Keuka College
Institutional Review Board
Application for Exemption

This form is used by investigators to apply for an exemption from further IRB review and approval. Some categories of research that otherwise qualify for exemption may require a limited IRB review. Each of the exemptions may be applied to the use of pregnant women as research subjects. Only some of the categories can be applied to children and only one to prisoners. If the research is FDA-regulated research, it is only eligible for exemption under Category 6. To learn more about how each of the exemptions may be applied, visit the "Resource Library" page at the Keuka College IRB website at https://sites.google.com/keuka.edu/kchsirb/home***. To learn more about KC IRB's submission and review process, refer to the page on "Submitting a Proposal to IRB".***

This form MUST be accompanied by a completed Research Project Protocol.

IMPORTANT:

- Save document as filename that includes the date of submission: **exempt_dd-mm-yyyy**
- For check boxes:
  In Google.docx: select the appropriate box then right-click and select ✓
  In MS Word: Highlight text to indicate selections

I. Project and Principal Investigator General Information

Principal Investigator/Researcher:
Email Address (Keuka College email account):
Telephone No.:
Academic Program or Department:
Credentials (Student/Faculty/Staff):

Faculty Sponsor (required for student projects):
Email Address (Keuka College email account):
Telephone No.:
Academic Program or Department:
Credentials:

Project Title: Click here to enter text.

(To check a box, select the appropriate box then right-click and select ✓)	
Does this research involve <u>any form</u> of interaction (e.g. interviews, surveys, testing) with or observation of individuals (humans)? ❑ **No** ❑ **Yes**	**Does this research involve the use of <u>existing data</u>?** ❑ **No** ❑ **Yes** **<u>If yes</u>:** **Are the data de-identified?** ❑ **No**

(Adapted from protocol templates from Buffalo State University and US Dept. of VA – rev. July 2019)

	❑ **Yes** **Are the data publicly available?** ❑ **No** ❑ **Yes**
Is the research being conducted limited to a review of existing research found in scholarly journals or other published work? ❑ **No** ❑ **Yes**	**What do you plan to do with the results of your research? Check ALL that apply.** ❑ **Students only: Submit the results to an instructor/faculty as part of the requirements for a course or degree program** ❑ **Students only: Share the results with other students in my class or cohort** ❑ **Evaluate or improve a non-experimental program or process already in practice** ❑ **Share the results at a public venue (e.g. professional conference, campus-wide presentation)** ❑ **Submit the results for publication in a peer reviewed serial** ❑ **Submit the results for publication in a non-peer reviewed publication** ❑ **Other:_____**
Is the research being conducted at an organization, or with subjects who are selected because of their membership with an organization? ❑ **No** ❑ **Yes** *If yes, provide a copy Site Permission Letter.* **Has another IRB reviewed an exemption request for this study?** ❑ **No** ❑ **Yes** *If yes, provide a copy of the IRB Determination.*	**If this research involves one or more of the following vulnerable populations, check the applicable boxes:** ❑ Children ❑ Pregnant Women ❑ Impaired Decision Making ❑ Prisoners ❑ Educationally or Financially Disadvantaged
Are you receiving funding for this study? If yes, briefly describe. **No** **Is there a risk for actual or perceived financial or other conflict of interest? If yes, this must be disclosed and explained.** **No**	**Will you be accessing, collecting, or analyzing Protected Health Information?** ❑ **No** ❑ **Yes** *If yes, attach either a 1) Request for HIPAA Waiver or 2) HIPAA authorization form as appropriate.*
What is your target start date (MM/DD/YY)? (Be reasonable. The review process can take up to 30 days, and this does not include time for revision and resubmission, if necessary.) 8/31/20	**What is your target end date (MM/DD/YY)? (May not exceed 1 year after the start date)** 12/10/20

Note: Target start and end dates should take into account IRB review schedule and processes, and are contingent upon the level of review required and the clarity and completeness of the protocol and supplements submitted for review.

II. Exemption Category– Attach your completed Research Project Protocol. Complete the category below under which your study qualifies for an exemption by carefully reading the qualifying criteria and checking any options as applicable.

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 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 and auditory recording).

A copy of any surveys or interview questions must be included with this submission.

Please answer the following questions so IRB can determine if the study meets the criteria for this category:

1. What methods will be used in this study? *Check all that apply below:*

❏ Educational Tests
❏ Surveys
❏ Interviews
❏ Observations of Public Behavior

2. If observations of public behavior is checked above, is the investigator participating in the observations being observed?

❏ No
❏ Yes

3. Does this research involve procedures for which written consent is normally required outside the research context?

❏ No
❏ Yes

If yes, Informed Consent document must be included with this request.

4. Does this research involve *more than minimal risk* to subjects? *Minimal risk* means that 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.

- ❑ No
- ❑ Yes

If yes, Informed Consent document must be included with this request.

5. Is the information obtained recorded by the investigator in such a manner that the identity of human subjects can be readily ascertained, directly or through identifiers linked to the subjects?

- ❑ No
- ❑ Yes

If yes, you may submit a Request For Waiver of HIPAA Authorization or Request for Waiver of Informed Consent, as appropriate, with this request. Limited IRB review may be required. Refer to guidance on Informed Consent (IC) and conditions under which IC may be waived in the IRB website Resource Library

If no is checked, will any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, educational advancement, or reputation?

- ❑ No
- ❑ Yes

Note: The exemption involving survey or interview procedures or observations of public behavior **does not apply to research involving children, except for** research involving observation 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.

- ❑ 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. Examples include having the subjects play an online game, solve puzzles under various noise conditions, or have them decide how to allocate money between themselves and someone else.

Please answer the following questions so the IRB can determine if the study meets the criteria for this category:

1. Describe the nature of the benign behavioral intervention(s) used in this study and how the prospective agreement is obtained or reference where in the protocol the description can be found:

Click here to enter text.

2. Does this research involve deceiving the subjects regarding the nature and/or purposes of the research?

- ❑ No
- ❑ Yes

If checked yes, this exemption is not applicable unless the subject authorized the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he/she will be unaware of or misled regarding the nature or purposes of the research. Ensure this requirement is adequately documented in the protocol and in the above question.

3. Is the information obtained recorded by the investigator in such a manner that the identity of human subjects can be readily ascertained, directly or through identifiers linked to the subjects?

- ❑ No
- ❑ Yes *If yes,you may submit a Request For Waiver of HIPAA Authorization, with this request. Limited IRB Review may be required.*

If no is checked, will any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, educational advancement, or reputation?

- ❑ No
- ❑ Yes

Category 4

- ❑ Secondary research uses of identifiable private information or identifiable bio specimens if at least one of the following criteria is met:

At least one of the below boxes must be checked and a Request for Waiver of HIPAA Authorization must be submitted.

- ❑ The identifiable private information or identifiable biospecimens are publicly available.

- ❑ 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.

- ❑ The research involves only information collection and analysis involving the investigator's use of identifiable 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 164.512(b).

- ❑ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities; if the research generates identifiable private information that is or will be maintained on the information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501note; 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.

Category 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, 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.

Category 6

❑ The research involves taste and food quality evaluation and consumer acceptance studies if one of the following criteria is met:

One or both boxes must be checked below:

❑ Wholesome foods without additives will be consumed.

❑ A food will be consumed that contains a food ingredient at or below the level 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 (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the US Department of Agriculture.

If your project involves FDA-regulated products, Category 6 is the only category that can be used to request exemption of an FDA-regulated study. Submission of a HIPAA authorization or a Request for Waiver of HIPAA Authorization may be required if PHI is accessed, collected, used, or analyzed.

Category 7 ***Note: Refer to the policy on broad consent and the use of broad consent forms.***

❑ 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. *Note: Limited IRB review is required for this exemption.*

Category 8

❑ Secondary research for which broad consent is required. Research involving the use of identifiable private information or identifiable bio specimens for secondary research use. *Note: Limited IRB review will be conducted if this box is checked.*

Both of the below boxes must be checked for the study to meet this category and a copy of the broad consent form and, if applicable, a request for Waiver of HIPAA Authorization, must be submitted.

❑ Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained.

❑ The research plan for this project does not include returning any results to subjects. This provision does not prevent an investigator from abiding by any legal requirements to return any individual research results.

III. Review Issues – Indicate in the below table where in the protocol each of these issues is addressed or mark the issue as N/A.

Exemption Issue *Note: Unless an issue is not applicable, be sure all portions of the questions are covered in the protocol*	**Reference the protocol page and section.**	**If not referenced in the protocol, cite document type, page and section where it is referenced.**	**Check this box if the issue is not applicable**
How is identifiable data, if applicable, being collected, recorded?			
What are the sources of any existing data that will be obtained?			
How will the identifiable data be used and stored, and what type of equipment will be used to store and analyze the data?			
Who will have access, share, or receive identifiable data?			
What are the protocol procedures or benign interventions?			
If deception is utilized, how will prospective agreement be obtained?			
If broad consent is used, how is this consent obtained, documented, and stored?			
What safeguards are in place to maintain the privacy and confidentiality of identifiable data?			
If interacting with participants, particularly vulnerable populations, what safeguards are in place to avoid undue influence and coercion?			
What measures are included in the protocol to minimize risk?			

IV. Document Checklist

Check all items that are being submitted with this Application for Expedited or Full Review:

- ❑ Copy of Research Project Protocol
- ❑ Copy of PI's Certification of Completion of Keuka College-approved IRB training on Revised Common Rule
- ❑ Copy of PI's CV

The following items must be included if applicable per the Exemption Category checked in Section II.

❑ Broad Consent Form (Category 7) Combined Consent/HIPAA **or** ❑ Consent Form only		❑ Copy of Approved Broad Consent (Category 8)
❑ Request for Waiver or Alteration of HIPAA Authorization		❑ IRB Approval Letter for Broad Consent (Category 8)
❑ Survey/Interview Instruments/Recruitment Tools/ etc.		❑ HIPAA Authorization
❑ Other: *List*		

V. Multisite Points of Contact

If multiple sites are involved in this research, list below the sites that will be engaged in this research and the Co-Investigators (CI) or Points of Contact (POC) at each site:

Additional rows can be added as needed.

Research Site (Organization/Location//City)	**CI or POC Name**	**CI or POC Email**	**CI or POC Phone**

VI. Investigator (and Faculty Sponsor, if applicable) Assurance and Certification

As the Principal Investigator (PI), and the Faculty Sponsor (FS) in the case of student research, for this project, I certify the following:

PI (initial)	**FS (initial)**	
		The information provided on this Request for Exemption and all associated attachments is complete and accurate to the best of my knowledge. Informed Consent and Assent forms (if applicable) are in Google.docx or MS Word format.
		My initials to the left indicate that I have read and understand the following policy: A key component of an Institutional Review Board (IRB) review is considering scientific merit as a function of protecting the rights and welfare of human subjects. Research that either 1) is not involving human subjects or 2) qualifies for Exempt level of review AND does not involve protected populations will not be reviewed for scientific merit. ALL other research - regardless of the level of experience of the researcher/principal investigator - will undergo a review process that is intended to ensure that the research is of sound design and methodology.
		If the IRB determines that the submitted project is exempt, I as the Principal Investigator/Study Chair maintain responsibility for the ethical conduct of the research and for safeguarding the rights and welfare of all involved human participants.
		I will submit all modifications that may affect the exempt status or exempt category of this study to the IRB for further review to ensure the project remains exempt or I will submit the study for full IRB review and approval.

		I will ensure a Keuka College-approved educational training program on Human Research Subjects Protections is completed by all project team members involved in the conduct of this research project. **Check one:** ❑ Copy of Certificate of Completion of Keuka College-approved IRB training by Principal Investigator is included in this application. ❑ Copy of Certificate of Completion of Keuka College-approved IRB training by Principal Investigator has yet to be completed but will be provided (note, this may result in a delay in approval of your application).
		The research will be conducted in such a manner as to comply with all Keuka College policies and procedures, as well as all applicable federal, state, and local laws regarding the protection of human participants, to include data security requirements.
		The research design does not provide for situations in which financial or other personal considerations may compromise — or have the appearance of compromising — the professional judgment of investigators in conducting or reporting research. (Note: if a financial or other conflict of interest is possible, this must be disclosed in writing.)
		I will notify the IRB upon completion of the project and will respond to any requests as to the status of the study as requested.

Note: Electronic signature only accepted for applications submitted in PDF. All other formats require handwritten signature. Learn how to include your electronic signature using Adobe Acrobat (Windows, Mac) or Preview (Mac only) HERE.

Printed Name of Principal Investigator Date

Signature of Principal Investigator Date

Printed Name of Faculty Sponsor, if applicable Date

Signature of Faculty Sponsor, if applicable Date