EXPECTATIONS & GUIDANCE ON EXEMPT CATEGORIES

The following information provides guidance on each Exempt category. If your project meets an Exempt category this does not mean that IRB review is not needed. A protocol application must still be submitted for approval of exemption determination. When in doubt, contact the Office of Research Protections and Integrity (ORPI) to discuss your project!

It is important that Investigators develop and design the study to fulfill their research goals and NOT to “fit” a certain category of human subjects protection and/or IRB review level.

IMPORTANT: Studies that qualify for Exemption are expected to have no risk or at most, a minor level of risk. The regulations do not address risk level and Exemptions directly. However, it is consider an indicator that risk is expected to be very minor or no risk at all given that an Exemption does not require (per regulation) consideration of the level of risk to participants.

All studies, including Exempt studies are expected to apply the Belmont Reports ethical principles for human subjects research.

EXEMPT CATEGORY 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.

Guidance

Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices may meet this Exempt category.

Commonly accepted educational settings include but are not limited to K-12 schools and college classrooms. They may also include after-school programs, preschools, vocational schools, alternative educational programs, and other sites where educational activities occur. This might also include non-school settings, such as libraries, training centers, workplaces (professional development), grocery store (nutrition class), or other similar locations if the setting is one where a person would go for an educational experience. The Investigator must provide rationale and justification when proposing that a setting is a commonly accepted educational setting.

The research must specifically involve normal educational practices. Therefore, if the research includes other components that are not specifically involved in normal education practices, this category is not applicable.

Normal educational practices may include established teaching methods, curriculum content and commonly accepted classroom management techniques that are planned and implemented by the classroom teacher. These activities typically occur in a classroom or other educational setting. Further, the instruction must be routinely used in similar educational settings and/or considered proven educational practice for the target study population. Importantly, interventions used must also be routinely used in similar education settings and considered proven educational practice for the target study population. Further, interventions cannot impact the student’s ability to
learn required content nor can the intervention have potential to negatively impact the student. In other words, it is not a proven educational based intervention for the target study population.

Examples may include:
- Test development –pilot testing of new educational assessment tools.
- Assessment of attitudes about learning or curriculum
- Evaluation of classroom or school activities
- Use of educational tools such as computers or smart phones

This category requires that the study activities are not likely to adversely impact students’ opportunity to learn required educational context and/or the assessment of educators who provide instruction. Studies may not have a detrimental impact on student achievement and therefore cannot take time and attention away from the delivery of regular educational curriculum. In addition studies that may adversely impact individual teacher are not eligible for this exemption category. There must not be any negative impact if the research involves an evaluation of the instructors.

Even when research meets an Exempt category, researchers using student educational records must meet the requirements of the Family Education Rights and Privacy Act (FERPA). Importantly, FERPA requires written permission from students and parents (for minors) to access student educational records for research purposes. Studies that are Exempt must still meet FERPA requirements. Studies wherein an Investigator may seek a waiver of consent are therefore not likely to qualify for Exemption.

Studies that includes the following (but not limited to), may not be eligible for Exemption review because some or all of these items may not be normal educational practices. Therefore, additional consideration is needed as to whether an Exemption determination is applicable.

- Studies that may involve normal educational practices but result in risk to participants that is greater than minimal risk.
- Studies that evaluates a radically new or novel instructional strategy or curriculum
- Studies that assigns students to different instructional strategies/curricula for comparison (experimental/intervention group and control group)
- Implementation of an untested curriculum that is not consistent with the current required curriculum
- Studies that involve a significant amount of time and attention away from the delivery of regular curriculum.
- Studies that involve withholding standard educational content.
- Studies that involve surveys that include content that is outside of normal educational practices
- Studies that involve interviews include content that is outside of normal educational practices
- Studies wherein the Investigator will request a waiver of informed consent (e.g., waiver of parental informed consent) may not be eligible for Exemption
- Studies involving vulnerable populations such as students with cognitive impairment or extensive behavior issues.
- Studies that require participants to complete activities, including testing, that are not part of the normal course/class activities
- Studies that involve whole-class audio or video recording
- The use of focus groups, depending on the population and subject matter.
- Assessing attitudes and perceptions (e.g., conducting a survey or interview) about non-classroom/course topics (e.g., students from low socioeconomic status groups, mental health, personal beliefs or opinions beyond those associated with learning or curricula).
- This category does not apply to Food and Drug Administration (FDA) regulated research.
## Examples

<table>
<thead>
<tr>
<th>Exempt under Category #1</th>
<th>Not Exempt under Category #1:</th>
</tr>
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<tbody>
<tr>
<td>A teacher, student teacher, or school counseling intern uses his/her students’ pre- and post-test results to assess the effectiveness of implementing the reading curriculum that meets state standards in a modified way. The modification is limited to extending the daily reading requirement from 15 minutes to 30 minutes.</td>
<td>A researcher wants to use an elementary school classroom to assess the effectiveness of a new reading curriculum using interviews, surveys and researcher designed tests. Generally, this is not exempt because it is not a normal educational practice for an outside researcher to interview students about a new educational program and the program is untested. Further there is no evidence that the researcher-designed tests are valid.</td>
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<tr>
<td>A teacher, student teacher, or school counseling intern uses his/her students’ pre- and post-test results to assess the effectiveness of a new reading program. In addition to using the test scores, the researcher also wants to survey (or interview) all the students to ask them questions about the new reading program.</td>
<td>A teacher, student teacher, or school counseling intern uses his/her students’ pre- and post-test results to assess the effectiveness of a new reading program. In addition to using the test scores, the researcher also wants to survey (or interview) all the students to ask them questions about their after-school activities, feelings, and perceptions about themselves. The researcher will examine how the characteristics of the child impact their performance on the testing.</td>
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<tr>
<td>A high school teacher wants to compare two math curricula being implemented at the school. One section/group of his/her students (e.g. 1st period math students) receive one curricula and the second section/group of students (e.g. 2nd period math students) receives the second curricula. Each group is learning the same curriculum in a normal educational setting but in using different instructional techniques.</td>
<td>A high school teacher randomly divides his/her single class into two groups and conducts an experimental/untested math curriculum with one group and conducts the normal educational program with second group for research purposes. (The activity is not normal educational practice.)</td>
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</tbody>
</table>

## Study Protocol Submission

The following are items should be considered when preparing a study protocol for Exemption category #1 consideration.

- Explain which activities will be implemented regardless of the research and which activities are for research purpose only.
- When will the research activities occur? During class time, before or after school or work hours?
- If new educational activities will be used, explain how the new activities differ from routine practice/standard methods.
- Specify if student work products/artifacts will be used. And if so will the work products be individually identifiable?
- If grades or standardized test scores will be used/access, specify what grades or scores, how the researcher will have access to this information and whether or not the information will be individually identifiable.
- When observing the classroom, explain who is being observed. Keep in mind that observations may include interactions between study participants and individuals who are not study participants.
- State if the educational activity is solely related to the research OR if the educational activity will occur regardless of whether the research is conducted.
• If extra credit will be offered for participation in the research activity, an alternative activity (involving an equitable amount of time and effort) must be provided to non-participating students for a comparable amount of credit.
• If the researcher(s) is not directly involved in the implementation of the intervention, explain how the surrogate researchers will be trained. Describe the plan to monitor and manage data collection.
• Coercion and undue influence is difficult to avoid in a classroom setting in which activities are determined and implemented by adults. Research designs should include strategies to reduce this risk. For instance, clear procedures should be in place for maintaining the educational activities of students who are not participating in the study in order to minimize interruption to the typical school day. Although students are generally obligated to participate in activity designed for the whole class, activities specifically implemented for the research need to be clearly explained and alternatives be provided for those choosing not to participate. Appropriate alternatives should be provided for those who opt out, and must be described in the protocol as well as the consent documents.
• The risks and inconveniences should be assessed and clearly described in the protocol and consent process.
• Describe how privacy and confidentiality of all participants (e.g., students, teachers) will be maintained. For example, will study results be shared back with the school on an individual level or in aggregate?

**EXEMPT CATEGORY 2 (45 CFR 46.104(d)(2))**

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

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily 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 the IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7). This requires consideration that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

**Guidance**

Studies that qualify for Exemption are expected to have no risk or at most, a minor level of risk. This applies to all categories of risk; psychological, social, economic, legal, and physical risk.

Many survey/interview projects fall within this Exempt category. The research must meet at least one of the following conditions to meet this category.

• This category involves exclusively, educational tests, surveys, interviews or observations of public behavior. It does not include interventions (e.g., manipulation of the environment or physical procedures, or manipulation intended to effect change in behavior, cognition, etc.)
• The data are collected without identifiers. This means that no identifiers can be connected to the data, either directly or through a coding system.
Further, this means that no one, not even the research team could link the data with an individual participant at any time, directly or indirectly through a coding system.

The information collected is identifiable (because, for example, the researcher has a key linking respondents’ names to coded identifiers), but the information is so innocuous (not sensitive) that in the event of disclosure outside of the research there would be no significant detrimental consequences to the subject.

The information collected is identifiable and potentially sensitive might be allowable. Importantly, this Exempt category requires Limited IRB Review. This means that the submission will be reviewed by the IRB with the focus of the review being on the privacy and confidentiality protections.

Public behavior refers to behavior taking place in a publicly accessible location in which the subject does not have an expectation of privacy (e.g., a public plaza or park, a street, a building lobby, a government building). If subjects have a reasonable expectation of privacy at the location where the researcher is conducting the observation, the project may not qualify for this Exempt category.

Children:

- Research involving surveys or interviews with children or observation of public behavior when researchers interact with the children does not qualify for this Exempt category.
- Exemption category 2iii for the collection of identifiable information does NOT apply to children.

Studies involving the collection of identifiable, potentially sensitive information may be eligible for Exemption determination with Limited IRB Review. The study is review by a member of the IRB for consideration as to whether the privacy protections for participants and confidentiality protections for the data are appropriate and adequate.

This Exemption considers that the potential risks are informational risks that are disclosed to participants and therefore the role of the IRB in to ensure that the study uses privacy and confidentiality protections.

Studies that include the following (but not limited to), may not be eligible for Exemption review:

- Studies that involve interventions. An “intervention” is a manipulation of the participant’s environment or physical procedures. An intervention is also a manipulation intended to effect change in behavior, cognition, etc. For example, a study that randomly assigns students to complete an interview and the study intervention includes varying the gender of the interviewer to see whether interviewee responses change, is not eligible for this Exemption category.
- Studies that include linking additional personally identifiable data to data collected via Exemption #2. For example, obtaining data from student educational records to link to study collected data.
- Studies involving collection of multiple pieces of information about a person, none of which are identifiable on their own, but may uniquely identify a person when brought together; in this case, the data would be identifiable and would not be considered anonymous. However, a study such as this may still be eligible for Exemption determination if any disclosure of the data would NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation.
- Studies involving the collection of biospecimens in addition to collecting survey/questionnaire information (whether verbal or written/online responses to questions).
- This category does not apply to Food and Drug Administration (FDA) regulated research.
Examples

<table>
<thead>
<tr>
<th>Exempt under Category #2</th>
<th>Not Exempt under Category #2</th>
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<tbody>
<tr>
<td>Observation of children interacting on the playground OR adults’ buying habits in a local</td>
<td>Observing the conduct of middle school students while interacting with them in a group game (NOTE: participatory observation of children is not exempt.)</td>
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<tr>
<td>McDonald’s restaurant OR passively observing (with pencil and paper) the interaction of</td>
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<tr>
<td>children with fathers at a public park (i.e., passive public observations, no identifiers, no-risk data, observations in a ‘public’ setting).</td>
<td></td>
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<tr>
<td>Anonymous survey of college students’ perception of college life.</td>
<td>Survey of college students’ perception of college life and linking the responses to student academic performance/outcomes.</td>
</tr>
<tr>
<td>Note: The online survey platform is set to NOT collect email addresses or IP addresses.</td>
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<tr>
<td>*Survey about opinions on the managerial skills of a person’s supervisor, without naming the supervisor. The survey is coded such that the researcher may determine who has and has not responded. The code links data with participant names. *Limited IRB Review required.</td>
<td>Survey about opinions on the managerial skills of a person’s supervisor following a leadership intervention. The survey is coded such that the researcher may determine who has and has not responded. The code links data with participant names.</td>
</tr>
<tr>
<td>Completion of a series of questionnaires about a participant’s experience with a counseling intervention.</td>
<td>Completion of a series of questionnaires before and after the participant takes part in the counseling intervention.</td>
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</table>

**EXEMPT CATEGORY 3 – (45 CFR 46.104(d)(3))**

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 recoding 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 45 CFR 46.111(a)(7). This requires
consideration that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

For purposes 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.

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.

Guidance

This category is intended for studies involving benign behavioral interventions combined with the collection of information from an adult subject through verbal or written responses including data entry or audiovisual recordings. Participants must prospectively agree to the intervention and information collection.

A behavioral intervention involves the performance of a cognitive, intellectual, educational, or behavioral task; or the manipulation of the subject’s physical, sensory, social, or emotional environment. The duration of the study must be brief. It should occur in a single day and not exceed more than a few hours.

Examples of benign behavioral interventions:
- Performing cognitive tasks
- Providing educational materials to participants with the intention of changing their behavior (e.g. smoking cessation, eating habits)
- Playing an online game
- Playing economic games
- Being exposed to stimuli such as color, light or sound at safe levels
- Solving puzzles under various noise conditions

This exemption differs from Exemption #2 in that under Exemption #3 the intervention may be distinct from the data collection method.

Importantly, if the study will involve incomplete disclosure or deception, the participant must prospectively agree/authorizes the deception. In other words, the participants must be informed that they will be unaware of or misled regarding the nature or purposes of the research.

Studies involving the collection of identifiable and potentially sensitive information may be eligible for Exemption determination with Limited IRB Review. The study is review by a member of the IRB for consideration as to whether the privacy protections for participants and confidentiality protections for the data are appropriate and adequate.

Studies that include the following (but not limited to), are not be eligible for Exemption review:
- Studies involving decisionally-impaired persons.
- Studies that include medical tests, medical procedures, and/or the use of medical devices.
• This category does not apply to Food and Drug Administration (FDA) regulated research.
• Studies involving data collection via physical procedures such as blood pressure monitoring, EEG, activity trackers, eye trackers, and blood draws.
• Studies wherein prospective agreement to participate from participants is not obtained.
• Studies where participants are not aware that they are participating in research.
• Studies that include linking additional personally identifiable data to collected data. For example, obtaining data from student educational records to link to study collected data.
• Studies involving collection of multiple pieces of information about a person, none of which are identifiable on their own, but may uniquely identify a person when brought together; in this case, the data would be identifiable and would not be considered anonymous. However, a study such as this may still be eligible for Exemption determination if any disclosure of the data would NOT reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation.

Examples

<table>
<thead>
<tr>
<th>Exempt under Category #3</th>
<th>Not Exempt under Category #3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants play a violent videogame and complete a written test. The Investigator describes the study procedures and intervention and participants prospectively agree to participate.</td>
<td>Participants play a violent videogame and complete a written test. In addition, participants have their eye movements captured using an eye tracker.</td>
</tr>
<tr>
<td>Investigators video record pedestrians in a building lobby area that has an art installation that allows pedestrians to engage with the installation by sitting on the installation in a meditation spot, listening to quiet music while reading a poem written on the installation, etc. There is signage around indicating that research is being conducted and video recording is occurring. In addition, there are flyers with details about the research and contact information for the Investigators.</td>
<td>Investigators video record pedestrians in a building lobby area that has an art installation that allows pedestrians to engage with the installation by sitting on the installation in a meditation spot, listening to quiet music while reading a poem written on the installation, etc. Pedestrians are unaware that research is being conducted and that they are being video recorded.</td>
</tr>
<tr>
<td>Online survey with embedded intervention (healthy eating scenarios).</td>
<td>Online survey with embedded intervention (healthy eating scenarios). Participants’ survey responses will be linked to their student academic record and food buying habits collected from student ID purchases.</td>
</tr>
<tr>
<td>Adult participants agree to be video recorded while reading and presenting a text designed to persuade an audience to buy a product. The recording will take place in a quiet room. Ratings of vocal inflection and body language will be captured to assess predictors of how successful the learner will be in persuading an audience. The presenter will self-report their perception of how successful they were in the persuasion. The procedure will take 90-120 minutes.</td>
<td>Adult participants agree to be video recorded while reading and presenting a text designed to persuade an audience to buy a product. The recording will be made with an audience of other study participants. Ratings of vocal inflection and body language will be captured to assess predictors of how successful the learner will be in persuading the audience. The audience will report their reflections on the success of the presenter. The procedure will take 3 research sessions to train the participants in persuasion techniques.</td>
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</table>
This is not exempt as there is potential for embarrassment in public speaking. The duration is not brief.

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<thead>
<tr>
<th>EXEMPT CATEGORY 4</th>
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<tr>
<td>Secondary research for which consent is not required. Secondary research uses of identifiable private information and identifiable biospecimens if at least one of the following criteria is met:</td>
</tr>
<tr>
<td>(i) The identifiable private information or identifiable biospecimens are publicly available;</td>
</tr>
<tr>
<td>(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 the subjects;</td>
</tr>
<tr>
<td>(iii) The secondary research activity is regulated under HIPAA; or</td>
</tr>
<tr>
<td>(iv) The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected.</td>
</tr>
</tbody>
</table>

**Guidance**

Secondary research refers to re-using identifiable information and identifiable biospecimens that are collected for some other “primary” or “initial” activity. The information and/or biospecimens are or will be generated for non-research purposes and/or from research studies other than that being proposed by the Investigator. This Exemption category applies to information or biospecimens that would generally be found in some type of records or repository.

Publicly available includes archives in a public library, government or other institutional records where public access is provided upon 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, registering or signing in as a visitor.

Research may meet the Exempt category #4 if the investigators initially and/or temporarily have access to identifiable private information, but abstract/extract the data needed for the research in such a way that the information can no longer be connected to the identity of the subjects. This means that the abstracted data set does not include any direct identifiers (names, social security numbers, employee or student ID numbers, etc.) or indirect identifiers (codes or pseudonyms that are linked to the participant’s identity).

Health Information:
The use of health information that is private identifiable information (i.e., Protected Health Information from a medical record) may be eligible under this Exemption category when the use is regulated under the HIPAA Privacy Rule (Health Insurance Portability and Accountability Act). Investigators main maintain identifiers if all study data is protected health information (PHI). In other words, if medical records will be used, the requirements under HIPAA that include where appropriate, the requirement to obtain a subject’s authorization for future, secondary
research use of protected health information or a waiver of authorization apply. Therefore, a study using PHI may be eligible for exemption if a HIPAA Privacy Board approves the authorization or waiver of authorization.

Importantly, UNC Charlotte is NOT a HIPAA Covered Entity (CE). Use of this category of exemption for identifiable health information will require documentation that HIPAA Authorization to release this information was obtained or will be obtained from participants or documentation from the Covered Entity’s Privacy Officer that a waiver of HIPAA authorization was granted by the Covered Entity.

Studies that include the following (but not limited to), are not be eligible for Exemption review:

- Studies that include primary data collection, whether information or biospecimens.
- This category does not apply to Food and Drug Administration (FDA) regulated research.
- Studies where the Investigator will have some type of contact with participants.
- Studies that involve linking multiple data sets wherein the Investigator maintains a linking ID/code.

**Examples**

<table>
<thead>
<tr>
<th>Exempt under Category #4</th>
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<tr>
<td>• Medical chart review where the researcher has access to identifiable data, but does not record it for research purposes.</td>
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<tr>
<td>• Analyzing de-identified data or tissue samples.</td>
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<tr>
<td>• A graduate student has access to coded data from a study previously conducted by his/her Responsible Faculty and records the information needed for the research without the code, so that the data being analyzed for the research can in no way be traced back to the individual subjects.</td>
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</table>

**EXEMPT CATEGORY 5**

Research and demonstration projects that are conducted or support 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.

**Guidance**

Exempt category #5 applies only to research on public benefit programs (such as Social Security) conducted by the federal government and therefore is rarely applied. Research and demonstration projects in general (e.g. state or city funded public service programs) do not meet this Exempt category. Projects that meet the Exempt category must be conducted pursuant to specific federal statutory authority.

This category does not apply to Food and Drug Administration (FDA) regulated research.
Research sponsored by the Department of Housing and Urban Development to assess the effectiveness of a housing subsidy program.

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.

Guidance
Taste and food quality evaluation studies conducted under this Exempt category may not involve consumption of any type or volume of food that would present any risk to the participants and should fall into what would be considered reasonable eating behaviors by the participant. Thus, the key element of this category is that the research can only involve foods that are known to be safe.

The food must be “wholesome” (no additives), or if it involves plants or animals raised for food products, the level of chemical additives or environmental contaminants must be at or below the levels approved by the FDA, EPA, or USDA. Studies involving the consumption of alcohol, vitamins, and other supplements do not qualify for this Exempt category.

Examples
- Taste testing of new calcium-enriched soda.
- Tasting of several yogurts to determine which texture is more pleasing.
- Test testing of different varieties of a fruit to determine consumer preference, when the fruits do not have any additives and participants are asked to indicate which fruit they prefer.
- Taste-testing pork products where the swine was fed corn and a chemical additive at a level designated below FDA guidelines that make the animal gain weight more quickly. The objective of the study is to determine whether the addition of the chemical changes the flavor of the pork.

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).

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 bio-specimens 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.

**Guidance for Exemption #7 and #8**

UNC Charlotte will not implement the Exemption #7 or #8 at this time.

These Exemption categories require Broad Consent which in turn requires,
- a) that the Broad Consent identify the types of research that may be conducted,
- b) researchers and institutions to record and track which participants have provided broad consent and which participants have refused broad consent, and
- c) the tracking of the terms of broad consent in order to allow for a determination regarding if the research is within the scope of the broad consent.

Therefore, UNC Charlotte has determined that it is not feasible to meet these additional requirements at this time given lack of capacity to meet technical requirements and given the lack of federal guidance regarding these categories. The Office of Research Protections and Integrity and the IRB may reevaluate this decision at such time that the Office of Human Research Protections provides guidance on the use of these categories and broad consent.

Investigators may continue to conduct secondary research using identifiable private information or identifiable biospecimens under:

- Obtaining IRB approval (non-Exempt review) with study specific consent
- Obtaining IRB approval (non-Exempt) with a waiver of consent
- Obtaining an Exempt Category #4 determination
- Obtaining de-identified data such that the study may result in a non-human subjects determination.
Adapted from:
UNC Chapel Hill guidance
University of Kentucky guidance
University of Michigan
UNC Greensboro
University of Kansas Medical Center
Clemson University