



POLICY STATEMENT
REGARDING
AUTOPSY AUTHORIZATIONS
11/14/2007

The Duke University Health System Institutional Review Board (DUHS IRB) recognizes that being asked to permit an autopsy of a loved one is a highly sensitive matter. Therefore it is incumbent upon clinical investigators and health care providers to obtain a clear and unambiguous understanding of the wishes of research participants and their family members when an autopsy is proposed as part of a clinical research study.

While pre-death autopsy permission may be obtained during the informed consent process of a research study, the DUHS IRB, in accordance with North Carolina law, requires post-death confirmation of the permission from the research participant's legally authorized representative.

Autopsy of a Competent Adult

For the competent adult research participant who may have given his/her permission for an autopsy, standard procedure continues to be to approach the appropriate family member(s) in the order designated by North Carolina law to seek authorization for an autopsy after death has occurred. Signature on the DUHS Autopsy Permit form by the appropriate family member is required as post-death documentation.

The order of authority to provide permission for autopsy after the death of the research participant is as follows:

- Court-approved guardian
- Health care agent
- Spouse
- Adult son and/or daughter
- Parent
- Adult brother and/or sister
- Uncle and/or aunt
- Other adult kin

Autopsy of a Minor

In the case of the death of a minor, the parent may have given permission for an autopsy already during the informed consent process of a research study in which his/her child was participating. Even in these circumstances the DUHS IRB, in accordance with North Carolina law, requires the parent's signature on

the DUHS Autopsy Permit form after the child's death as confirmation of the parent's wishes.

Request for Autopsy Authorization During the Informed Consent Process in Research

When an autopsy is proposed as part of a clinical research study, the investigator should discuss this with the research participant and his/her family members as part of the informed consent process prior to enrollment in the study. In the **protocol summary** submitted to the DUHS IRB, the investigator must describe who on the study team will be approaching the participant and/or family members for autopsy authorization. The DUHS IRB suggests that on the consent form, the research participant may be asked to initial next to YES/NO statements, declaring a desire to have (or not have) an autopsy. When authorization for an autopsy is sought in the consent form, statements presenting the following concepts should also appear:

- “According to North Carolina law, your family members are able to override your wishes about an autopsy after your death, if they disagree with your choice. Therefore it is important to talk about your wishes now with your family so that they are aware of how you feel.”
- When an autopsy is proposed as part of a research study, the consent form should state that neither the participant nor the family will be responsible for the cost of the autopsy.

The IRB recommends, but does not require, that a copy of the autopsy report be given to the family member after the report becomes available.