Form 6

CENTRA HEALTH-- Institutional Review Board

EXEMPT RESEARCH FORM

Version 10, 01MAR2023

This Exempt Research Form (ERF) application is to determine if your research requires submission of an application to Centra Health Institutional Review Board.

If the **ONLY** involvement of human subjects will be in one or more of the following categories listed in this document **AND** all the answers in one or more categories are "True" (except as noted in statements 7 and 11 below), the research may be eligible for exemption. However, the research must be determined to be exempt by the IRB.

Case study submissions should also be submitted for approval with required documents using this form. Include the title of the case report along with all other required documentation (see submission checklist in Appendix A). Please mark the box on page three of this form to indicate if you are seeking review for a planned publication or presentation.

Supplemental documentation is required for consideration of exemption status. A submission checklist (Appendix A) is attached to assist you.

Complete and send the application and **all** other pertinent electronically as a pdf via email irb@centrahealth.com.

Address for all Applications and Other Correspondence
irb@centrahealth.com

Centra IRB
Received (date):

Action:

Date: _____

Centra IRB #: _____ (will be assigned by the IRB upon submission)

IRB of Record _____

Facility:

Principal Investigator:

Email address:

Phone number:

Title of Research Project/Study Title:

Please read the following to answer the question below:

Do the HHS regulations for the protection of human subjects in research (45 CFR part 46) apply to quality improvement activities conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes?

No, such activities do not satisfy the definition of "research" under 45 CFR 46.102(d), which is "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge..." Therefore, the HHS regulations for the protection of human subjects do not apply to such quality improvement activities, and there is no requirement under these regulations for such activities to undergo review by an IRB, or for these activities to be conducted with provider or patient informed consent.

Having read the above,

1. Is this research? If yes, stop and complete the initial application Form 1 unless your research meets all criteria below.

2. Is this quality improvement activities? If yes and you anticipate publication, please indicate here ☐ and continue to fill out the form.

3. Check below if this is a case report submission for review and approval from the IRB exempt research committee. If so, go to signature(s) page. ☐

Supplemental documentation is required for consideration of exemption status.

	True	Not True
Criteria that must be met for the research to be determined to be consistent with IRB ethical standards.		
The research holds no more than minimal risk to subjects.		

Selection of subjects is equitable.		
If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.		
There are adequate provisions to maintain the privacy interests of subjects.		

PLEASE CHOOSE ONLY ONE PERTINENT CATEGORY BELOW:

Checklist Statements	**True**	**Not True**
Category 1 – For Educational Settings		
1. The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.)		
2. The research will involve only normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.		
3. The research will not involve individuals as participants who are known to be prisoners.		
4. The research is not subject to FDA regulations.		
Category 2 – For Educational Tests, Surveys, Interviews, Public Behavior Observation:		
5. The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.		
Address statement 6 only if the research will involve children as participants. If children will NOT participate, state N/A and continue with statement 7. 6. The procedures will be limited to the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the investigator will NOT participate in the activities being observed.		
7. The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects. ***"True" to <u>either</u> statement 7 or 8 will qualify for exemption provided that statements 9 <u>and</u> 10 are true.***		
8. Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.		
9. The research will <u>not</u> involve individuals as participants who are known to be prisoners.		
10. The research is not subject to FDA regulations.		
Category 3 – For Educational Tests, Surveys, Interviews, Public Behavior Observation of Public Officials:		
11. The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND the human subjects are elected or appointed public officials or candidates for public office. (Applies to senior officials such as mayor or school superintendent rather than a police officer or teacher.)		

"True" to <u>either</u> statement 11 or 12 will qualify for exemption provided that statements 13 <u>and</u> 14 are true.		
12. The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior AND federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.		
13. The research will <u>not</u> involve individuals as participants who are known to be prisoners.		
14. The research is not subject to FDA regulations.		
Category 4 – For Existing Data, Documents and Specimens:		
15. The research will involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. ("Existing" means existing before the research is proposed to the IRB to determine whether the research is exempt. All materials to be reviewed currently exist at the time of this exemption request.)		
16. The sources of the existing data, documents, records or specimens are publicly available **<u>OR</u>** the information will be recorded by the investigator in such a manner that participants cannot be readily identified either directly or through identifiers (such as a code) linked to them.		
17. The research will <u>not</u> involve individuals as participants who are known to be prisoners.		
18. The research is not subject to FDA regulations.		
Category 5 – For Public Benefit or Service Programs (Federal):		
19. The project is a research or demonstration project conducted by or subject to the approval of a (federal) Department or Agency head and which is designed to study, evaluate, or otherwise examine: (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 public benefit or service programs.		
20. The research will <u>not</u> involve individuals as participants who are known to be prisoners.		
21. The research is not subject to FDA regulations.		
22. The program under study delivers 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).		
23. The research or demonstration project will be conducted pursuant to specific federal statutory authority.		
24. There is no statutory requirement that the project be reviewed by an IRB.		
25. The project does not involve significant physical invasions or intrusions upon the privacy of participants.		
26. The exemption has authorization or concurrence by the funding agency.		
Category 6 – For Taste and Food Quality and Consumer Acceptance Studies:		
27. The research involved only a taste and food quality evaluations or a food consumer acceptance study in which (i) wholesome foods without additives will be consumed **<u>OR</u>** (ii) food will be consumed that contains		

a food ingredient, agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration or is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.		
28. The research will <u>not</u> involve individuals as participants who are known to be prisoners.		
Emergency Use of an Unapproved Test Article (i.e., a drug, device or biologic that is not FDA-Approved)		
The activity involves emergency use of an investigational drug, device or biologic. Such an activity is not exempt from IRB review. However, this emergency use may occur prior to IRB review and approval (see Category A and B in the Emergency Use Policy for details.) Note that such an emergency use must be reported to the IRB within five business days.		
The activity does not meet with DHHS definition of "research."		

Signature of Principal Investigator:

_____

Typing my name on the line above constitutes an electronic signature.

Printed Name

_____

Date _____

FOR THE IRB REVIEWER ONLY:

Is the activity exempt? YES [ ] NO [ ]

Does the research meet the standards of ethical conduct? YES [ ] NO [ ]

Which exemption category or categories apply to the activity? _____

1/2/3/4/5/QI/PI/EBP/Case Report

Approved by IRB Exempt Committee (date): _____

Signature of IRB Reviewer:

_____

Typing my name on the line above constitutes an electronic signature.

Printed Name _____

Date _____

APPENDIX A

EXEMPT SUBMISSION CHECKLIST

_____ Letter of support from Unit Manager (if applicable)

_____ Primary Investigator and Co-Investigator(s) CV

_____ All educational materials for staff and patients (if applicable)

_____ Research or EBP project proposal form

_____ Data collection tools/instruments (surveys, etc.)

_____ Any additional subject information materials

_____ Any other pertinent documents related to this study

_____ Documentation of completed onboarding with OMESA (students only)

_____ Name and CV of Centra employee PI or preceptor (non-Centra employee/student projects only)

CASE REPORT REQUIREMENTS

_____ Primary Investigator and Co-Investigator(s) CV

_____ Documentation of completed onboarding with OMESA (students only)

_____ Name and CV of Centra employee PI or preceptor (non-Centra employee/student projects only)

_____ Authorization of Protected Health Information Form

_____ Summary of Proposal