BAPTIST HEALTH
INSTITUTIONAL REVIEW BOARD
Changing Health Care for Good.®

Checklist for Determining Research Status

The IRB Chair or designee will follow this checklist to assure that IRB determinations are compliant with regulations and Baptist Health policy. The Checklist may be used as a reference or guide. Or the user may choose to use this to document the review. A signature is not required.

Date of Submission:

Principal Investigator:

Title of Study or Project:

Is this human subject research according to DHHS Regulations? (See definition below)

DHHS regulations under 45CFR46.102(f) define a human subject as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information .

Are **both** of the following true? • The activity is a systematic investigation, including research development, testing and evaluation. • The activity is designed to develop or contribute to generalizable knowledge	☐ Yes, **the project is research. Continue.** ☐ No, the project is not research. Comment:
Are **both** the following true? • The investigator will obtain data about living individuals. • *And, either or both* of the following are true: i. The investigator will obtain that data through intervention (physical procedures by which data are gathered and manipulations of the participants or participants' environment for research purposes) or interaction (communication or interpersonal contact between investigator and participant) with those individuals. ii. The information obtained is both private *and* identifiable. 1. *Private* because the information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place OR the individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record). 2. *Individually identifiable*, because the identity of the participant is or may readily be ascertained by the investigator or associated with the information.	☐ Yes, this is HSR per DHHS regulations. ☐ No, This is not HSR per DHHS regs. Comment:

Is this human subject research (HSR) according to FDA Regulations?

Are ***any*** of the following statements true? • The activity involves the use of a drug, other than the use of a marketed drug in the course of medical practice. • The activity involves the use of a device to evaluate safety or effectiveness of that device. • Data from the activity will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.	☐ Yes, go to next question. ☐ No, this is not HSR per FDA regulations. **Comments:**
Are **any** of the following statements true? • The test article will be used on one or more humans. • Data obtained from controls will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product. • Data obtained from use of a device on tissue specimens will be submitted to, or held for inspection by, the FDA in support of a marketing or research application for an FDA-regulated product.	☐ Yes, this is HSR per FDA regs and requires initial review by the convened IRB. (Except for Exempt Category 6: Taste and food quality evaluation and consumer acceptance studies. or Expedited Category 1: Clinical studies of drugs and medical devices only when the research is minimal risk and IND/IDE not required.) ☐ No. This is not HSR per FDA regulations. Continue. **Comments:**

If a project has been determined to be human subject research, it may meet the criteria for exempt status, or for review by the expedited procedure.

Before determining whether the research is eligible for exempt status or expedited review, complete this checklist. **If any of the answers are 'Yes", the research is not eligible** for either exempt status, or expedited review.

The research activities present more than minimal risk to human participants.	☐ Yes. ☐ No.
The research employs deception of research participants.	☐ Yes. ☐ No.
The research involves fetuses, pregnant women or human in vitro fertilization.	☐ Yes. ☐ No.
Identification of the participants or their responses may place them at risk of criminal or civil liability or may be damaging to their financial standing, employability, insurability, reputation, or stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.	☐ Yes. ☐ No.

IRB Use Only (to be completed by the Chair or designee):

☐ Yes. The submitted project does ***not*** meet the definition of human subject's research.
☐ No. The submitted project does constitute human subjects research and requires submission to the IRB for review.

Date of Review:

Reviewed by: