The Wright Center for Graduate Medical Education
Institutional Review Board
WCGME – IRB

Exemption Determination Checklist

PI Name:	**IRB Number:**
Protocol Title:	
Reviewer:	**Date:**

I. Reviewer COI

1. Do you have any interests, financial or otherwise, related to this submission that could present a conflict of interest?

☐ Yes. Please do not conduct this review, contact the IRB office so that the review can be reassigned.
☐ No

II. Evaluation of Exemption

1. If the research is federally conducted or supported, has the funding agency determined this research, or type of research, exempt?

☐ NA – the research is not federally conducted or supported
☐ Yes.* Explain:
☐ No

**After explaining the agency exemption, skip ahead to Section IV.*

2. Does the research involve prisoners?

☐ Yes. The research is not eligible for exemption. Skip ahead to Section V.
☐ No

3. Is the research FDA-regulated (i.e., clinical investigation of drug, device, or biologic)?

☐ Yes.*
☐ No

** Category 6 is the only allowable exemption category (other than Emergency Uses) unless the FDA has declared the research exempt.*

4. Exemption Categories. In order to be exempt, the research activities involving human subjects must fall wholly within one or more of the following categories. Indicate all of the categories that apply:

☐ **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.

☐ **Category 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 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
(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 subject, and an IRB conducts a limited IRB review to make the determination required by .111(a)(7).

Note: The exemption for research involving survey or interview procedures or observation of public behavior, does not apply to research with children except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

☐ **Category 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 recording if the subject prospectively agrees to the intervention and information collection and 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 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
(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)

Benign behavioral interventions do not employ deception unless otherwise authorized by the participant/s, are brief, harmless, painless, not physically invasive, offensive/embarrassing to the subjects

☐ **Category 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 the 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 [HIPAA], for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or "public health activities and purposes" as described under 45 CFR 164.512(b)

(iv) The research is conducted by, or on behalf of, a Federal dept. 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 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. [§__.104(d)(4)]

Note: This category can be applied to research involving the temporary, short-term, recording of identifiers (separate from the actual research data) in which an investigator does the following:

- accesses identifiable private information from one source, for example, outpatient clinic records;
- records only identifiable information (not private information), for example, name or medical record number for the purpose of identifying individuals whose existing data, documents, records, or specimens might be necessary to conduct the research analyses;
- in a document separate from the document in which identifiable information is recorded, records information obtained from the data, documents, records, or specimens accessed for the intended research purposes to create a separate dataset of non-identifiable data;
- destroys the document containing identifiable information immediately after the data collection is complete; and,
- conducts the research analyses on the non-identifiable dataset.

☐ **Category 5:** Research and demonstration projects which are conducted or supported by a Federal dept. or agency, or otherwise subject to approval of dept. 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 benefit:

(i) Public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; **or**
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

The following additional criteria must be satisfied for research to qualify for this exemption:

(i) The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).

(ii) The research or demonstration project must be conducted pursuant to specific federal statutory authority.
(iii) There must be no statutory requirement that the project be reviewed by an IRB.
(iv) The project must not involve significant physical invasions or intrusions upon the privacy of participants.
(v) Institutions should consult with the HHS funding agency regarding the above conditions before invoking this exemption.

Are the above described additional requirements for this exemption satisfied?

☐ Yes
☐ No. Explain:

☐ **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 FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S.D.A.

Note: If the research is FDA-regulated, this exemption only applies to the requirement for IRB review at 21 CFR 56. The regulations at 21 CFR 50, including informed consent, still apply. However, if the research is minimal risk, the requirement for informed consent may be able to be waived.

5. Do all research activities involving human subjects fall within the above categories?

☐ Yes
☐ No. Explain:

Exempt categories 7 & 8 have not been adopted by TWC at the is time

III. HIPAA

1. Does the proposed research involve the access, use, or disclosure of Protected Health Information (PHI)?

☐ Yes
☐ No. Skip ahead to Section IV.

2. Has the investigator requested a waiver or alteration of the requirement for HIPAA authorization?

☐ Yes
☐ No. Skip ahead to Section IV.

3. Please indicate which of the following the investigator has requested: *(check all that apply)*

☐ A full waiver of the requirement for HIPAA authorization
☐ A partial waiver of the requirement for HIPAA authorization (e.g., for screening or recruitment)
Briefly describe:

☐ An alteration of authorization (e.g., removal of the signature and date requirement)
Which core element(s) or statement(s)?

4. Based upon the information provided by the investigator, indicate whether the criteria for a waiver or alteration are satisfied ('Yes).

Criteria (45 CFR 164.512(i))	**Yes**	**No**
The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:	☐	☐
☐ An adequate plan to protect the identifiers from improper use and disclosure		
☐ An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law		
☐ Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by HIPAA		
The research could not practicably be conducted without the requested waiver or alteration	☐	☐
The research could not practicably be conducted without access to and use of the PHI	☐	☐

Reviewer Comments:

IV. Ethical Standards for Exempt Research

1. Based upon the information provided by the investigator, indicate whether the following ethical criteria are satisfied ('Yes). A NA option has been provided where appropriate.

Criteria	**Yes**	**No**	**NA**
The research holds out no more than minimal risk to participants	☐	☐	
Selection of participants is equitable	☐	☐	
If the research uses identifiable information/biospecimens, it could not be practically carried out without using such information/biospecimens in an identifiable format	☐	☐	☐
If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data	☐	☐	☐
If there are interactions with participants, there are adequate provisions to protect the privacy interests of participants	☐	☐	☐
If there are interactions with participants, the consent process or information provided to potential subjects includes the following: ☐ NA – there are no interactions and no other need for consent			
That the activity involves research	☐	☐	☐
A description of the procedures	☐	☐	☐
That participation is voluntary	☐	☐	☐
Name and contact information for the researcher	☐	☐	☐

Reviewer Comments:

V. Determinations

Based upon the information provided by the investigator, the proposed research:

Exemption:

☐ Qualifies for exemption under category(ies):
☐ May qualify for exemption, but changes or additional information are needed (describe below)

☐ Does not qualify for exemption (describe why below). Select one of the following:

- ☐ The proposed activity is not human subjects research (complete Human Subject Research Checklist)
- ☐ Refer for expedited review
- ☐ Refer for convened board review

Ethical Standards:

☐ The research is consistent with TWC's ethical standards for exempt research
☐ The research may be consistent with TWC's ethical standards for exempt research, but changes or additional information are needed (describe below).

HIPAA Waiver or Alteration:

☐ NA
☐ Satisfies the criteria for Waiver or Alteration, the request is approved as described
☐ May qualify for a Waiver or Alteration, but changes or additional information are needed (describe below)
☐ Does not qualify for a Waiver or Alteration (describe why below).

Reviewer Comments – Please use this space to describe any changes or clarifications that are needed; or, If the research does not qualify for exemption or for HIPAA waiver or alteration, to describe why. Please word as you would like the information to appear on the determination letter to the researchers.