**De-identification agreement: Model letter to include in IRB submission**

**- for sending de-identified material to an outside institution**

**- for sending coded material if outside investigator will never receive identifiers**

**- for receiving de-identified or coded material from outside\* institution**

(\*outside means outside of MCW/FH, CHW, VA, or Blood Research Institute.)

***Note:*** *The MCW/Froedtert IRB cannot agree that the steps taken to de-identify material (data or biospecimens) are adequate under regulations and IRB policy unless the MCW investigator submits a detailed description of the project and the de-identification method for IRB review and prior approval. If the material originates at MCW/FH, and the MCW investigator will de-identify the material, he/she must submit an IRB application for Expedited Review. If the MCW investigator will receive de-identified material, he/she must submit an IRB application for Exemption or for Non-Human Subjects Research.*

*The following model letter is to be completed by both the MCW/FH and non-MCW investigator and included with the IRB application.*

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MCW/Froedtert Hospital study

Principal Investigator:

Study title:

PRO #:

Other non-MCW investigator

Name:

Institution:

Department:

This memorandum is submitted to the MCW/Froedtert Hospital IRB as documentation that one of the above-named parties has identified material (data or biospecimens), and plans to share completely de-identified material with the other party, and that the de-identification will be irreversible. The party with identified material will never under any circumstances re-identify that material for the other party. The party receiving de-identified material will never ask for identifying data, and will never attempt to re-identify the material.

For this project, the party with identified material is: \_\_\_\_\_\_\_\_\_\_ [*Name, corresponding to one of the two parties named above*].

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_          Date: \_\_\_\_\_\_\_\_\_\_\_\_\_

The party receiving de-identified material is: \_\_\_\_\_\_\_\_\_\_ [*Name, corresponding to the other party named above*].

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_        Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

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