Who Are You?

The Ethics of HIPAA, Privacy & Body Donors
Brief History of Privacy in the Anatomy Lab

Originally criminals and other identified individuals were used for dissection. The dissection was further “punishment” for the criminal. The identity and crime of the individual was advertised and known by the public.

As more unidentified individuals were used (unclaimed bodies), their names may not have been known. They were anonymous by nature – and this continued into the present time even though the names of the individuals are known (Jones and King, 2017).

The reason for the maintenance of anonymity is not known, although it may reflect back on the past when dissection was a punishment and was not a voluntary act. There may also be valuable emotional and educational reasons for maintaining anonymity (Jones and King, 2017).

The Anatomy Lesson of Dr. Nicholas Tulp, Rembrandt, 1632
Brief History of Privacy in the Anatomy Lab

Recently, there have been programs that provide the identities (and medical records) of the donors to the students. This is to “humanize” the donors and help with professional development of the students (Bohl, et al., 2013; Talarico, 2013; Gerwer and Gest, 2017).

There is ongoing debate about this practice with only a small minority of schools currently providing this information. While the majority of the debate centers on the educational / professional aspects of this practice, the roles of privacy and HIPAA have also been raised.

While it may be debatable whether privacy laws (HIPAA, PHI) apply to body donors, the proper ethical treatment of body donors should always be first and foremost.
Brief Review of HIPAA and PHI

To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was passed by the US Congress. It has provisions that required HHS to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security. At the same time, Congress recognized that advances in electronic technology could erode the privacy of health information. Consequently, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information.
Brief Review of HIPAA and PHI

PHI = Protected Health Information

Covered for 50 years after death

Identifiable information

De-identified data is allowable

Examples of Protected Health Information (PHI)

- Names
- All geographic subdivisions smaller than a state
- All elements of dates (except year)
- Telephone, fax numbers
- Email addresses
- Social Security numbers
- Medical Record numbers
- Health plan beneficiary numbers

- Account numbers
- Certificate/License numbers
- Vehicle ID’s including plates and serial numbers
- URLs, IP
- Biometric ID’s incl. finger and voice prints
- Full face photographs
- Any other unique identifying number or characteristic

https://www.hhs.gov/hipaa/index.html
Brief Review of HIPAA and PHI

General Data Protection Regulation (GDPR)

The GDPR is a new, European data privacy regulation that went into effect May 25, 2018. The GDPR, which replaces the 1995 Data Protection Directive, is designed to strengthen and unify data protection for all citizens and residents in the European Union (EU). The GDPR will allow consumers greater protection and control over their personal data, including the right to be informed how their data is being used, the right to know if their data is lost or stolen, and the right to rectification and to opt out of data collection.

Why Privacy in the Anatomy Lab?

While privacy and anonymity are one of the hallmarks of body donation in the United States and Europe, in some Asian programs, the identities of the donors are made fully public and the donors are praised and lauded by their community (Winkelmann and Guldner, 2004; Lin, et al., 2009).

It therefore appears that privacy in the anatomy lab is a cultural phenomenon. Privacy / anonymity do not appear to be foundational ethical principles.

In fact, in the Tzu Chi program in Taiwan, there may be a higher ethical principle displayed; the respect and dignity afforded every human being – living or dead. The students, faculty, staff and administrators are all involved in honoring the donors. This lays the proper groundwork for treatment of future patients.
The historical background for human use ethics can be traced to the Nuremberg Trials after World War II. Due to the atrocities committed, a 10 point Nuremberg Code was developed. The number one point is voluntary consent. The other points of the code include, among others, the ability to withdraw at anytime, avoiding unnecessary physical or mental suffering and ending the research if harm could occur.

Following other lapses in ethical treatment (Tuskegee syphilis study), additional safeguards were established (Belmont Report, 1978): the Institutional Review Board (IRB), HIPAA, mandatory ethics training. These all apply to research with living humans.

Some of these safeguards have been used in body donor programs, but none are required by law. In fact, IRB’s will not address research that utilizes dead bodies or tissues.
The Ethics of Human Tissue Use

The ethics behind the use of human tissue in research and education is complex. There is variability depending on the type of tissue used (cells, organs, whole bodies) as well as the intended usage (organ transplant, genomics, medical education). There are no broad, well defined national regulations (Charo, 2006).

There are few regulations or requirements detailing the ethical use of body donors. The US Anatomical Gift Act, ethical use statements from the AAA, the AACA as well as the IFAA are the only available ethical guides for the proper use of body donors (see reference list).

This allows for some ethically dubious arrangements: the establishment of “body brokers”, the selling of human tissues (bones, blood and other tissues) and the consideration of human tissue as “property”.

Cultured HeLa Cells

Informed Consent

The primary ethical concern in all human research and education is detailed informed consent.

Has the donor consented to the use of their body and/or the release of their personal information? If so, then the information could be released, especially if there is a valid educational or research need.

This would allow the information to be shared with the students who should still abide by HIPAA requirements and not share this information with others. From an ethical standpoint, the students should not discuss any aspect of the body donors outside of the lab, irrespective of regulations.

Conversely, just because a donor has provided informed consent, this does not mean that the information must be released.
Examples of Body Donor Programs

University of California System Anatomical Specimen Management

A system-wide policy and management program was established at the University of California campuses. This included the development of human specimen oversight committees. (https://policy.ucop.edu/doc/5000431/AnatomicalMaterials)

Examples of Body Donor Programs

University of Pittsburgh has an Office for Oversight of Anatomic Specimens (OOAS) (http://www.ooas.pitt.edu/) and a committee to examine use of data from descendents (cadaveric tissue) (CORID).

“The OOAS was established in May, 2007, to provide a centralized support service to faculty, physicians and staff for the approval, procurement, and tracking of human cadaveric tissue required for use in teaching, training and research within the Health Sciences community, as well as for oversight of the utilization, storage, and disposition of tissue.”
A regional office of the State of Florida Anatomical Board is maintained at the University of Miami (http://www.sofab.med.miami.edu). It supplies donors to medical schools and allied health schools in south Florida.

This program only provides the age, sex, cause of death and profession of the donors to the students. Donor-supplied health information may be provided in the future. Anonymity of the donors is maintained even during memorial ceremonies in which the families of the donors attend.
What Should Body Donor Programs Do About Privacy?

1) Have clear, transparent policies and procedures.

2) Have proper, detailed informed consent documents.

3) Work with and understand the wishes of the donors.

4) Be cognizant of the societal and community views.
Dialogue:

Due to a lack of regulations, most body donor programs rely on guidelines from anatomical organizations or their own historical culture. This allows for variability and little comparability between programs.

There is an ongoing shift in anatomist’s views on how donated bodies should be used and treated. Donors are being accorded more respect and dignity.

“A higher bar” – since the donors altruistically donated their bodies with no thought for reward, we have a higher duty to protect their privacy and honor their wishes. On the other hand, there are basic fundamental ways that all bodies in the lab should be treated irrespective of source.

Prof Pieter Carstens, when speaking on the Pernkopf atlas of anatomy: “An anatomist's fundamental crime is the violation of his subjects' dignity”
Discussion Questions

1) Provide students with information about the donor (medical, social, historical).
   
   What is protected health information in this case? Should the information be anonymized?

2) Provide students with CT and MRI images of the donors.
   
   Is this protected health information (PHI)? Can these images be saved? If so, for how long?

3) Are photographs of donors allowed?
   
Discussion Questions

4) Invite families of body donors to a memorial service.

Who mails the invitations?
Can the students know the names of the donors / families?

5) Can anyone withdraw the donor’s consent to release health information?

Can family members withdraw the consent to release health records of the donor? What if it were to invade their privacy (or provide information about their own health; e.g., genomic analysis)? (Gerhard, et al., 2016; Siminoff, et al., 2016)
Discussion Questions

6) Conversely, can health information of the donor be provided to the family?

   If a donor is rejected from a program due to HIV status, can the program inform the family? What if a genetic analysis of the donor showed a dominant inheritable disease (Huntington’s)? Should this be shared?

7) What if a famous actor donated his body to a donor program?

   Would there need to be special policies put in place? Would he be treated differently than the other donors? Shouldn’t all donors have the same expectation of privacy?
Conclusion / Suggestions:

1) Respect, dignity and privacy for all human tissues should be the standard ethical benchmark. Human tissue should not be treated as property.

2) Informed consent is the foundation for donation and use of all human tissues. Specific consent for health information should be received.

3) If informed consent of the donor is not available, family members may be able to provide consent on behalf of the donor as long as no economic or other incentives are involved.

4) In the United States, regulations should be clarified as to the applicability of HIPAA and other privacy laws on body donor programs. Anatomical organizations should offer certification for willed body programs that meet or exceed established procedural and ethical standards.

5) Donor programs should have the option for stricter privacy policies irrespective of the laws. No program should be required to release donor information.
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