April 2, 2019

Subject: REMINDER: Investigator Signature Line in Consent Forms (MCARE)

Attention: All individuals involved in human subjects research who interact with the Jefferson IRB.

This is a reminder that the correct investigator signature line must be included in all consent forms.

This applies to all consent forms that will be used in Pennsylvania, <u>including consent forms submitted to commercial IRBs</u>.

Due to a Pennsylvania Supreme Court ruling, a physician must discuss the procedures, risks, benefits, and alternatives with the patient when certain MCARE procedures are involved.

To make sure this occurs, you must have the correct investigator signature line in the consent form. There are 3 Investigator signature line options. To determine which one should be used, you need 2 pieces of information:

1. Does the study involve MCARE procedures (see the OHR-2 or OHR-9)?

2. Did the study receive FULL IRB review initially or at any time?

This determination must be made at the time of initial review, and if not already done, at the time of continuing review. Both the OHR-2 and OHR-9 contain the list of MCARE procedures and the 3 Investigator signature line options to help you make your determination.

Below are the 3 Investigator signature line options from the OHR-8 consent template. With the information discussed above, you will be able to determine which investigator signature line should be used in the consent form.

Once the correct signature line has been added to your IRB approved consent form, the Investigator is responsible for ensuring that the consent process is consistent with the investigator signature line.

For both initial and continuing reviews, the IRB will be checking that you have selected the correct investigator signature line. So to avoid delays with your submission, please make sure you add the correct option to your consent form.

From the OHR-8:

Note: Only the appropriate signature line is added to the consent form. The other 2 options and the yellow prompts are not included in the OHR-8.

Choose one of the following 3 options for the investigator's signature (for studies being done in Pennsylvania).

Include for studies involving any MCARE procedures (See OHR policy IC 701).

The **physician investigator's** signature certifies that s/he **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

Include for studies that receive FULL IRB review (initially or at any time) but do not include any MCARE procedures (See OHR policy IC 701).

The **investigator's** signature certifies that s/he **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

Include for all other studies.

The investigator's signature certifies that the study participant has been provided with a description of the study, study procedures, risks, benefits and alternatives to participation.

_____	_____	_____
Name of Investigator	Signature of Investigator	Date

If you have any questions about this announcement, please contact patrick.herbison@jefferson.edu

This information will also be posted in the myJeffHub Jefferson Enterprise Clinical Research Community.

As a Reminder:

To stay informed of important IRB communications and announcements you must join the myJeffHub Jefferson Enterprise Clinical Research Community.

Very soon, all IRB announcements will only be sent to people who have joined this MyJeffHub community. IRB announcements will no longer be sent out to the Listserv distribution lists that you may have joined previously.

To join this myJeffHub community, please contact Julia Center at julia.center@jefferson.edu

We are in the process of transitioning all communications related to clinical research to myJeffHub. By joining this community, you will also receive other announcements relevant to clinical research.

Please Note: All previous IRB announcements can be found on the OHR website under IRB Reference Documents: https://www.jefferson.edu/university/human_research/irb-reference-documents.html

If you have any questions about this notice, please contact patrick.herbison@jefferson.edu

Thank you,

The Office of Human Research