Title: Exemption Requests
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Standard Operating Practice: 5

5.1 Executive Summary

This document provides information regarding NC State University policy and standard operating practices for the conduct of administrative review resulting in an exemption determination. This document outlines the processes of preparing, conducting, and documenting administrative reviews resulting in an exemption determination.

5.2. Standard Operating Practice

IRB office staff or IRB full board members will conduct administrative reviews resulting in an exemption determination for minimal risk research eligible for exemption under 45 CFR 46, NC State University Regulation 10.10.03 (opens in a new window), and this standard.

5.3.a. Operational Procedures

5.3.a.i. Definition of Key Terms for Exempt Studies

1. **Benign behavioral interventions** are brief, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and no reasonable person would find the research OR the use of the research data offensive or embarrassing.

2. **Deception**: The research team knowingly provides false information to prospective participants.

3. **Incomplete disclosure:** When the research team withholds information about the real purpose or nature of the research from participants.

4. **Minimal risk:** The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. *All exempt studies must be deemed minimal risk, or they are ineligible for an exemption determination*.

5. **Readily ascertainable**: when the data are directly identifiable, linked to a master list that the researcher(s) can access, indirectly identifiable to anyone on the research team where an individual can be identified from the data due to researcher(s) access, role, or expertise, or a participant can be identified from the content of data, triangulation of data content, pairing with other data, or sample size.

5.3.a.ii. Studies Eligible for Exemption under 45 CFR 46
Federally funded or contractually obligated minimal risk research activities in which the only involvement of human subjects will be in one or more of the categories listed in this section, are exempt from the federal requirements at 45 CFR 46. The NC State University IRB makes this determination.

The federally defined categories eligible for an exemption under which the NC State IRB could issue an exemption determination include:

1. **Exempt category d.1:** "Research conducted in established or commonly accepted educational settings that involve normal educational practices that do not adversely influence students' opportunity to learn required educational content or the assessment of educators who provide instruction."
    a. Minors and adults can be research participants in exempt category d.1.

    b. Researchers must justify how the proposed research setting qualifies as an "established" or "commonly accepted" educational setting Some educational settings formally identified by SACHRP (opens in a new window) include:
        i. K-12 and college classrooms, preschools, vocational schools, and alternative education programs
        ii. Study abroad programs
        iii. Massive online courses (MOOCs)
        iv. Afterschool programs
        v. Professional programs (e.g., medical school, veterinary school)
        vi. Training simulators (e.g., flight simulator)
        vii. Professional development programs
        viii. Workshops for idea generation and problem solving

    c. Researchers must provide evidence of how the research procedures are "normal educational practices…that are routinely used" or are evidence-based best practices that support the required curriculum and benefit students. Some examples of "normal educational practices" include:
        i. Classroom observation
        ii. Assessment of learning attitudes or behaviors
        iii. Evaluation of instructional methods or curricula
        iv. Instructional design variations – but the variations must be "routinely used" or be an established evidence-based best practice.

    d. Exemption Category d.1 and FERPA:
        i. Protocols where prospective FERPA consent from the parent or eligible student, and prospective FERPA assent from students in high school is sought to access past, current, or future student records for studies to develop, validate, or administer predictive

tests; administer student aid programs; or improve instruction, will be reviewed and approved by the IRB under exemption category.

ii. Protocols that request the access or receipt of past, current, or future identifiable FERPA data where the data must remain identifiable or re-identifiable and prospective FERPA consent was not or will not be sought, will be reviewed by the IRB under this category if:
    1. the protocol qualifies for a FERPA exception because the study is being done on or behalf of the educational institution and it aims to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction. If the research is not done for this purpose or on behalf of the educational institution holding the records, the study cannot be exempted;
    2. when accessing their own records for research purposes, researchers must have written permission from their supervisor or department. This does not need to be submitted to the IRB, but it must occur.

iii. Protocols that qualify for a FERPA exception where the researcher records the data (including data from their own courses) in such a way that an individual's identity cannot be readily ascertained, and the researcher will make no attempt to re-identify an individual from the data, will be reviewed and approved by the IRB under this exemption category.
    1. If the researcher is accessing their own records, this requires written permission from the researcher's supervisor or department head so that someone on the site knows that the researcher is completing the research activity. This written permission does not need to be submitted to the IRB, but it must occur and the process must be described in the IRB application.
    2. If the researcher wants to access the past, present, or future FERPA information as data for research, the researcher can record that FERPA information in a way that makes a de-identified dataset and the researcher states that they will not seek to re-identify people, this can be reviewed and approved by the IRB under this exemption category.

iv. Protocols where a researcher is accessing/receiving identifiable FERPA data only AND the researcher is doing the project on or behalf of an institution or an educational agency *or* the research is intended to develop, validate, or administer predictive tests, administer student aid programs, or improve instruction, the study will be reviewed under this exemption category

2. **Exempt category d.2:** Research that includes educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior (including visual or auditory recording).

    a. Only adults can be included for most types of research that qualify for an exempt d.2 determination including tests completed solely for research purposes, surveys, interviews, and focus groups.

    a. Minors and adults can be observed in public for research purposes within exempt category d.2 only if:
        i. The setting in which the research will occur is a truly public space. Observations in public school classrooms or locked/private social media forums are not considered to be public spaces.
        ii. No member of the research team will interact with the minor(s) that are being observed.

    b. Deception and incomplete disclosure (Word document) can be a part of exempt category d.2 only if all the components in section 5.3.a.iii of this SOP are a part of the research design.

    c. For all research data that is approved under exempt category d.2, it must fit into one of the three categories below:
        i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained
            1. through direct or indirect identifiers (Word document);
            2. through the research team's role, expertise, and access to the raw data;
            3. from the content of research data or triangulation of data points;
            4. pairing the research data with other data; or
            5. participant group/subgroup size.

        ii. Participant identities can be readily ascertained and
            1. any disclosure of the research participants' responses 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.

        iii. Participant identities are readily ascertained, and the IRB completes a "limited review"
            1. The research team implements appropriate data management strategies in accordance with NC State data sensitivity levels.

2. The research team implements appropriate privacy protections for the participant as they complete the research activities.
3. The NC State IRB conducts a limited review in accordance with section 5.3.b.ii.2

3. **Exempt category d.3**: Research involving benign behavioral interventions (Word document) in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording (Word document).

    a. Only adults can participate in exempt category d.3 research.

    b. Deception and incomplete disclosure (Word document) can be a part of exempt category d.3's benign behavioral interventions only if all the components in section 5.3.a.iii of this SOP are a part of the research design.

    c. For all research data that is approved under exempt category d.3, it must fit into one of the three categories below.

        i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained
            1. through direct or indirect identifiers (Word document);
            2. through the research team's role, expertise, and access to the raw data;
            3. from the content of research data or triangulation of data points;
            4. pairing the research data with other data; or
            5. participant group/subgroup size.

        ii. Participant identities can be readily ascertained and
            1. any disclosure of the research participants' responses 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.

        iii. Participant identities are readily ascertained, and the IRB completes a "limited review"
            1. The research team implements appropriate data management strategies in accordance with NC State data sensitivity levels.
            2. The research team implements appropriate privacy protections for the participant as they complete the research activities.

3. The NC State IRB conducts a limited review in accordance with section 5.3.b.ii.2.

4. **Exempt category d.4:** is a request to use secondary data (Word document) for which consent is not required for research purposes when at least one of the following criteria is met:

    a. The identifiable private information and/or biospecimens are now publicly available;

    b. 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;

    c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under HIPAA.

        i. This identifiable private data is considered as “highly sensitive red data” under NC State University data categorization for which a data access and security plan must be submitted completed with OIT’s security and compliance and provided to the IRB with the protocol.

        ii. If the data are a “limited data set” under HIPAA, a data use agreement (DUA) (opens in a new window) is likely required by the data provider and it must be uploaded to the exemption application once executed. The IRB will treat limited datasets as “yellow” data under NC State University data categorization unless otherwise determined by a data use agreement.

        iii. If the data are covered under HIPAA and identifiable as defined by HIPAA, a Business Associate’s Agreement (BAA) is likely required by the data provider and it must be uploaded to the exemption application when executed.

5. **Exemption category d.5:**
    a. This is review category rarely used at NC State University because it includes “research and demonstration projects conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads […] and 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."

6. **Exemption category d.6:** This category includes studies on taste and food quality evaluation and consumer acceptance studies if the food involved:

    a. Is wholesome and without additives or

    b. Contains an ingredient at or below the level and for a use found to be safe, or an 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.

    c. Refer to the NC State IRB guidance for Consumer Preference testing (opens in new window)

7. **Exemption category d.7:** for the storage or maintenance for secondary research for which broad consent was originally sought at the time of primary data collection.

    a. Under this category, the research team can retain and preserve identifiable private information or identifiable biospecimens for potential secondary research use regardless of initial approval level if at the time of initial data collection, participants gave broad consent for their re-identifiable and/or identifiable private information and biospecimens to be used for future unspecified research.

    b. The NC State IRB conducts a limited review in accordance with section 5.3.b.ii.2.

    c. The following criteria must be provided to the IRB:
        i. Proof that IRB approval was previously obtained for use of the secondary data set, including broad consent.
            1. If the study was approved by the NC State IRB, providing the IRB protocol number within the IRB application materials will suffice.
            2. If the study was approved elsewhere, a copy of the IRB protocol, the official notice of IRB approval of the study, and the broad consent form used, should be uploaded to the application for IRB review.

8. **Exemption category d.8:** Research involving the use of identifiable private information or identifiable biospecimens for secondary research use for which broad consent was originally sought at the time of primary data collection.

a. Under this category, the research team can use identifiable or re-identifiable data for secondary research purposes regardless of initial approval level if at the time of initial data collection, participants gave broad consent for their re-identifiable and/or identifiable private information and biospecimens to be used for future unspecified research.

b. With exempt d.8 studies, the research team can re-use identifiable private information or identifiable biospecimens for research. Even if the initial data collection received at a higher level of IRB review, broad consent allows for reuse of the secondary data to be reviewed at the exempt level.

c. The NC State IRB conducts a limited review in accordance with section 5.3.b.ii.2.

d. The following criteria must be provided to the IRB:
    i. Proof that IRB approval was previously obtained for use of the secondary data set, including broad consent.
        1. If the study was approved by the NC State IRB, providing the IRB protocol number within the IRB application materials will suffice.
        2. If the study was approved elsewhere, a copy of the IRB protocol, the official notice of IRB approval of the study, and the broad consent form used, should be uploaded to the application for IRB review.

5.3.a.iii Deception and Incomplete Disclosure in Exempt Research

1. Deception and incomplete disclosure (Word document) can be a part of exempt category d.2's tests, surveys, interviews, focus groups only if all the following components are a part of the research design.

    a. The participant must prospectively agree (via consent processes) to participate in research where they will be unaware of or misled regarding the nature or purposes of the research. The NC State IRB exempt consent templates have stock language researchers can use about deception.

    b. After the study procedures conclude, the research team must debrief participants on any aspect of the study that was untruthfully presented to participants or the information that was withheld from them. The NC State IRB requires that the debriefing script is uploaded to the IRB application.

    c. The research team must re-consent participants to the use of their data for research purposes after the participants have been debriefed.
        i. How this will occur is unique to each research study.
        ii. Re-consent does not mean that you need a second separate consent form, but it does mean that you must get consent from

participants to use their data after they know the true purpose of the study and how the data will be used.

d. Include the following information in your exemption request:
    i. Justification for why deception or incomplete disclosure is necessary to answer the research question
    ii. What the debrief process will be
    iii. What the re-consent process will be
    iv. Upload the debriefing script to the supporting documentation of your IRB application in addition to the consent/permission materials that will be used with participants.

5.3.a.iv NC State University FLEX Exemption Category

1. NC State University's decision to limit the scope of its Federal-wide Assurance (FWA) to federally funded research allows for an appropriate level of flexibility without compromising the protections of human subjects enrolled in research. Our FLEX special exemption category is designed to provide protections equivalent to those found in the Common Rule, also called the "Final Rule" and 45.CFR.46, while also reducing administrative workload and regulatory excess.

2. Studies that are eligible for a FLEX exemption are:
    a. Not funded from any source
    b. Not contractually obligated to follow 45 CFR 4
    c. Not subject to additional oversight from any federal agency
    d. Minimal risk to participants
    e. Can include adult and minor participants
    f. The research includes one or more of the following procedures
        i. Surveys
        ii. Interviews
        iii. Focus group
        iv. Observations of private behavior
        v. Benign behavioral interventions
        vi. Non-invasive collection of human body data by tools that are not being tested for safety or efficacy
            1. Body weight measurement using a scale
            2. Height measurement using a tape measure
            3. Eye movement tracked with an eye tracking device
        vii. Use of identifiable private identifiable or indirectly identifiable secondary data for research

3. Studies Ineligible for Exemption under the NC State University FLEX Special Exemption Category
    a. Any study that is more than minimal risk to participants
    b. Any research with human subjects that is internally or externally funded or may become funded.

        i. This includes a plan for future federal sponsorship (e.g., proof of concept studies for federal RFPs, pilot studies intended to support a federal grant application, training and program project grants, no-cost extensions).
    c. Any research supported by federal signatories of the Common Rule (opens in a new window) including all agencies within the Department of Health and Human Services.
    d. Any research that involves people who are incarcerated.
    e. Any research with human subjects that has contractual obligations requiring adherence to 45 CFR 46.
    f. Any cooperative research that requires a reliance agreement where NC State University serves as the IRB of record (reviewing IRB).
    g. Any research regulated by or subject to additional oversight from the U.S. Food and Drug Administration (FDA).
    h. Any research that has been issued or has a pending NIH Certificate of Confidentiality.
    i. Federally classified research (research procedures and/or results are legally knowable only by individuals with United States government security clearance).
    j. Any therapeutic or biomedical clinical intervention, regardless of funding source.
    k. Any research that is subject to NC State University's clinical trials unit standard (Word document) and required to register with www.clinicaltrials.gov (opens in a new window)
    l. Any protocol testing the safety or efficacy of a medical device (including software applications and AI), drug, biologic, and/or wearables

4. Post-Approval Obligations for FLEX Special Exemption Category Studies

    a. After a study is approved by the NC State IRB office under the FLEX special exemption category, the Principal Investigator is responsible for submitting project revisions to the NC State IRB office in advance of initiating any changes that might affect the study's eligibility for the FLEX special exemption category.

    b. If the proposed revisions render the study ineligible for the FLEX special exemption category, the PI must revise the protocol to bring it into compliance with 45 CFR 46. It is the responsibility of the PI to notify the NC State IRB office of any changes related to eligibility for FLEX special exemption category.

    c. Adherence to post-approval requirements for exemptions as stated in 5.3.c of this document.

5.3.b. Submission and Approval of Exemption Request

5.3.b.i. Submission of Exemption Request

Submission of an exemption request entails submitting an IRB application to the NC State University IRB office with appropriate materials.

1. All applications must include the following materials:
    a. Consent information (use the appropriate NC State University IRB consent template for exempt research)

    b. All stimuli, measures, and instruments (ex: surveys, interview protocols, focus group protocols, observation protocols, benign behavioral intervention protocols, taste test protocols)

    c. Any additional documentation required by the IRB office such as IRB required conditional procedures applicable to all NC State University researchers

    d. Proof of human subjects training (Word document) completion for all research team members who recruit and consent participants, collect data from participants, implement the intervention with participants, or analyze private identifiable data used in the research project. Note undergraduate student personnel (unless it is the student's project) do not have to have their proof of completion uploaded.
        i. The lead PI is responsible for ensuring and tracking who has joined and left the research team including tracking their proof of human subjects research training.
        ii. The IRB may ask for this information if there is an issue. This can also be applied to large scale graduate student support on a study. Please discuss with the IRB office as needed.

    e. Where applicable, applications must also include:
        i. A NIH Data Management and Sharing Plan (Word document) if the study is funded or supported by NIH
        ii. A completed a data and access security plan (DASP) (opens in a new window) if the research study will handle highly sensitive ("red") or ultra-sensitive ("purple") data
        iii. Relevant agreements such as a data use agreement (opens in a new window)
        iv. The implemented broad consent addendum form used at primary data collection if the research team wishes to use secondary data where broad consent was sought and given by participants
        v. Debriefing materials if deception or incomplete disclosure (Word document) will occur in the study

vi. The “opt out form” sent to participants/guardians regarding recordings in classrooms. Refer to the IRB guidance for images and recordings in research with humans (Word document).
vii. The HIPAA authorization form that was used/will be used with participants/guardians or the submission of a HIPAA waiver request form. Refer to the IRB’s HIPAA standard (Word document)
viii. The Family Educational Rights and Privacy Act (FERPA) consent information used with participants and guardians. Refer to the IRB’s FERPA standard (Word document)

5.3.b.ii. Approval of Exemption Request

1. The IRB office will review and approve exemption requests in accordance with 45 CFR 46 and the NC State University FLEX special exemption category. Once the IRB office approves a study as exempt, approval for the protocol does not expire.

2. At initial approval, some exemption requests require the IRB to complete a “limited review”

    a. A limited review is part of the federal regulations requiring a finding that “there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data” for research studies qualifying for exemption.

    b. When conducting a limited review for studies eligible for exemption under 45 CFR 46, the IRB must ensure:
        i. adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
        ii. broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained;
        iii. broad consent is appropriately documented or waiver of documentation is appropriate; and
        iv. that if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

    c. At NC State University, a limited review is performed by IRB staff and consists of the following elements:
        i. The IRB reviewer may require specific information be disclosed to participants through the consent process as required by NC State University.
        ii. The IRB reviewer may require additional procedures be put in place to ensure adequate participant considerations regarding participant privacy throughout the implementation of the research procedures.

iii. The IRB reviewer may require additional procedures be put in place to ensure adequate confidentiality protections for data accessed, generated, handled, and reported as a result of the research protocol.
    1. Data classified by the IRB as highly sensitive (red) or ultra-sensitive (purple) associated with a protocol eligible for exemption will require a Data Access and Security Plan be completed with NC State's Security and Compliance.

5.3.c. Post-Approval Requirements for Exemptions

5.3.c.i. Amendments that must be submitted to the IRB for review and approval before implementation:

1. Change in faculty point of contact.

2. Changes to student researchers if the research is their project:
    a. For exemptions, changes in research team members for undergrads and large groups of graduate students do not need to be approved by the IRB unless it is their project.
    b. The lead PI must keep track changes in student personnel for their own records. Tracking should include training, overview of activities completed, and the time period during which the new team member is working on the project.

3. Correction of documents beyond spelling, grammar, background pictures, or one-word replacements that do not affect the meaning of the sentence or study.

4. Addition of
    a. funding and/or subsequent changes in the project's funding.
    b. participant groups. This includes but is not limited to the addition of minors, pregnant people, incarcerated people, participant populations that are contextually vulnerable, or participant group(s)not initially described in the approved protocol.
    c. data collection procedures such as new surveys or new observations. This includes adding an interview where there was not one before, addition of questions on an approved survey, interview, or focus group.
    d. a data set that requires a data use agreement, material transfer agreement, or addition of any identifiable or indirectly identifiable data that is not publicly available. This includes many records subject to Family Educational Rights and Privacy Act (FERPA) even if a member of the research team already has access to the data due to their role as an educator.
    e. any information that will be collected that directly links the participant to the study or the study data. This includes the collection of identifiable information to provide compensation to one or more participant.

f. audio or video recording of participants, use of photography, screen recording, and/or motion tracking.
g. multimedia such as videos and/or images that participants will view.
h. of compensation.
i. any procedures that are physical in nature.

5.3.c.ii. Amendments that <u>do not</u> have to be submitted for review and approval before implementation:

1. Change in participant numbers if the change is no more or less than 10% of the approved amount listed in the IRB application and supporting documents.

2. Change in undergraduate student personnel (unless it is the student's project). For any undergraduate student additional personnel, you are responsible for ensuring and tracking who has joined and left the research team and you are responsible for tracking their proof of human subjects' research training. The IRB may ask for this information if there is an issue.

3. Minor editorial changes (such as punctuation, single word changes, or grammar) or re-ordering of questions.

4. Removal of
    a. questions on surveys, interviews, questionnaires, and focus groups.
    b. images or video presented to the participants.
    c. audio recording or video recording.
    d. recruitment documents or modes of recruitment
    e. content from consent language THAT MATCHES the removal of data collection procedures

5.3.c.iii. Annual renewal of approval

1. Unless otherwise specified, research studies that qualify for an exemption do not undergo annual approval renewal.

2. Exception to this rule: All studies sponsored by the NIH will undergo annual renewal due to the NIH requiring their data management and sharing plan to be completed.

5.3.d. Participant Group(s) Eligible for Exempt Research

1. People who are pregnant can be involved in all research categories eligible for exemption under both the 45 CFR 46 section d.104 (opens in a new window) and the NC State University FLEX special exemption category.

2. People who are incarcerated can only be involved in research categories that are exempt if the research is aimed at involving a broader subject population that only incidentally includes people who are incarcerated. They cannot be involved in the NC State University FLEX special exemption category unless they are incidentally included where the general population is the main targeted group.

3. People who are under the age of 18 years of age (or are legally considered a minor) may have restrictions regarding involvement in research categories that qualify for exemption. However, under the federal regulations governing research with human subjects, minors can be involved in some research that qualifies for exemption.

    a. d.1: normal educational research in educational settings. Minors may be involved in this type of exempt research under 45 CFR 46 section d.104 (opens in a new window)

    b. d.2: surveys, interviews, focus groups, and observations. Minors cannot be involved in this type of exempt research unless the only involvement of minors is observation of public behavior when the investigator(s) do not participate in the activities being observed.

    c. d.3: benign behavioral interventions. Minors cannot be involved in this type of exempt research.

    d. d.4: use of some secondary information as research data. Minors may be involved in this type of exempt research under 45 CFR 46 section d.104 (opens in a new window) but use of secondary data subject to Family Educational Rights and Privacy Act (FERPA) cannot be included in this exemption category.

    e. d.6: taste and food quality evaluation and consumer acceptance. Minors may be involved in this type of exempt research under 45 CFR 46 section d.104 (opens in a new window).

    f. d.7 and d.8: storage, maintenance, and use of secondary research data when broad consent was initially sought and documented. Minors may be involved in this type of exempt research under 45 CFR 46 section d.104 (opens in a new window).

    g. NC State FLEX special exemption category. The NC State IRB can review select research projects with minors that would be normally reviewed at the expedited review level under the FLEX special exemption in accordance with section 5.3.a.iv of this SOP.