

Ethics and Research with Deceased Patients

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In a provocative 1974 article entitled “Harvesting the Dead,” Willard Gaylin explored potential uses of “neomorts,” or what are currently referred to as “heart-beating cadavers”—that is, humans determined to be dead by neurological criteria and whose cardiopulmonary function is medically maintained by ventilators, vasopressors, and so forth.¹ Medical research was one of the potential uses Gaylin identified. He pointed out that tests of drugs and medical procedures that would have unacceptable health risks if performed on living human subjects could be performed on neomorts without any health risks. According to Gaylin, the potential benefits of such research could be enormous, including not subjecting patients to ineffective or harmful medical procedures and eliminating delays in providing effective therapies to dying patients.

When Gaylin wrote his essay, the use of heart-beating cadavers for research was largely science fiction. However, by the beginning of the next decade, published reports confirmed that reality had already caught up with science fiction. Two of the earliest reports were about research with children who satisfied the whole brain criteria of death. In one study, lithium was administered to determine its effects on antidiuretic hormone.² The second study was designed to develop an esophageal obturator airway (EOA) for pediatric patients.³ An experiment with an adult who satisfied the neurological criteria of death was reported several years later.⁴ The aim of that research was to test the usefulness of a monoclonal antibody as an antithrombotic agent.

Subsequently, interest in research with heart-beating cadavers appeared to wane. However, a February 2002 article in *Science* described a renewed interest in such research.⁵ That article focused on the use of “brain-dead and near-death patients” at the M.D. Anderson Cancer Center in Houston, Texas, for research related to targeted cancer drugs. It also included a brief reference to plans to conduct research with heart-beating cadavers at the University of Pittsburgh. A subsequent *Science* article on research with the dead focused on the University of Pittsburgh.⁶ As evidenced by a feature story in *U.S. News & World Report* entitled “Science Calls at the Deathbed,” even the popular media reported on a renewed interest in research with the dead.⁷ That article described the targeted cancer drug research at M.D. Anderson and two research projects with heart-beating cadavers at the University of Pittsburgh. One of the latter involved testing a blood oxygenation device (a small catheter inserted into the inferior vena cava), and the second involved testing a method for sustaining heart functioning after removing it from the body.

Beyond these three instances, as Gaylin suggested, the potential scope of research with heart-beating cadavers is almost limitless. It could provide an opportunity to test experimental medications, medical devices, nanotechnology, surgical procedures, transplant technology (e.g., xenotransplantation, anti-rejection drugs, and procedures), and genetic technology (e.g., genetic manipulation and modification). In many instances similar research would be unethical if conducted on living human subjects. Moreover, using the dead avoids exposing living humans and nonhuman animals to risks of morbidity, mortality, pain, distress, and suffering.

Recognizing the potential scope of research with the dead and the need to identify and observe relevant ethical standards, the University of Pittsburgh created a policy and a special oversight committee, the Committee for Oversight of Research Involving the Dead (CORID).⁸ The Pittsburgh policy applies to *all* postmortem research and not only to research with heart-beating cadavers. M.D. Anderson also produced a policy, but their guidelines apply only to “brain-dead” and “terminal wean” patients, and their IRB is responsible for oversight.⁹ In February 2004, the Winship Cancer Institute and the Center for Ethics at Emory University hosted a multidisciplinary expert consensus panel that drafted ethical guidelines for research with the recently deceased (both heart-beating and non-heart-beating cadavers).¹⁰

Are Ethical Guidelines Needed?

Although the need for ethical guidelines in relation to research with living human subjects is firmly established, skeptics might challenge a corresponding requirement in relation to the dead. There are at least three possible reasons for such skepticism: (1) Whereas ethical guidelines are designed in part to protect living subjects from morbidity, mortality, pain, distress, and suffering, the dead are not subject to those kinds of harms (experiential harms) and therefore do not need such protections. (2) Whereas ethical guidelines are designed in part to protect the autonomy of subjects and prospective subjects, it makes no sense to protect the autonomy of the dead. As Iserson put it, “corpses no longer are individuals, and so they cannot be the basis for either autonomy or informed consent. They are merely symbols.”¹¹ (3) Whereas ethical guidelines are designed to protect subjects from being harmed and wronged, it is impossible to harm or wrong the dead. According to Joan Callahan, “there cannot be a good philosophical reason for holding that the dead can genuinely be harmed or wronged, and the conviction that the dead can be harmed and/or wronged is, therefore, precluded from being a genuine moral conviction.”¹²

It is undeniable, as the first reason alleges, that the dead are not subject to morbidity, mortality, pain, distress, and suffering. However, because there are other grounds for ethical constraints in relation to research with the dead, it does not follow that ethical guidelines are unnecessary. With respect to the second reason, it certainly is true that corpses cannot make autonomous choices. In this respect, then, it does not make sense to apply the concept of autonomy and the associated principle of respect for autonomy to corpses. However, permanently unconscious persons and persons with advanced dementia also lack autonomy, but their prior autonomous decisions and preferences continue to have moral weight. If giving moral weight to past autonomous

choices and preferences of nonautonomous living individuals is not foolish and confused, it is not obviously foolish and confused to adopt a similar practice with respect to the dead. Reasons for respecting the premortem decisions and preferences of the dead will be examined below. One possible response to the third reason for skepticism would be to argue that the dead *can* be harmed and/or wronged. However, this is not the place to attempt to resolve such a complex and unsettled philosophical debate.¹³ Fortunately, it is not necessary to do so to identify, explain, and support ethical guidelines for research with the dead.

Respect-Based Ethical Guidelines

A fundamental ethical concept in relation to research with the dead is *respect*, and a corresponding basic principle can be stated as follows: Research with deceased patients should be *respectful* of them as well as their families. Accordingly, it is necessary to identify the requirements of respectful research.

Respect for Deceased Patients

An important requirement of respect for deceased patients is honoring premortem decisions they made about whether or not to allow their bodies to be used for postmortem research. It is clearly disrespectful to fail to honor such decisions. In the United States, this ethical requirement is also a legal requirement. The Uniform Anatomical Gift Act (UAGA) authorizes people to give or withhold consent to use their bodies after death “for transplantation, therapy, medical or dental education, *research*, or advancement of medical or dental science” (emphasis added).¹⁴

Many, if not most, people do not make explicit *decisions* about postmortem research prior to dying. However, people may have *preferences* concerning the use of their bodies for postmortem research and/or who should decide on their behalf after death. Accordingly, another requirement of respect for deceased patients is to honor such premortem preferences, if known.

A skeptic might question why any moral weight should be given to the decisions and preferences of people who have died. After all, it might be claimed, once dead, they cannot be affected because they will never know whether or not their decisions and preferences have been honored. Nevertheless, there are several reasons for giving moral weight to premortem decisions and preferences: (1) It demonstrates respect for (living) persons. To show respect for a person is to acknowledge her worth, dignity, and autonomy, and we would fail to show such respect if we were to believe and act as if an individual’s distinctive aspirations, plans, and preferences left no “moral traces” after her death. (2) It promotes the well-being of the living. Generally, the belief that all of one’s preferences and values will not simply be disregarded after one’s death can be a source of considerable reassurance and comfort while one is alive. Conversely, the belief that one’s preferences and values will be given no moral weight after one’s death can be a source of considerable anxiety, anguish, and distress. In addition, by continuing to respect premortem decisions and preferences after death, survivors give expression to the view that death does not signify a total annihilation of any “traces” of the person who

once was. This practice can be comforting to the living, who know that they, too, will die some day. (3) It is an accepted practice with respect to wills, burial, and organ donation, and that established practice gives rise to corresponding legitimate claims and expectations.

Respect for Human Corpses

Respect for human corpses is a corollary of respect for deceased patients, and it is generally acknowledged that human corpses should be treated with respect. A few years ago, news media disclosed that a crematory in the United States located in Noble, Georgia, dumped bodies slated for cremation on the facility's grounds, where they were discovered later in various stages of decomposition.¹⁵ The public response of horror and outrage confirms a general commitment to the principle of respect for human corpses. A commitment to this principle was vividly demonstrated again more recently in connection with a scandal involving the Willed Body Program at the University of California, Los Angeles. A series of articles appeared in the *The New York Times*, one of which appeared to assume that readers would be disturbed to learn that corpses were "mangled in automobile crash tests, blown to bits by land mines or cut up with power saws to be shipped in pieces around the country or even abroad."¹⁶

What constitutes respectful treatment of human corpses? Whether a particular action is respectful or disrespectful is in part context dependent and can depend on the intent and objective. For example, both medical examiners and psychopathic killers may cut open corpses and remove organs. But from the perspective of whether they violate the principle of respect for human corpses, there is a significant difference between them.

Standards of respectful treatment of corpses can vary considerably from culture to culture, group to group, time period to time period, and even person to person.¹⁷ Because there is considerable variation in standards of respectful treatment of corpses, an appropriate aim is to avoid treating a corpse in a way that *the deceased person* would have considered disrespectful. Absent explicit instructions from the deceased, family members may well be in the best position to determine whether using the body for research is consistent with the deceased's conception of respect for corpses. However, even if the deceased's conception is unknown or nonexistent (e.g., in the case of infants and young children), it seems appropriate for the family to act as the deceased's representative for the purpose of determining whether postmortem research is compatible with respect for human corpses, just as it is generally appropriate for family members to act as surrogates for patients in clinical contexts even when it is impossible to make accurate substituted judgments. In the United States, the role of family members in determining what constitutes "abuse of corpses" is legally recognized. For example, the section of the Model Penal Code entitled "Abuse of Corpse" states: "Except as authorized by law, a person who treats a corpse in a way that he knows would *outrage ordinary family sensibilities* commits a misdemeanor" (§250.10, 2001; emphasis added). In any event, a simple general rule is to handle and treat cadavers in a manner that is consistent with their having once been the bodies of living persons.

Family Consent

When deceased patients have not decided prior to death whether to allow their bodies to be used for research, respect for them and their families generally requires the consent of family members. There are several respect-based reasons for a family consent requirement.

Respect for deceased patients. A family consent requirement promotes respect for deceased patients. Absent explicit premortem decisions, the deceased's family members generally are the most reliable sources of information about the deceased patient's premortem preferences concerning the postmortem use and disposition of their bodies. Moreover, absent premortem decisions or expressed preferences, it is likely that deceased patients would have wanted family members to decide on their behalf.

Respect for corpses. For reasons presented above, a family consent requirement can help to promote respectful treatment of corpses.

Respect for family members. A family consent requirement promotes respect for family members. Family members are likely to perceive a significant continuity between the person who died and the dead body. Hence, what happens to a loved one's body can matter very much to family members. They can feel a deep responsibility to "protect" a loved one's remains. The perceived importance of protecting a family member's remains is illustrated by a common response of parents when they discovered that after their children died in Alder Hey Hospital in Liverpool, England, organs had been removed and retained for research without their knowledge. For example, when one parent learned in 1999 that organs from her son were removed after his death 5 years earlier, she reportedly said: "I feel like I failed to protect him even in death."¹⁸ Accordingly, it is to be expected that many family members would want to decide whether to authorize research. Two studies report that a majority of respondents want to be asked for permission to practice procedures on recently deceased family members, and there is no reason to believe that a similar result does not hold with respect to research.¹⁹ Significantly, both studies report that a desire to be asked is *not* correlated with a predisposition to refuse. Severe emotional distress can result if family members discover that a loved one's body has been used for research without their knowledge and authorization. The Alder Hey episode is an unfortunate illustration. According to one report, the "revelation that the organs of hundreds of children had been retained by a hospital has dismayed and distressed parents."²⁰

Respect for the family as a social institution. Respect for the family as a social institution requires recognizing a zone of family privacy and autonomy.²¹ Decisions about the use and disposition of family members' bodies appear to fall within the scope of this zone of privacy.

In addition to the foregoing respect-based reasons, a family consent requirement also prevents loss of trust in healthcare professionals and institutions. A failure to request the consent of family members is likely to engender suspicion and mistrust no matter how "benign" the reasons are for not seeking consent. Such suspicion and mistrust may undermine the physician-patient relationship

and may diminish the willingness of people to make anatomical gifts. U.K. Health Secretary Alan Milburn expressed his concern about loss of public trust in relation to the Alder Hey incident when he remarked: "It is essential that we now seek to restore public confidence in health services at Alder Hey Children's Hospital."²²

Despite these reasons in support of a family consent requirement, it might nevertheless be objected that such a requirement will seriously limit opportunities for research. Iserson presents a similar claim with respect to practicing and teaching on recently deceased patients: "If a legal or ethical requirement existed for consent prior to postmortem ED instruction, it would simply decrease the number of clinical personnel trained in lifesaving procedures."²³ His reason for this conclusion is that requesting permission "from distraught relatives would raise significant emotional barriers for clinicians to overcome."²⁴ To be sure, respect for grieving family members and concern for their emotional well-being are important. However, the experience in relation to organ transplantation suggests that requesting consent may not have a predominantly negative impact on the deceased's family. Studies report that family members appreciate having been given an opportunity to donate a loved one's organs and that donation can lessen grief.²⁵ For many, it can provide comfort and meaning in a context of loss and senselessness, and a similar benefit may be associated with consent for research. This may well be a case in which paternalism is not only unwarranted, but counterproductive as well. Significantly, one study about requests for training on newly deceased patients reported that only 1 of 32 families who were asked for permission to perform a cricothyrotomy on a recently deceased patient stated 6 weeks later that they were "offended or upset about being approached for the procedure."²⁶

It is crucial not to confuse concern for the emotional well-being of grieving family members with the discomfort of *physicians*. A reluctance to talk about death and interact with grieving relatives can also present "emotional barriers" to requesting permission for postmortem research and practice.²⁷ Benfield and colleagues speculate that "self-protection" may help explain why some physicians fail to request permission to practice on newly deceased patients: "Perhaps then, intubating newly dead adults without consent is done not only to protect family emotions but also to protect some physicians from emotional discomfort and the possibility of being refused."²⁸ Such obstacles can be addressed by means of special training sessions or, using the model of requests for organ donation in the United States, assigning the task of seeking permission to designated procurement personnel.

Another possible reason for thinking that a consent requirement will seriously limit opportunities for research is a belief that family members are likely to refuse. To trump an ethically justified requirement, there should be unambiguous evidence to support the underlying assumption that if asked, family members are unlikely to consent. However, there are studies that challenge this assumption. For example a study of family consent for postmortem research on retrograde tracheal intubation reported an approval rate of 59%.²⁹ There are also studies that challenge a similar assumption with respect to practicing on recently deceased patients.³⁰ Some studies, however, suggest significant demographic differences.³¹ Significantly, 40 families who initially demanded the return of children's organs kept at Alder Hey Hospital changed their minds after the potential benefits of research were explained to them.³²

An additional objection to a family consent requirement is based on the presumed consent or opting out policy that several countries have adopted to increase the availability of organs for transplant. According to such a policy, if, prior to death, deceased individuals did not formally or informally communicate their objection to transplanting their organs, it is justified to assume that they did not object and consent is not ethically required. Presumed consent policies vary, and some permit family members to object to transplantation, but their consent is not required.³³

This is not the place to evaluate the two competing policies from an ethical perspective. However, even if a policy of opting out is justified in relation to *organ donation*, there are significant differences between organ donation and research: (1) There is a documented shortage of organs for transplant and the benefits are more immediate and certain than postmortem research. Whereas the benefits of organ transplants (i.e., saving lives) are known and immediate, the benefits of research are speculative and distant. (2) Organ donation is more amenable to informed advance decisionmaking than postmortem research. Currently, postmortem research can range from studies of tissue removed at autopsy to experiments with heart-beating cadavers. Looking to the future, it may not be feasible to specify in advance the types of studies that will fall within the scope of postmortem research 5, 10, or 20 years from now. Accordingly, some people who may be willing to participate in certain types of postmortem research may decide to opt out to prevent the use of their bodies for potentially objectionable research. Conversely, others may fail to opt out because they did not understand the broad scope of “research.” It seems reasonable to assume that most people understand that if they do not opt out of organ donation, their organs will be removed and transplanted in patients with the aim of saving their lives. However, it is hardly safe to assume that most people understand that if they do not opt out of postmortem research, cardiopulmonary function can be maintained indefinitely in their bodies after death in order to test devices, medications, or procedures. The Alder Hey incident once again may be instructive. Some parents of children whose organs were retained for research claimed that they did not understand what they were authorizing when they signed a form agreeing to a “post mortem examination” and permitting pathologists to keep “tissues” for “diagnostic, teaching and research purposes.”³⁴ (3) Organ retrieval can take place without delaying funerals and without affecting whether bodies will be suitable for viewing. In contrast, depending on the type of postmortem research, there can be significant delays and bodies may not be suitable for viewing.

For all of these reasons, then, the case for a policy of opting out in relation to research may be significantly weaker than the case for a similar policy in relation to organ donation. Moreover, even if a policy of opting out is applied to research as well as organ donation, it is arguable that the policy should at the very least include a requirement to *inform* family members and enable them to *object* and *veto* research participation.

Other Respect-Based Ethical Requirements

There are several additional ethical requirements associated with the principle of respect for deceased patients and their families:

1. Research should address a significant question and use methods likely to produce valid results. This is a general requirement pertaining to all human subjects research. In the case of living subjects, if this requirement were not satisfied, it would not be warranted to expose subjects to risks. Although there are no health risks associated with postmortem research, performing research that fails to address a significant question or that utilizes flawed methods nevertheless constitutes disrespectful treatment of the dead. Insofar as permission for research is given with the understanding that it will benefit humanity, postmortem research that does not address a significant question or that uses flawed methods also fails to respect the expectations of family members and/or the premortem expectations of deceased patients.
2. The degree of invasiveness to the corpse should be minimized and justified in terms of expected scientific benefits. If a corpse is subject to unneeded or pointless interventions, research may cross the line that separates respectful treatment from mutilation or desecration. Such research may also fail to respect the expectations of family members and/or the premortem expectations of deceased patients when they authorized research.
3. The duration of the research should not be excessive. Similar to the principle of respectful treatment of human corpses, there is no single objective standard associated with this requirement. First, the standard of excessiveness may vary according to the type of research involved. For example, what is thought to be an excessive duration with respect to research with heart-beating cadavers may not be considered excessive in relation to research with tissue samples obtained at autopsy. Second, even with respect to the same type of research, there can be considerable variations in standards of excessiveness. For example, in relation to research with heart-beating cadavers, whereas some conceptions of respectful treatment may require burial within a specified period of time or may view maintaining cardiopulmonary function for extended periods of time as disrespectful, these views are not universally held. Accordingly, even in relation to research with heart-beating cadavers, the principle of respect may not require an absolute time limit. At the very least, however, respectful treatment requires that the duration of the research (a) not exceed what is scientifically necessary and (b) is not excessive according to the standards of the deceased and/or the deceased's family.
4. Confidentiality should be protected. The protection of confidentiality is a general ethical requirement pertaining to all human subjects research, including research with the dead. It is incompatible with respect for persons to give no moral weight to a deceased person's premortem preferences and interests, and, prior to death, people's confidentiality concerns may well extend beyond the time of death. A failure to protect confidentiality may also fail to respect the expectations of family members and/or the premortem expectations of deceased patients when they authorized research. Finally, because information that is disclosed after death can significantly affect a deceased person's image and reputation, if it is possible for people to be harmed by actions that occur after they have died, breaching confidentiality would appear to be a prime candidate for

such a harm.³⁵ Respect for family also requires sensitivity to potential privacy concerns. For example, despite an understandable temptation to seek media coverage of innovative and potentially breakthrough research with heart-beating cadavers, the permission of family members should be obtained before the media is given access to information or visual images that could identify deceased patients.

Additional Ethical Guidelines

Guidelines pertaining to research with the dead are not limited to requirements derived from respect for deceased patients and their family members. Additional guidelines include the following:

1. Conflicts of interest should be avoided. Avoiding financial conflicts of interest is a general ethical requirement pertaining to all human subjects research. With the exception of minimizing morbidity, mortality, pain, and suffering, the reasons that support this requirement in relation to living subjects apply as well to research with the dead, and there is no need to repeat them here. However, there is one potential conflict of interest that is specific to research with the dead, namely, when the deceased patient's physician proposes to conduct postmortem research with the patient's body. Because research with the dead can take place only after patients have died and investigators have an interest in securing subjects, there is a potential conflict when a physician involved in end-of-life decisionmaking or declaring death plans to conduct postmortem research on a patient's body. Accordingly, physician-investigators generally should not participate in decisions about determination of death or termination of life support if they plan to conduct postmortem research with the patient.
2. The deceased's family members, surrogates, or estate should not be responsible for any additional costs associated with research. Because friends or family members are not expected to be the primary beneficiaries of the research, making them responsible for its costs would place an unfair burden on them. Moreover, from a practical perspective, bearing the responsibility for additional costs associated with postmortem research is likely to act as a significant disincentive for patients and families to authorize postmortem research. There is considerable controversy concerning whether financial incentives should be offered to individuals before death and/or to family members of deceased patients to increase organ donation. This is not the place to engage this debate. However, it is worth reiterating that whereas the benefits of organ transplants (i.e., saving lives) are known and immediate, the benefits of research are speculative and distant. Accordingly, even if the reasons for financial incentives in relation to organ donation outweigh the reasons against, a similar conclusion need not follow in the case of postmortem research.
3. Healthcare workers should not be required to participate in postmortem research if they believe it is morally objectionable. Some healthcare workers may have moral objections to certain types of postmortem research (e.g., research with heart-beating cadavers). It seems reasonable to include postmortem research within the scope of the generally recognized right of conscientious objection.³⁶

Conclusion

To be ethically acceptable, research with recently deceased patients must be respectful of deceased patients as well as their families. Respect for deceased patients requires honoring premortem decisions about whether their bodies may be used for research and respecting premortem preferences, if known. When deceased patients have not decided prior to death whether to allow their bodies to be used for research, respect for them and their families generally requires the consent of family members.

Respect for deceased patients and their families also requires respectful treatment of human corpses, ensuring that research addresses a significant question and uses methods likely to produce valid results, and protecting confidentiality. Additional guidelines for postmortem research include avoiding conflicts of interest, ensuring that the deceased's family members, surrogates, or estate do not bear any of the additional costs associated with research, and providing healthcare workers an opportunity to refuse to participate in postmortem research if they believe it is morally objectionable.

Notes

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