OBERLIN COLLEGE
REQUEST FOR IRB REVIEW OF
USE OF HUMAN PARTICIPANTS IN RESEARCH

For use by IRB Administrator only
Proposal No:
Date Received:
Date Approved:
Expiration Date:
☐ Exempt (Category:)
☐ Expedited (Reviewers:)
☐ Full Committee
Notification Sent:
Signature:

Submit a completed copy of your application and all supporting materials to **ocirb@oberlin.edu**. Please do not send Google docs. Review of protocols cannot begin until the IRB has received all materials in the required formats. To ensure expeditious review of this project, be as specific and complete as possible in responses and provide all necessary supporting materials (e.g., recruitment text, consent forms, letters of support from participating organizations, surveys, interview questions, and, if relevant, debriefing).

All investigators must sign forms before submitting and **student protocols** must have the faculty supervisor's signature at the end of this document.

Today's Date: 10/10/2025
Principal Investigator (PI): Rebecca Totton
PI T# (Students Only):
PI Telephone: 7402495165
PI Email: rtotton@oberlin.edu

List all **other investigators/team members** who will participate in the consent process, interact with subjects, analyze data, or contribute to the project.

Name: Jessie Carney	**Role on project:** Student Researcher	**Email:** **Justin Carney**
Name:	**Role on project:** Student Researcher	**Email:**
Name:	**Role on project:** Student Researcher	**Email:**
Name:	**Role on project:** Student Researcher	**Email:**

If the Principal Investigator is a **student**, please list the faculty supervisor's name and email. The supervisor's signature must also appear at the end of this form.

Name of faculty supervisor: **Email:**

What is the **Project Title?** Adjusting Threat Perceptions toward Transgender People in the United States

Which of the following does this **Project Involve?**

☒ **Faculty research**
☐ **Student course-based research (in a faculty taught course)**
☐ **Student independent research (Honors, or other independent study)**
☐ **Other** (please specify):

What is the **Anticipated Start Date?** 10/24/25 or following IRB approval, whichever is later
What is the **Anticipated End Date?** 10/24/28

Please Note: The anticipated start date cannot predate IRB approval. NO RESEARCH may be done before IRB approval of your protocol.

A. NATURE OF THE PROJECT

A1. In 250 words or less, briefly **summarize your proposed research project** in terms suitable for a general audience. What are the study objectives? What is the population or sample size? What is the basic methodology? How do the benefits of the research justify any possible risks that might be incurred by the participants in the study?

Enter Text:
Preliminary research in my lab demonstrated that perceived realistic (threats to tangible resources) and symbolic (threats to moral or social values) threats about transgender people simultaneously predict support for anti-transgender legislation. In this study, we will examine the impact of framing of proportion of the population on support for anti-trans legislation. The sample will be composed of up to 800 heterosexual, cisgender US-based adults recruited through an online survey platform called Prolific. Participants will read a brief paragraph that manipulates identity (transgender population or gay population) and the framing of the proportion (increasing rapidly, still a very small percentage of the country, or informational only control). Although participants will be exposed to information framing the proportion of trangender or gay people as more or less prominent, information will be factual, so participants will not be misinformed. For example, participants in the increasing condition will read that the number of people who identify as transgender (gay) has increased 3 fold in recent years, while the small percentage condition will read that the number of transgender (gay) people is a very

small percentage of the overall population. After reading their assigned paragraph, all participants will respond to a variety of scales including their perceived symbolic and realistic threats from the target group, support for restrictive legislation, as well as their prejudice level. The goal of this research is to understand the implications of media discussion around growing numbers of LGBTQ+ individuals and the impact that has on support for restrictive legislation.

A2. Specify the procedures that will be used in the study. This section should include the following:

> **(a)** a description of your **methods**, including rationale for the method(s), details of data collection including how you will record the information: if you use a data sheet, include the sheet. If multiple experiments are to be done, describe each separately. Include all interventions, experimental manipulations, data collection procedures, and measurements;
>
> **(b)** a description of how you will **recruit** your subjects;
>
> **(c)** all verbal/written **statements** that will be made to participants, particularly any statements that might be misleading or deceptive, as well as statements during the debriefing period;
>
> **(d)** all **written materials**, including questionnaires, surveys, or tests, to be given to or served online to participants during the course of the study. If your methods involve conducting "open-ended" interviews or focus groups, you should submit an outline of the areas you will cover and basic questions that will be asked to guide the subjects. (All supporting materials should be sent as MS Word files via email to ocirb@oberlin.edu at the same time you submit the application.)

Enter Text:
A. Participants will be recruited through Prolific, an online survey platform in which participants can take surveys for payment. We will not be collecting any personally identifiable information. We will aim to recruit no more than 800 US-based heterosexual, cisgender adults. Participant selection will occur by selecting eligibility criteria on Prolific before posting the study. Participants will initially be told they are participating in a survey about political attitudes, but will be fully informed of the goals of the study during the debriefing. Participants will be randomly assigned to read one paragraph using a 3 (increasing proportion, small proportion, control) x 2 (gay people, transgender people) design. Although participants will be exposed to information framing the proportion of trangender or gay people as more or less prominent, information will always be factual, so no misinformation will be presented to participants. For example, participants in the increasing condition will read that the number of people who identify as transgender (gay) has increased 3 fold in recent years, while the small percentage condition will read that the number of transgender (gay) people is a very small percentage of the overall population. After reading their assigned paragraph, all participants will respond to a variety of scales including their perceived symbolic and realistic threats from the target group,

support for restrictive legislation, as well as their prejudice level. Finally, all participants will respond to demographic questions and will be debriefed and provided with resources. This line of research is based on previous research demonstrating that presenting evidence that LGBTQ communities are growing is associated with an increase in symbolic threats and prejudice (Mackey & Rios, 2025). However, this research has evaluated how information around growing demographics impacts support for restrictive legislation. Research in my own lab suggests that anti-transgender legislation is driven by both symbolic and realistic threats (unlike anti-LGBT attitudes, which are driven by symbolic but not realistic threats).

B. Data will be collected through Prolific.com. The website provides security checks to ensure the validity of participants and to allow researchers to select locations and demographic characteristics of participants eligible to participate. Only participants who are located in the U.S. and identify as cisgender and heterosexual will be eligible to participate.

C. Participants will first read and agree to the consent form. All participants will first answer demographic questions. After this, all participants will read one of the randomly assigned paragraphs describing demographic trends for the target group. Participants will be asked to respond to a manipulation check to ensure that they read the materials. Responses from participants who did not correctly answer the manipulation check will be excluded during the data analysis process. Next, all participants will respond to a series of scales previously used in our lab. This includes: symbolic threat scales, realistic threat scales, deception scales, semantic differential prejudice measures, and support for restrictive legislation. After completing all scales and measures, participants will be debriefed and provided with resources about the nature of the study. We anticipate that the study will take 10-15 minutes, and participants will be compensated $1.50 for their participation.

D. The consent and debrief forms, and all scales and measures, are attached.

A3. Where will your research take place (i.e., geographic location and/or performance site)? If outside the U.S., please discuss the country's research regulations and any possible added risks for your subjects. Projects dealing with advocacy, history, minorities, politics, religion, refugees, roots or sexuality may not be welcome in the host country. See International Research for information. Investigators should have a resource person in the country where the research will be carried out.

Enter Text: Data will be collected through Prolific.com. The website provides security checks to ensure the validity of participants and to allow researchers to select locations and demographic characteristics of participants eligible to participate. Participants will all be over 18, located in the US, and indicate that they identify as cisgender and heterosexual on their Prolific response form.

A4. Which of the following **data collection methods** are used in this study? (Indicate all that apply.)

☒ **Survey**
☐ **Social Media**
☐ **Observation**
☐ **Interview**
☐ **Focus Groups**
☐ **Video Recording**
☐ **Audio Recording**
☐ **Photographs**
☐ **Scientific or Technological Devices (ex. EEG, biometrics, etc.)**
☐ **Other** (please describe):

A5. If your project includes an **online survey,** please attach a PDF and describe any security measures to maintain anonymity and confidentiality. A copy of the survey must be sent to the IRB before the proposal can be reviewed and approved.

Enter Text: See attached survey link. Participants will be collected through Prolific, an online survey platform, where they will be routed to a Qualtrics survey. Only the participant's Prolific ID will be recorded, which will be deleted upon download. No other personal identifiable information will be collected in the survey.

Enter Survey Links:
Survey Link:
https://oberlin.qualtrics.com/survey-builder/SV_3m8iqzQtJQrHPh4/edit?Section=SV_3m8iqzQtJQrHPh4&Tab=Builder

Consent and debrief link:
https://docs.google.com/document/d/1Aa9eMebp7vtx4Cqi55sV1FnqdoGAFXc4yEm6GFdNLVM/edit?usp=sharing

A6. If your project involves **observation**, describe what behaviors/interactions you will be observing and how you will record the data.

Enter Text: NA

A7. What is the **anticipated product** of this research project? (Indicate all that might apply.) Please note that additional use or presentation of the research that is not listed here will require an amendment request to IRB.

☐ **Course paper**
☐ **Web page**

☒ **Public presentation**
☐ **Honors thesis**
☒ **Publication**
☐ **Other** (please describe):

A8. Is the Project currently funded? If yes, by whom? Is funding is being sought for the project? If yes, from whom?

Enter Text: This will be funded by Rebecca Totton's start up fund provided by Oberlin College

A9. Does this research project engage in **Community Based Research** or **Community Based Participatory Research** (i.e., a collaborative approach that involves engaging community members, researchers, and organizational representatives as equal partners in the research)? If no, write "no." If yes, please explain.

Enter Text: No

A10. Does this research potentially qualify as **Exempt Research**? (See sections J for Exempt Categories.) If no, write "no." If yes, please explain and list the possible category numbers (1-8).

Enter Text: Yes

B. PI TRAINING

B1. All Oberlin College student researchers involved with human subjects research must complete one of the prescribed, CITI Human Subjects online training courses. (All CITI completion records are automatically sent to the IRB Chair.) If you are confused about which course or learner group to sign up for, visit the IRB website or email ocirb@oberlin.edu.

☒ I have successfully completed a CITI **Human Subjects** course (either Social & Behavioral Research Investigators **OR** students conducting no more than minimal risk research).

Certificate #: Rebecca Totton - 9466611

☒ All other members of my research team have completed a CITI course.

Names and Certificate #: (Include a separate document if the list is extensive.)

Justin Carney - 65209456

B2. If you are a student, please describe your **training and preparation for this project** (e.g., a methods course, work on previous research projects).

Enter Text:

B3. If applicable, please describe how you will **train your research team members.**

Enter Text: Jessie has worked in my lab for the last year and has completed the research methods series in the department. I will meet with him weekly

C. PARTICIPANT POPULATION

C1. What **type of participants** will be involved in your research? (Indicate all that apply.) Please note that research involving Minors requires an assent process in addition to parental consent and that some Oberlin Students may not be 18 years old and may not participate in research without parental consent. Plan consent and assent procedures or your consent form should say, "you must be 18 years old to participate."

☒ **Adults**
☐ **Minors** (under 18 years old)
☐ **Oberlin Students**
☐ **Other Vulnerable Populations** (e.g., institutionalized persons, persons with diminished capacity) (please specify)
☐ **Other:** (please specify)

C2. Does your research involve any **Institutional Affiliations?** (Indicate all that apply). Please note that research involving off-campus institutions such as hospitals, schools, prisons, or other social service agencies requires approval from that institution's IRB or comparable research review board or agency official. Documentation of approval from external agencies is required and should be submitted along with this application. If you plan to work with other institutions, please describe who you are working with (name, contact info) within the organization/agency and any procedures or review process that you have been asked to follow.

☒ **No institutional affiliation outside of Oberlin College is involved**
☐ **Schools** (please specify)
☐ **Hospitals** (please specify)
☐ **Other** (please specify)

Enter Text:

C3. How will the participants be **solicited or contacted** (e.g., ads, telephone, letter,

announcements made in courses, M-TURK, etc.)? Include all materials, texts, scripts that will used with participants with your application.

Enter Text (or attach a copy): Participants will be recruited through Prolific (an online survey website).

C4. Will any participants need to have documents (invitation, recruitment, consent, directions) or verbal interactions **translated?** If no, write "no." If yes, please explain who will translate and include any translated materials with your application.

Enter Text: No

C5. Will any **incentives** (ex. payment, course credit, etc.) be offered to the participants? If no, write "no." If yes, please explain the nature and amount of incentive and how any monetary payments are being funded.

Enter Text: Yes; We anticipate that the study will take approximately 10-15 minutes to complete and participants will be compensated $1.50 for their participation.

C6. How long will it take a participant to complete all study procedures (e.g., 2 hours, 15 minutes)? Please be specific.

Enter Text: We anticipate that the survey will take 10-15 minutes, and participants will be compensated $1.50 for their participation.

D. RISKS and BENEFITS

D1. Will participants incur any psychological, social, physical, or legal **risk**? This includes any psychological distress associated with experimental manipulations. If no, write "no." If yes, please explain the nature of the risk.

Enter Text: We anticipate minimal psychological risks, no more than in daily life. We recognize that some of the questions may be sensitive given that we are asking about attitudes about transgender individuals as well as helping behaviors. However, we do not anticipate any of these questions to be distressing or outside of the types of conversations participants may be exposed to in their day to day life.

D2. Will the participants be **deceived or misled** in any way? If no, write "no." If yes, please explain the nature of the deception.

Enter Text: Participants will not be actively deceived during the survey. However, the hypothesis of the study will be withheld until after the completion of the survey, for the sake of accurate and unbiased data collection.

D3. Will there be any probing (either verbal or in written form) for information that participants might consider to be **personal or sensitive**? If no, write "no." If yes, please explain the nature of the information.

Enter Text: We recognize that some of the questions may be sensitive given that we are asking about attitudes about transgender individuals as well as helping behaviors. However, we do not anticipate any of these questions to be distressing or outside of the types of conversations participants may be exposed to in their day to day life.

D4. Will participants be presented with materials, or be exposed to social interactions, that they might consider to be **offensive, threatening, or degrading**? If no, write "no." If yes, please explain the nature of the materials or social interactions.

Enter Text: No

D5. Will participants be **recorded** in any of the following ways? (Indicate all that apply.) If you answer "yes" to any of the options, please describe the device and/or program and how/when these records will be used, protected, archived or destroyed. If you are recording, filming or photographing participants, your consent process/documents must include a statement that recording/photographic devices will be used. You must also state what will be done with the recordings/pictures upon completion of the study (published, destroyed, erased, archived, kept for future studies, etc.). Please provide a separate line on the consent form for the subjects to agree to be photographed, filmed or recorded.

☐ **Audio Recorded**
☐ **Video Recorded**
☐ **Filmed**
☐ **Photographed**

Enter Text: NA

D6. If you answered "yes" to any of the questions in this section, please explain how you will minimize any risks. Include a description of the Data Protection methods/programs that will be used.

Enter Text: Risks are minimal as they do not exceed those one may come across in daily life.

Additionally, participants cannot be personally identified. Demographic information is not specific enough to risk identification, and no other personal information will be collected. Furthermore, participants will be reminded in the consent form that they have the option to withdraw from the study at any point and still receive compensation.

D7. How might a subject **benefit** from participating in this research?

Enter Text: Apart from the previously mentioned compensation, there is no direct benefit for participants. However, the study aims to provide participants with a social benefit, as the researchers hope to take away new knowledge on threat perception and addressing bias with which to design interventions that boost inclusive behaviors.

E. CONFIDENTIALITY

E1. Will data be collected that **identifies individuals** or that will be recorded in a way that allows observations to be linked to individuals? Please note that too many demographic data points may allow unintended identification of subjects. If no, write "no." If yes, please explain the nature of the information and the manner in which it will be disseminated.

Enter Text: No

What types of **demographic data** will be collected? (Please indicate all that apply.)

☐ **Names of People**
☒ **Ethnicity**
☐ **Names of Employers**
☐ **Addresses**
☐ **Marital Status**
☐ **Types of Employees**
☐ **Phone Numbers**
☒ **Gender Identification**
☐ **Income**
☐ **Social Security Number**
☒ **Age**
☐ **Job Title**
☐ **Religious Affiliation**
☐ **Membership** (team, group, club, political party, etc.)
☒ **Other unique information** (explain)

- Transgender identity (yes/no)
- Sexual orientation
- Political views

- Education level

E2. Will any personal data be drawn from **institutional files or archives** (e.g., school files)? If no, write "no." If yes, please explain the source and nature of such data, and who will give you permission and access to these records.

Enter Text: No

E3. Who will have access to **raw data** (e.g., PI, Research Assistant, Faculty Adviser, staff, public, funder)?

Enter Text: Raw quantitative data will be made available on Open Science Foundation, in line with best practice for open-science.

E4. What steps will be taken to ensure **confidentiality of personal data?** Please be specific. Will research personnel (including students) be informed of their responsibilities in maintaining confidentiality? How will confidentiality be preserved as data are collected, stored, analyzed and published? When will data identifying individual participants be destroyed?

Enter Text: The full raw dataset will be stored in password protected computers. No personally identifiable information will be included in the study.

F. DATA STORAGE/DISPOSITION

F1. Describe how will you keep your **data secure and maintain confidentiality** during the course of your project.

Enter Text: Participants will be collected through Prolific and routed to a Qualtrics survey. The Qualtrics survey will only be accessible to the PI and Research assistants. Data will not be downloaded until after data collection is complete.

F2. Describe how you will ultimately **dispose of your data** (notes, drafts, lists of subjects, photographic records, tapes, computer disks, etc.) after you have completed your research (e.g. shredding, burning). Please note that all research records must be maintained for at least three years after the completion of the research, including consent forms, flyers, etc. If you do not plan to destroy research data, please provide a justification for maintaining the data for an indefinite period of time and how you will ensure confidentiality.

Enter Text: Raw quantitative data will be posted on OSF, and thus indefinitely maintained, in line

with Open Science practices. Prolific IDs will be deleted from the dataset after connecting the data across time points; no other personally identifiable information will be collected.

G. VOLUNTARY PARTICIPATION/INFORMED CONSENT

The information below should be included in an informed consent document, that should be submitted with this protocol. Include with your application a copy of the consent form or alternate information form/text if you have requested a waiver. The form you submit should be the **exact form** that you will use with your subjects.

Federal law requires that, except in special circumstances, informed consent must be obtained. In brief, consent forms must include (1) a statement explaining the purpose, procedures, and duration of the project, (2) a description of benefits to the participant and others, (3) a statement describing the manner in which confidentiality will be maintained (4), a statement of any risks involved (5), contact information should questions arise in the future, and (6) a statement that participation is completely voluntary.

If a consent form is not to be used, the researcher must provide a justification, for instance in the case of web-based surveys where consent can be implied by participants accessing a web-site. In addition, researchers must provide participants with contact information for a person affiliated with the project and for the IRB should questions arise. Include the following: "Should you have questions regarding your rights as a research participant, please contact the Oberlin College Institutional Review Board, Cox 101, (440-775-8410) or email: **ocirb@oberlin.edu**." Sample consent forms may be viewed and downloaded from the Oberlin College IRB forms web page.

G1. What steps will you take to ensure that participation is **voluntary**? Be sure to provide the script for information provided by research personnel or written materials to be given to the participant.

Enter Text: The consent form will clearly state that participation is voluntary and that participants can choose to withdraw at any point in the study. Participants who withdraw from the study at any point will still receive full compensation for the time point they withdrew from (e.g. participants who withdraw from time 1 will not be compensated for time 2 since they will not be invited to participate). After time 1 participants will receive a short message providing information that there will be additional studies they would be eligible to participate in and encouraging them to participate. After time point 2 participants will be fully debriefed and provided with helpful resources on trans allyship. The consent and debriefing forms are attached.

G2. How will **information about the study** be provided to potential participants? If it is

necessary to obtain participation without informing participants of the true nature of the study, include a script for information that will be provided by research personnel or written material that will be given to participants. If participants are to be debriefed after participating, include debriefing script or materials.

Enter Text: Participants will be told that they are participating in a study intended to assess political attitudes, because awareness that the study investigates the link perceived helping behaviors and threats could cause participants to answer dishonestly (consciously or unconsciously), participants will be debriefed on the true nature of the study only after completing the second time points. The script is attached.

G3. If research involves **participant observation**, how will the researcher's role be explained to other participants in observed activities?

Enter Text: **NA**

G4. If participants are **minors** (under 18 years old), will parents' or guardians' consent be obtained? If not applicable, write "not applicable." If no, please explain. If yes, please explain and include a copy of the consent and assent forms with the application.

Enter Text: NA

H. LEVEL OF REVIEW: IRB Committee Use Only

☐ Exempt (*check off all categories that apply*)

☐ Expedited

☐ Full Committee

Protocols MUST be received by the IRB at least 2 weeks before the next scheduled IRB meeting. See **schedule**. Send application and any/all additional documents as email attachments to ocirb@oberlin.edu. Please remember to keep copies of all materials submitted to the IRB. If you need help, please call 440-775-8410 or email ocirb@oberlin.edu

I. ASSURANCE STATEMENT

I confirm that the procedures described above are accurate and will be followed in the course of the research project. I will notify the IRB of any changes to procedures and if unanticipated problems arise during the research process.

Printed Name of Researcher: Rebecca Totton **Date**:

Students: This form **MUST** be reviewed and submitted via email by your faculty supervisor

Printed Name of Faculty Supervisor: **Date**:

Faculty Supervisors/Advisors: Please initial below, indicating you have performed the duties listed for **Faculty Advisors**

Initials: RT

J. Exemption Categories: IRB Committee Use Only

☐ (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.

☐ (2) 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).

☐ (3)(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.

☐ (4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, 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 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described

under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ (5) Research and demonstration projects that are conducted or supported 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. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

☐ (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.

☐ (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).

☐ (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.