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| **Exempt from IRB Review Application – Research or Quality Improvement Project** | | | |
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| Date: | | | |
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| 1. **Project Identification** | | | |
| 1. Title of Research or QI Project | | | |
| 1. Sponsor Investigator-Initiated Other (Specify) | | | |
| 1. Investigators | Name | Contact: Phone Number and email address | Position |
| Principal Investigator |  |  |  |
| Sub-Investigator |  |  |  |
| Sub-Investigator |  |  |  |
| Study Coordinator |  |  |  |
| Administrative Contact |  |  |  |
| 1. **Mark each category describing the proposed research or quality improvement project** (*Research activities* in which the only involvement of human subjects will be in one or more of the following categories are exempt from review. If the research activity is FDA regulated or collects Protected Health Information, it cannot be exempt. *Quality improvement initiatives* may be exempt from IRB review if they do not satisfy the definition of “research”). 2. Unless otherwise required by department or agency heads, *research activities* in which the only involvement of human subjects will be in one or more of the following categories are exempt from Basic HHS Policy for Protection of Human Research Subjects per 45 CFR 46.101 (b) (1 thru 6) or the *quality improvement project* does not satisfy the definition of “research” 45 CFR 46.102 (d). Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. | | | |
| |  |  |  | | --- | --- | --- | |  | **Category 1** | **Educational Purposes.** Research conducted in established or commonly accepted educational settings, involving 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. | |  | **Category 2** | **Educational Tests, Surveys, Interviews, Public Observation.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. | |  | **Category 3** | **Elected or Public Officials.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. | |  | **Category 4** | **Research with Existing Data.** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. | |  | **Category 5** | **Public Benefit or Service Programs.** Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are 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 programs. (This category may be used for federal programs only) | |  | **Category 6** | **Taste Tests.** 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 USDA. | |  | **Category 7** | **Quality Improvement Activities.** An activity being conducted by one or more institutions whose purposes are limited to: (a) implementing a practice to improve the quality of patient care, and/or (b) collecting patient or provider data regarding the implementation of the practice for clinical, practical, or administrative purposes. | |  | **Category 8** | **Quality Improvement Activities.** An activity being conducted by one or more institutions whose purposes are limited to: (a) delivering healthcare, and (b) measuring and reporting provider performance data for clinical, practical, or administrative uses. | | | | |
| 1. **Summary of Research Activities or Quality Improvement Project** | | | |
| Briefly describe the intent of the research or QI project. | | | |
| Describe why the research procedures or QI project will not cause a subject either physical or psychological discomfort or be perceived as harassment above and beyond what the person would experience in daily life. | | | |
| What is the subject population? How will they be recruited / identified? | | | |
| Does the research or QI project involve minors? If yes, explain | | | |
| Identify the specific items of data that are to be collected. | | | |
| Does the research or QI project involve deception? | | | |
| Describe provisions to maintain confidentiality of data both during and after study completion. | | | |
| Will the research or QI project involve obtaining data through intervention or interaction with subjects? *(e.g., physical procedure, manipulations of participants or their environment, communication or interpersonal contact between researcher and participant including interviews, surveys, focus groups, online surveys, etc.)*  Yes No | | | |
| Describe the provision(s) included in the research or QI project to protect the privacy interests of subjects. | | | |
| How will you inform subjects about the research project and procedures? | | | |
| Where will the research or QI project be conducted (where will you interact with subjects or obtain existing data)?  Baptist Memorial Hospital and Clinics (list all sites)         Department        Address           Department        Address  *For any additional sites please attach a separate sheet*  Non-BMHCC Site (specify)        Address  *If the study will be done at a non-Baptist institution, you must document approval by an authorized official of the institution. If the institution has an IRB, you must provide documentation that it has either approved this research or accepted the oversight of the Baptist IRB.* | | | |
| 1. **Attachments –** List and attach all instruments to be used *(surveys, questionnaires, interview questions, scripts, consent forms, etc.)* | | | |
| **VI. Principal Investigator’s Assurance Statement:**  I understand the Baptist policies concerning research involving human subject research participants and I agree:   1. to comply with all Baptist IRB policies, decisions, conditions, and requirements; 2. to accept responsibility for the scientific and ethical conduct of this research study; 3. to obtain prior approval from the IRB before amending or altering the research protocol or implementing changes in the approved consent form as it could change the exempt status of this research study; 4. to report to the IRB in accord with IRB policy any adverse event(s) and/or unanticipated problem(s) involving risks to participants; 5. each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.   Furthermore, by signing below, I also attest that I have appropriate facilities and resources for conducting this study.  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Signature Date**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Sub-Investigator Signature Date**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Sub-Investigator Signature Date**    **Baptist IRB CHAIR’S ASSURANCE STATEMENT:**  This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study: to the competency of the investigator(s) to conduct the project and the time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate.  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature Date** | | | |