TEMPLATE LANGUAGE FOR INVESTIGATORS USING MCW CLINICAL RESEARCH DATA WAREHOUSE (CRDW) (FOR USE IN THEIR MCW IRB APPLICATIONS)

Please explain your use of the CRDW using the following templated language within the indicated sections of the IRB application SmartForm… otherwise the IRB will not understand what you are doing and the review of your application, as well as the approval of your data request(s), will be delayed.

FOR ALL 5 SCENARIOS BELOW: Investigators that MIGHT utilize CRDW data MUST link their eBridge study applications to the CRDW bank (PRO00013874) in Section 26 of the SmartForm.

I. FOR INVESTIGATORS USING THE CRDW TO IDENTIFY AND/OR CONTACT ELIGIBLE PARTICIPANTS

In the Recruitment section (17.1) of SmartForm, the investigator must clearly state whether the CRDW is the ONLY way potential participants will be identified or the CRDW is one of *several* recruitment strategies.

The investigator should state:

"To identify potential participants and obtain their contact information for recruitment, the investigator will (a) search for eligible participants with the following inclusion/exclusion criteria by querying a cohort discovery tool (i2b2 and/or TriNetX) from the MCW Research Clinical Data Warehouse (PRO00013874), and then (b) seek IRB approval to extract the following contact information for each identified potential participant using the Honest Broker tool:

a. *<Specify cohort inclusion/exclusion criteria to be queried>*
b. *<Specify participant contact information to be extracted>*

Using this contact information, the investigator will then..."

II. FOR INVESTIGATORS USING THE CRDW TO ACCESS IDENTIFIED DATA WITH OR WITHOUT PARTICIPANT RECRUITMENT

In the Procedures section (30.1) of SmartForm, the investigator must clearly state whether the CRDW is the ONLY way potential participants will be identified or the CRDW is one of *several* recruitment strategies.

The investigator should state:

"Clinical data for this study will be obtained by... *<indicate one of the following options>*

(1) ...searching for eligible participants by querying a cohort discovery tool (i2b2 and/or TriNetX) from the MCW Clinical Research Data Warehouse (PRO00013874) with (a) the following inclusion/exclusion

criteria, and then (b) seeking IRB approval to extract or access the following clinical information for each identified participant using the Honest Broker tool:

a. *<Specify cohort inclusion/exclusion criteria to be queried>*
b. *<Specify clinical information to be extracted/accessed>*

(2) ...entering a list of medical record numbers for identified participants into the Honest Broker tool and then submitting an approval request to the IRB for the following clinical information for each participant:

a. *<Specify clinical information to be extracted/accessed>*

Using this identified clinical information, the investigator will then..."

III. FOR INVESTIGATORS USING THE CRDW TO ACCESS DE-IDENTIFIED DATA for purposes other than participant recruitment

Some investigators may not be required to submit anything to the IRB for this scenario – contact CRDW.mcw.edu for guidance. Other investigators may have "mixed" projects involving CRDW de-identified data *AND* other activities requiring IRB review.

In the Procedures section (30.1) of SmartForm, the investigator must clearly state whether the CRDW is the ONLY way potential participants will be identified or the CRDW is one of *several* recruitment strategies.

The investigator should state:

"Clinical data for this study will be obtained by searching for eligible anonymous participants using a cohort discovery tool (i2b2 and/or TriNetX) from the MCW Clinical Research Data Warehouse (PRO00013874) with (a) the following inclusion/exclusion criteria, and then (b) extracting the following de-identified clinical information for each identified participant:

a. *<Specify cohort inclusion/exclusion criteria to be queried>*
b. *<Specify clinical information to be extracted>*

Using this de-identified clinical information, the investigator will then..."

IV. IMAGE DE-IDENTIFICATON (the most <u>typical</u> situation) the investigator has IRB approval to access identified F&MCW images but wants them de-identified so the images can be sent outside F&MCW in de-identified format

The investigator should "prove up" to the CDW gateway that the investigator already has IRB approval to access or use these specific images, and IRB approval for access to IDENTIFIED images. When in doubt, the CRDW can and should always check with an IRB staff person.

The investigator wants to send a scan image to an external party (sponsor, collaborator) de-identified because the STUDY PROTOCOL requires de-identification in this situation, and/or the IRB APPLICATION

promised de-identification in this situation, and/or the STUDY CONSENT FORM promised de-identification in this situation. Thus -- even though scrutiny of the HIPAA authorization language may show that the subject has in general authorized the investigator to share some identified information with the third part – de-identification of the image scan is still REQUIRED.

In the Procedures section (30.1) of SmartForm, the investigator should state in the IRB application:

"Identified scan images to be provided to XXX and YYY (external third parties) will be totally de-identified per study protocol by submitting index images and destinations to the Honest Broker / Image De-Identification Service of the MCW Clinical Research Data Warehouse and having that Honest Broker send the de-identified images." [Though it may be clear elsewhere in the protocol, the PI should again state here what kinds of images and how many images will be sent this way.]

V. IMAGE DE-IDENTIFICATION (less common situation) where the investigator wants to use a CRDW cohort discovery tool (i2b2 and/or TriNetX) to identify eligible participants and then have the CRDW deliver de-identified images for that cohort, so the activity (on the part of the PI receiving de-identified images from a valid honest broker) does not technically qualify as "human subjects research."

In the Procedures section (30.1) of SmartForm, the investigator must clearly state whether the CRDW is the ONLY way potential participants will be identified or the CRDW is one of *several* recruitment strategies.

The investigator should state in the IRB application:

"Clinical data for this study will be obtained by using a cohort discovery tool (i2b2 and/or TriNetX) from the MCW Clinical Research Data Warehouse (PRO00013874), to (a) search for eligible participants with the following inclusion/exclusion criteria, and then (b) seek IRB approval for this project asking the CRDW to provide the following clinical information and SCANS for each identified subject:

a. *<Specify cohort inclusion/exclusion criteria to be queried>*
b. *<Specify clinical information to be extracted>*

Note: this method of accessing de-identified data may ultimately be deemed "not human subjects research" depending on what else the investigator will be doing.