**Research Involving Coded or Anonymous Private Information**

**and Biological Specimens:**

**Does It Require IRB Review?**

**Version Date – FOR OHR USE: 8/23/19**

**STUDY TITLE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PRINCIPAL INVESTIGATOR:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ADDRESS/FAX# :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ TELEPHONE#/ E-MAIL:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Instructions:** This form is to be completed if your study involves only obtaining coded or anonymous private information or specimens, and is intended to determine whether IRB approval or exemption is required. Submit one copy of OHR-19. If you know that your study is exempt, then you should instead submit the OHR-18. Following review of the OHR-19, the Office of Human Research will return this cover page to you with a determination regarding IRB requirement for further review.

**Background:** Under the definition of human subjects in the 2018 Common Rule at 45 CFR 46.102(e)(1) obtaining *identifiable* private information or *identifiable* specimens for research purposes constitutes human subjects research. This would include an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens that are received, accessed, or already in the possession of the investigator. Private information or specimens are individually identifiable when they can be linked to specific individuals by the investigator either directly or through coding systems. If this is not the case, then private information and specimens are not considered to be individually identifiable, and neither IRB review nor IRB exemption are required.

Do not fill out this section – For IRB Use

**IRB DETERMINATION**

**\_\_\_** This study does not constitute human subjects research. You may proceed **without** IRB approval or exemption.

\_\_\_ This study constitutes human subjects research, and IRB **exemption** is required. Please submit the OHR-18.

\_\_\_ This study constitutes humans subjects research, and IRB **approval** is required. Please submit appropriate internal forms.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**

IRB Official Date

Walter Kraft, M.D. Kyle Conner, M.A., CIP

Director, OHR Associate Director, OHR

***To be completed by Principal Investigator***

**SECTION 1:**

If your study involves **only** coded or anonymous private information or specimens, please check the appropriate items below. (Both #1 and #2 **must apply** in order for research to be designated as not human subjects research according to HHS regulations)

\_\_\_ (1) The private information or specimens were not collected specifically for the currently proposed research through an interaction or intervention with living individuals.

\_\_\_ (2) The investigator cannot readily ascertain the identity of the individuals to whom the private information or specimens pertain, because (*check as appropriate*):

\_\_\_ (a) the private information or specimens are completely anonymized and there is no code that can be used to re-identify them.

\_\_\_ (b) a key to decipher the code either does not exist or will be destroyed before the research begins. (In other words, the information or specimens are permanently *de-identified* or *anonymous*.)

\_\_\_ (c) the investigator and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (This agreement **does not** require IRB review).

\_\_\_ (d) there are legal requirements prohibiting release of the key to the investigators, until the individuals are deceased.

Regarding (1), examples of private information or specimens to be collected in the future for purposes other than research are: (1) medical records; and (2) ongoing collection of specimens for tissue repositories.

**SECTION 2**:

|  |  |  |
| --- | --- | --- |
| Does your study involve the testing of an FDA-regulated device on coded or anonymous specimens? | YES\_\_\_\_ | NO\_\_\_\_ |

If YES, your study *does* qualify as human subjects research according to 21CFR812.3(p) which states: “Subject means a human who participates in an investigation, either as an individual on whom or *on whose specimen an investigational device is used* or as a control. A subject may be in normal health or may have a medical condition or disease.”

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**SECTION 3:**

Please provide or attach a brief summary (in lay language) of your research. Include: 1) a **description** of the tissue and/or data you are obtaining, and 2) an explanation of their source(s).You may also include any information that further explains your choices above.

**SIGNATURES**

|  |  |  |  |
| --- | --- | --- | --- |
| Person completing this report Date |  | Principal Investigator Date |  |