BAYCARE Institutional Review Board **POLICY/PROCEDURE**

TITLE: Exemptions from IRB Review Requirements	**POLICY NUMBER:** IRB-E02W61
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ISSUED FOR: All BayCare, Investigators and Research Personnel **SPONSORED BY:** BayCare Institutional Review Board	**ORIGINAL ISSUE DATE:** 04/14 **REVISION DATE:** 10/18, 01/19 **REVIEW DATE:**
APPROVED BY: BayCare Health System (BCHS) Institutional Review Board (IRB)	

The Department of Health and Human Services (DHHS) issued revised regulations governing research involving human subjects altering the scope of previous Department regulations by exempting categories of research which present little or no risk of harm to human beings. At BayCare Health System, the Institutional Review Board (BCHS IRB) accepted the exempted research categories.

PURPOSE:

The Department of Health and Human Services (DHHS) issued in June 19, 2018 revised regulations governing research involving human subjects. The amended regulations alter the scope of previous Department regulations by exempting categories of research which present little or no risk of harm to human beings. This is explained in the transition provision (45 CFR 46.101(l), as amended June 19, 2018).

POLICY:

The BCHS Institutional Review Board (IRB) and hospitals have accepted the exempted DHHS research categories. Exemption from IRB review and approval must be based on the exemptions specified in the Federal Regulations of 1981 and revised in 1983 and in the Final Rule of 2018, and the responsibility for certifying the exemption rests with the IRB Co-Chairperson and or IRB Expedited/Exempt sub-committee.

PROCEDURE:

1 Investigator completes IRB Exemption Form (see the Human Subject Regulations Decision Chart for assistance)

2 The Investigator identifies which research exemption category applies.

3 EXEMPTION CATEGORIES (45 CAR 46.101(b)1-8)

3.1 Research activities in which the only involvement of human subjects will be in one or more of the following categories:

3.1.1 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.

3.1.2 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).

3.1.3 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 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.

3.1.4 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 non-research 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 applicable federal privacy standards found in the E-Government Act, Privacy Act and the Paperwork Reduction Act.

3.1.5 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. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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.

3.1.6 Taste and food quality evaluation and consumer acceptance studies: if wholesome foods without additives are consumed, or 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.

3.1.7 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 §__.111(a)(8).

3.1.8 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 §__.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 §__.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §__.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 479

(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 any legal requirements to return individual research results.

4 The IRB Office, Expedited/Exempt sub-committee

4.0.1 IRB Office uploads the exemption information into the Data Base (IRBANA)

4.0.2 Expedited/Exempt sub-committee reviews the submission

4.0.3 deems the exemption is accurate, and confirms the exemption and approves the submission

4.0.4 IRB Office includes the information for inclusion on the month's Agenda for reporting to the Board and inclusion on the Agenda and subsequent Minutes

5 A letter approving and confirming the exemption will be sent to the investigator.

6 If the proposal is determined to be exempt, the investigator, if requested by the IRB to do so; must still inform potential subjects as to the proposed research procedures and their rights as subjects.

7 If a research proposal is certified as exempt by the IRB, the investigator need not resubmit the proposal for continuing IRB review as long as there are no modifications to the exempted procedures.

8 If the IRB does not accept the exemption, the investigator is required to submit the project to the IRB for Full Board review.

9 Proposal receiving an exempt determination are not subject to an annual Continuing Review process. An amendment is required only if the change to the proposal project would modify the criteria for the exemption previously submitted. Please note that an exemption from IRB review determination does not in any way lessen the investigator's ethical responsibility to the subject(s) as pronounced in the Belmont Report.