Jefferson
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# MCARE and Consent - Refresher

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# Shinal Case

PA Supreme Court:  Shinal vs. Toms M.D. – Decided 6/20/2017 (Treatment not Research)

Mrs. Shinal suffered injury as a result of brain surgery.

Although Dr. Toms indicated that he had discussed the procedures, risks, benefits and alternatives, his physician assistant also discussed aspects of the procedure and obtained consent.

The Court Decided:  " . . . a physician may not delegate to others his or her obligation to provide sufficient information in order to obtain a patient's informed consent."

# Mcare - MEDICAL CARE AVAILABILITY AND REDUCTION OF ERROR ACT

When Consent is Required - The following list of procedures is based on Pennsylvania's Mcare law as applicable to research:

- Administration of anesthesia
- Performance of surgical procedures
- Administration of chemotherapy and radiation
- Administration of blood and/or human source products
- Insertion of a surgical device or appliance
- Performance of any HIV-related testing
- Administration of an experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner, or removal of bone, fluids or tissue for use in research or in the manufacture of a product. (This would not include leftover tissues from clinical procedures.)
- Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization. (Routine needle sticks, such as peripheral intravenous catheter placement, vaccination, and venipuncture are not considered invasive in the context of this policy.)

Choose one of the following 3 options for the investigator's signature.

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 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 |

# Internal Audit

# Process

- It is the IRB/reviewer's responsibility to ensure the correct investigator signature option is being used.

- This must be done:
  - At the time of initial and continuing review
  - For full and expedited reviews

  A study should not leave the meeting or expedited review without the correct signature line.

  If you need more information from the PI, request it.

# Process

- The Decision is Based on 2 Factors:
  - Does the study involve MCARE procedures?
  - Is it a Full review?

Note: If subjects are still enrolling, the MCARE signature option should be based on the INITIAL review (was it full or expedited) unless the risk assessment has changed.

# Process

## If the study has a consent form:

1. Does the new section of the OHR-2 / OHR-9 indicate MCARE procedures?

2. Compare OHR-2 / OHR-9 / protocol – Does the study actually involve MCARE procedures?

3. Has the correct signature line been added to the OHR-8?

# Policy and Form Revisions

The OHR Policies and Forms have been Changed

- OHR-8 (Consent Template) – Contains the 3 Options

- OHR-2 (Initial) and OHR-9 (Continuing Review)

  Both Include:

  List of MCARE Procedures

  The 3 Signature Options

- RQ-1

# OHR-2 and OHR-9

Does the study include any of the following MCARE procedures (check all that apply)?

a. ☐ The study's initial or last continuing review was approved after March 2018 and already contains the new Investigator signature template text.
b. ☐ No MCARE procedures
c. ☐ Administration of anesthesia
d. ☐ Performance of surgical procedures
e. ☐ Administration of chemotherapy and radiation
f. ☐ Administration of blood and/or human source products
g. ☐ Insertion of a surgical device or appliance
h. ☐ Performance of any HIV-related testing
i. ☐ Administration of experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner, or removal of bone, fluids or tissue for use in research or in the manufacture of a product. (This would not include leftover tissues from clinical procedures.)
j. ☐ Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization. (Routine needle sticks, such as peripheral intravenous catheter placement, vaccination, and venipuncture are not considered invasive in the context of this policy.)

Select the most appropriate text to appear with the investigator signature line in the consent form (check one):

☐ **Include the text below 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 the text below for studies that receive FULL IRB review 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 the text below 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.

Choose one of the following 3 options for the investigator's signature.

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 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 |

# Questions? Comments?