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| Study Title: |  |
| IRB Reference No: |  |
| Principal Investigator: |  |

**This waiver request applies to the following research activity or activities:** [mark the appropriate check box(s)]

No-subject-contact studies / Direct access of Electronic Health Records (EHR) by a member of the Research Team who is also a PHCC employee with authorized access to EHR as part of his clinical duties. (Retrospective medical record review)

Ascertainment (identification, selection) of potential research subjects by direct access of Electronic Health Records (EHR) by a member of the Research Team who is also a PHCC employee with authorized access to EHR as part of his clinical duties. Identifiable private information (classified as protected health information / PHI) will be recorded to facilitate future contact with eligible research participants followed by full informed consent for the rest of the study

Ascertainment (identification, selection) of potential research subjects by direct approach by a member of the Research Team who is also a PHCC employee not involved in the patient's care. The contact is either in person or by phone or written communication like email followed by full informed consent for the rest of the study

Large-scale epidemiological studies and other population-based studies requiring ascertainment (identification, selection) of potential research subjects through data repositories and registries (Like CERNER in PHCC). The researchers may need to contact prospective subjects directly (in person or by phone or written communication like email) rather than through professionals involved in the prospective subjects' health care.

**List the specific protected health information (PHI) to be collected and its source(s) specifying the date range**

*[Note: PHI = health information + identifiers]*

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**PHI Source:**

Electronic Medical/Clinical records (extracted by Research team)

Electronic Medical/Clinical records (extracted by BHI)

Pathology records

Radiology records

Other (describe**)**

**Subject information:**

How many subjects do you plan to study?

Approximately how many charts do you need to review in order to complete the project?

**IV. To obtain approval for a waiver, the research project must meet the criteria listed below. Please describe how your study meets these criteria.**

1. There is an adequate plan to protect subject identifiers from improper use and disclosure.

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1. There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

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1. The provision of adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project

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1. The recruitment could not practicably be conducted without the waiver of authorization (i.e., that it would not be practicable to obtain prior authorization directly from the research subject.)

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1. The research cannot be carried out without access to and use of the PHI.

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**Principal Investigator's Assurance**

With my signature on this submission, I assure the PHCC RSC/IRB that:

* the information provided in this waiver application is accurate and complete;
* the PHI that I request is the minimum amount of identifiable private information necessary for my research project;
* the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study