maker space"; skills development programs in children's summer camps)
- Distance and online educational programs
- Internships and study abroad programs

Normal educational practices are activities that could occur in the specific educational setting regardless of whether the research is conducted. This includes a variety of activities that normally occur in the classroom or that are considered "best practice". Examples include established teaching methods (not considered to be experimental) or curriculum, and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher.

- Examples that **would likely** be considered normal educational practice:
    - A study evaluating the effectiveness of a commonly accepted science curriculum. For the study, researchers will observe classroom instruction and collect quizzes and class evaluations that are part of the curriculum and classroom practice.
    - Comparisons of curricula, different instructional methods, or classroom management techniques that are currently being implemented in a school. Researchers will observe a classroom as well as interview instructors about their experiences implementing the instructional materials or methods (but not interview specific students).
    - A study comparing driver's education curricula offered by area driving schools. The researcher will observe and compare group driving test scores at the end of the course.
    - Evaluation of student attitudes toward learning.
- Examples that are generally **not** considered to be normal educational practice:
    - Research that involves deception because deception is not a normal education practice.
    - Collecting privileged or sensitive personal information for research purposes.

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Exempt Category 2 – Educational tests, surveys, interviews, observations of public behavior.

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).

Research involving children does not qualify for this category if: (1) the research involves surveys, interviews, and/or observations of public behavior when the research team participates in the activities being observed; or **(2)** if limited IRB review is required.

Risk and risk mitigation. Although it is conceivable that there may be psychological risks to participating in surveys or interviews, or situational risks where awareness that someone was surveyed or interviewed poses a risk, the assumption for this category is that the potential risks are largely informational. It is reasonable to expect that individuals will understand that actively providing responses to educational tests, surveys, or interview procedures constitutes agreement to participate and that the risks associated with their participation are related to disclosure of the information they provide. Thus, the most important role the IRB (or other determination body) might play in reducing potential harm is to ensure appropriate privacy and confidentiality safeguards.

Limited IRB review. For details review the section on Limited IRB Review

Protected and vulnerable populations. There are no restrictions on the involvement of pregnant women. Research in this category must comply with the general restriction on the involvement of prisoners. Children may not be involved in this category as described above.

Survey means the collection of information about individuals through questionnaires or similar procedures. It does not include the collection of biospecimens.

Public behavior means behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy. Examples of location include: a public plaza or park, street, building lobby or sections of a government building that are open to the public, some websites and social media sites. The Preamble to the Revised Common Rule states that the public behavior must not be influenced by the investigator and cannot involve an intervention. For examples, research involving observation of

public behavior does not qualify for this exemption if the investigator intervenes with the subject by offering them a supposedly lost wallet to see if they will accept it.

Intervention. The use of an intervention is not allowed. The Preamble to the Revised Common Rule states that interventions that are distinct from the information collection methods allowable under this exemption do not satisfy the conditions of this exemption. It notes, however, that educational tests may include exposing test takers to certain materials as part of the test, and that such materials do not constitute interventions distinct from the test.

- **Examples of activities that are *not* interventions,** because the activities are not distinct from data collection:
    - A reading comprehension test that directs subjects to read a passage and then answer questions about it
    - A geography test that presents a map to the subjects and asks them to draw information from the map
    - Survey that contain some information about which the subjects are asked questions
- **Examples of activities that *are* interventions:**
    - Randomly assigning students to take an education test in a quiet room or a room with moderate noise
    - Randomly assigning students to consume a snack (or not) before taking a test
    - Surveys or interview in which the purpose is to see whether respondents answer questions differently depending on the interviewer's gender

***Task* compared with *intervention*.** The purpose of an intervention is to determine how an activity changes the subjects or their performance. Many tasks do not meet this definition of an intervention. In general, asking subjects to physically manipulate an object, play a game, complete a specific physical action, read, write, look at visual stimuli, listen to auditory stimuli, or imagine something would be considered interventions only if the intent of the activities were to change subjects or to compare results across different activities, physical stimuli, visual stimuli, auditory stimuli, etc.

- **Not an intervention –** Ask subjects to physically manipulate an object as part of an educational test and ask subjects about the object or their manipulation of it
- **Not an intervention –** Activities intended to elicit subjects' strategy, method, or ability for performing a specific goal-directed activity
- **Intervention –** Ask subjects to manipulate two objects with the purpose of comparing the results for object 1 versus object 2
- **Intervention –** Ask subjects to read a paragraph about a current event in order to assess subjects' attitudes about a societal problem before and after reading the paragraph
- **Intervention –** Research that uses activities or stimuli in order to see whether the subjects' thoughts, emotions, behaviors, or cognitive performance can be manipulated or changed by the activities or stimuli

Interpretation of the word "only". Longwood IRB interprets the word "only" (i.e., the third word in the regulatory description) as defining what is acceptable for category 2. It does not exclude research from

being considered exempt if some parts of the research fit into category 2 and the rest of the research fits into one or more of the other exempt categories.

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Exempt Category 3 - Benign behavioral interventions.

(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.

Research involving children does not qualify for this exempt category.

Category 3 versus category 2. Unlike category 2, this category allows: **(1)** interventions distinct from other data collection methods; and **(2)** audiovisual recording is allowed without any educational tests, survey or interview procedures occurring.

Benign behavioral interventions are defined as brief in duration[1], harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the subjects, and the researcher has no reason to think that the subjects will find the interactions/interventions/observations to be offensive or embarrassing.

[1]**Brief in duration** is intended to refer to the intervention as opposed to the intervention and the data collection activities together. Thus, the data collection activities could proceed over a longer period of time without precluding the applicability of this exemption. If the intervention and the data collection are intertwined and difficult to separate, the entirely of the activity should be brief in duration. To meet the requirement of brief in duration, the benign behavioral intervention should occur within one month and not exceed a few hours in its entirety.

Prospective agreement. Subjects must be asked to agree to participate in research. This is not the same as the requirement for consent or for documentation of consent. The request may be tailored to the nature of the specific study.

Deception. If the research involves deceiving subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subjects authorize deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research.

Limited IRB review. For details review the section on Limited IRB Review.

Examples that qualify for this category

- Having subjects play an online game
- Having subjects solve puzzles under various noise conditions
- Having subjects decide how to allocate a small amount of received cash between themselves and someone else
- Comparing the test performance of test takers in quiet versus noisy surroundings

Examples that do not qualify for this category due to having some reason to think subjects would find the interventions offensive or embarrassing.

- Milgram's obedience experiments
- Stanford Prison Experiment

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Exempt Category 4 - Secondary research

Use of identifiable private information or identifiable biospecimens for which consent is not required, 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 HIPAA regulations, for the

purposes of health care operations, research, or public health activities and purposes (as those purposes are described in the HIPAA regulations).

Note: Longwood IRB generally does not grant exempt status for the use of private health information as this use becomes complicated when the PHI moves from one covered entity to another, or from a covered entity to a non-covered entity. Exempt status may be granted on a case by case basis.

(iv) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information originally obtained for non-research activities, if the original collection and the secondary use of the information or biospecimens occurs in compliance with three specific federal statues meant to safeguard privacy.

The category allows the use of both retrospectively and prospectively gathered information or biospecimens.

Data from prisoners. This category allows for the use of identifiable information or biospecimens obtained from prisoners so long as the research does not intentionally recruit prisoners (i.e., only incidental inclusion of prisoners is allowed).

The category is limited to the secondary use of information or biospecimens. Secondary means re-using identifiable information and identifiable biospecimens that are collected from some other "primary" or "initial" activity; in other words, not for the purpose of the specific proposed study.

"For which consent is not required" is not defined in the Common Rule or its Preamble. In the absence of federal guidance, Longwood IRB's interpretation is the same as the SACHRP federal advisory body. It means: **(1)** there are no federal or state laws that require subject consent for the proposed secondary use; and **(2)** during the original collection of the information or biospecimens, the individuals (if asked) agreed to secondary uses that were described in a manner consistent with the proposed research.

Publicly available is described as applying to secondary research use of (for example) archives in a public library, government or other institutional records where public access is provided on request, or from a commercial entity if the information is provided to members of the public on request or if the only requirement for obtaining the information is paying a user fee or registering or signing in as a visitor to an archive. It also applies if a commercial entity makes identifiable biospecimens available to anyone on request for a fee.

- Longwood IRB generally interprets the use of publicly available identifiable information or specimens as being not human subjects because the public availability seems inconsistent with considering the information or specimen to be private. **Private** is defined by the Common Rule as being **(1)** information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and **(2)** information/biospecimens that have been provided for specific purposes by an individual where the individual can reasonably expect they will not be made public.

Use of identifiable health information means use of personal or protected health information (PHI) that is covered by the HIPAA regulations. This means that **(1)** the subjects must have provided HIPAA authorization for future, secondary research uses of PHI, or that **(2)** an IRB or HIPAA Privacy Board granted a waiver of the HIPAA authorization requirement. This part of the exempt category cannot be used for PHI from anywhere where there are state laws requiring consent (as distinct from authorization) or an IRB-granted waiver of consent.

- **The PHI provision of exempt** category 4 **does not apply to research involving data or specimen sharing, even if the shared data are specimens that are de-identified.** The Common Rule states that this application of exempt category 4 is valid only for PHI collection and analysis "involving the investigator's use of identifiable health information" (45 CFR 46.104(4)(iii).
    - Longwood IRB interprets "the investigator" as meaning the investigator's research team, not a broader national group of investigators. For example, sending identifiable PHI to a data repository would not be considered exempt.
    - This also means that this exempt category is not appropriate for research that will establish a database of PHI for use by multiple investigators. For example, this category does not apply to the establishment of a departmental database. Such research would be reviewed by the expedited process.
    - If the researcher's application is not clear about data/specimen sharing but it mentions a database or repository, the PI will be asked to clarify.
- **Researcher's obtaining consent** may still qualify for the PHI provision of exempt category 4, as long as the consent is not being obtained because of a state or federal law.
- **The proposed data security protections should be appropriate** for the sensitivity or risk associated with the specific PHI being accessed and used, so that the research may appropriately be considered minimal risk.
- **Combination with other exempt categories.** This category can be combined with other categories, but the PHI must be *secondary use*. In generally, this means that the PHI is already being collected as part of routine clinical care – it does not refer to PHI that is generated specifically because of the study.

An example of research that qualifies for this category would be if a graduate student has access to identifiable data from a study previously conducted by a faculty advisor, and they record the information they need in a way so that the data being analyzed for the research cannot be traced back to the individual subjects.

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Exempt Category 5 – Research supported by federal departments or agencies.

Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department of 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.

As described in federal guidance, *all* of the following criteria must be satisfied:

- The program under study delivers a public benefit or service
- The project must be conducted pursuant to specific federal statutory authority
- There must be no statutory requirement that the project be reviewed by an IRB
- The project does not involve significant physical invasions or intrusions upon the privacy of participants
- The funding agency concurs with the exemption

Minimal risk is not a requirement for this exempt category.

Requirement for the federal department or agency conducting or supporting the project. The federal department or agency conducting or supporting the project must establish, on a publicly accessible federal Web site or in such other manner as the department of agency head may determine, a list of the research and demonstration projects the federal department or agency conducts or supports under this exempt category. The department or agency head can determine what sort of information will be included on this list and maintains its oversight. The project must be published on the list before the researcher can begin the project; however, exempt status can be granted before the publication occurs. Review the OHRP guidance for more information.

Examples of public service or benefit programs per federal guidance: **(1)** programs that provide financial or medical benefits under the Social Security Act; **(2)** social supportive or nutrition services as provided un the Older Americans Act.

Specific federal statutory authority means there is a federal law requiring the research or demonstration project to be conducted.

Concurrence of federal agency. A member of HSD Leadership will contact the funding agency on behalf of HSD for this purpose.

Example of research in this category. The Federal Department of Housing and Urban Development (HUD) is charged by Congress with providing periodic reports about the effectiveness of a federal housing subsidy program, as indicated by perceptions of individuals about the procedures and time required to qualify for the program. HUD contracts with a UW researcher to collect data for this project.

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Exempt Category 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.

Definition of food. Research involving the consumption of alcohol, vitamins, and nutritional supplements does not qualify for exempt status because these items are not considered "foods".

Acceptable sources of food. Foods may be obtained from: **(1)** a public retail facility that has a valid permit/inspection from the applicable health department (such as a restaurant or grocery store), or **(2)** a licensed commercial kitchen if they are used without manipulation. Foods not meeting this description are evaluated for this exempt category on a case-by-case basis.

Unacceptable risk. The research may not involve the consumption of any type of food, or volume of food, that involves the risk physical harm (significant indigestion; serious allergic reaction; vitamin or other nutrient deficiency). The research must involve what would be considered reasonable eating behaviors.

Examples that qualify for this category:

- A taste test on different varieties of a fruit to determine consumer preference, when the fruits do not have additives and subjects are asked to indicate which fruit they prefer
- A study that involves taste testing of various beef products from cattle that have been given feed with a chemical additive if the investigator can document that the amount of the additive was at or below the levels approved by the USDA.

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Exempt Category 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).

> **Important**: At this time, the Longwood University IRB will not mandate nor implement the institutional use of broad consent, as the tracking requirements may be burdensome. Exempt categories 7 and 8, which rely on broad consent, will not be utilized. Longwood University IRB will continue to support investigators seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through other processes including comprehensive IRB review and consent procedures as appropriate.

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Exempt Category 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.

Important: At this time, the Longwood University IRB will not mandate nor implement the institutional use of broad consent, as the tracking requirements may be burdensome. Exempt categories 7 and 8, which rely on broad consent, will not be utilized. Longwood University IRB will continue to support investigators seeking subject permission for the collection and storage of identifiable private information/biospecimens for future secondary use research through other processes including comprehensive IRB review and consent procedures as appropriate.

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Longwood Exempt Category 100 (L-100)

Must not be utilized for research involving federal funds or regulations [e.g. NIH, NSF, DoD]). Research meeting all of the criteria of a Benign Behavioral Intervention under federal guidelines (Exemption Category 3 above), but also involving data collection of physical measurements intended to assess the effect of a Benign Behavioral Intervention. Measurements must be obtained with low risk, commercially-available automated measurement technology. Examples include but are not limited to: commercial eye-tracking sensors, wearable activity trackers, electronic blood pressure cuffs, plethysmography, and heart rate monitors during submaximal exercise and used by appropriately trained Study Personnel under supervision of the Principal Investigator or Faculty Mentor. L-100 studies must not involve collection of biospecimens (e.g. saliva, blood), use of virtual reality headsets, or any procedures requiring non-exempt review referenced under 45 CFR 46 or 21 CFR 56. Examples that do not qualify for L-100 review include, but are not limited to: Magnetic Resonance Imaging, maximal exercise studies, electrocardiography, electroencephalography, thermography, ultrasound, use of radiation, clinical investigations of experimental drugs/devices, venipuncture, echocardiography.

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Document Attributes

Last approved by IRB: 5/26