

Summary Report on the Harvard Medical School Anatomical Gift Program

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I. INTRODUCTION

This report has been prepared at the request of Harvard University (“Harvard” or the “University”) as an assessment of the Harvard Anatomical Gift Program (the “AGP”). The AGP is organized within the Program in Medical Education (the “PME”) at the Harvard Medical School (“HMS”) and serves to support HMS, the Harvard School of Dental Medicine, residents at Harvard-affiliated hospitals, and educational programs at academic institutions such as Simmons University, the Massachusetts College of Pharmacy and Health Sciences, and the MGH Institute for Health Professions. After criminal allegations were brought against a former HMS employee relating to the remains of donors who gifted their bodies to the AGP, Harvard convened an expert review panel (the “Panel”) to assess areas for improvement in the AGP going forward. The Panel’s charge does not include review of the factual events giving rise to, or investigation of, the alleged criminal conduct. Instead, the Panel has been directed to assess the AGP program for the purpose of improving its future operations. This is the Panel’s summary of AGP current practices, best practices in body donation, and recommendations to align the two.

A. Body Donation Program background

Formalized body donation programs began in academic institutions in the United States in the middle of the 20th century and fostered a process by which individuals can gift their bodies to science. The purpose of these programs has been to ensure that adequate teaching and research resources are available to meet an institution’s mission and goals, typically in the delivery of health sciences education, clinical training, and research. Clinical skills, training, and facilities are important and attractive resources to students, clinicians, and communities for modern health sciences education delivery. Basic sciences and other educational activities also may be supported. Anatomical gift programs serve as a point of contact for information on body donation; should model respectful conduct with donors; and should reflect the institution’s norms and values. Ethical consideration for the donors, donor families, and program operations is vital to the overall success of anatomical gift programs. It is through learning the discipline of anatomy that students in health sciences gain experience with a donor, sometimes referred to as their “first patient” or “silent teacher,” that often profoundly shapes their professional conduct and empathy for others.

The primary relevant regulation for anatomical gifts in the United States is the Uniform Anatomical Gift Act, the most recent version of which was developed by the Uniform Law Commission and released in 2006 (the “Act”). The language in the Act generally covers who can donate, how they can donate, who can receive a donation, and the general uses of anatomical gifts under the categories of transplant, clinical therapy, education, and research. There are other regulations that may have some application to donation programs (for example, the Health Insurance Portability and Accountability Act, regulations of the Occupational Safety and Health Administration, and other state and local laws that apply to funerals, cemeteries, and the handling of human remains), but these typically do not include requirements for oversight or operations of a body donation program.

Body donation program personnel perform administrative and technical duties and represent the institution through outreach in the community. The way in which personnel, as well as students, clinicians, and researchers, treat and speak about their work with donors can affect an individual's decision to donate and an institution's reputation. A well-run program can be a vital asset to the institution and foster positive community relations. Knowledge and training for program personnel is often "on-the-job," combined with formal education in mortuary science and anatomy. Professional association resources and development opportunities (available through consortia, conferences, presentations, publications, and interactions with colleagues at other institutions) are important for keeping current on regulations, best practices, trends, and current events in academic body donation programs.

Academic body donation programs provide an alternative to traditional funerals and offer donors an opportunity to participate in the public service mission of an academic institution. Such a program can be a mechanism by which community members become invested in the goals of the institution. Decisions to donate one's body, arguably the ultimate form of altruism, should be honored.

B. The AGP

For over 60 years, Harvard has maintained an anatomical gift program operated under various names. The current AGP is part of the PME and its morgue, teaching labs and offices are located on the HMS campus. Harvard receives whole body donations under the Massachusetts Uniform Anatomical Gift Act (the "Massachusetts UAGA"), the current version of which was adopted in 2012. Donations come from individuals who preregister with the AGP, and AGP does not procure donors from any third parties. Currently, all donors have registered themselves with the program by signature of a formal Instrument of Anatomical Gift. There are no payments to AGP donors or designees; Massachusetts law prohibits the buying and selling of dead bodies. Individuals may revoke their donation at any time by informing the AGP in writing of their decision to do so. The AGP has not accepted donations after death by consent of an agent or next of kin since before the COVID pandemic.

Over the last eight years, the program has averaged 95 donations annually. (This average is affected by the suspension of program operations from March 17, 2020, until February 10, 2021, owing to the COVID pandemic.)

The AGP supports foundational education in anatomy for Harvard's medical students in the first and second years of their programs and dental students in the first year of their program. Some HMS students also go on to take an advanced clinical anatomy elective, typically during their fourth year, for which AGP also provides educational resources. Advanced degree students from the Division of Medical Sciences in the Harvard Griffin Graduate School of Arts and Sciences and the Harvard School of Dental Medicine also study anatomy in the program's laboratories, as do orthopedic and surgical residents from Harvard-affiliated hospitals. The anatomy facilities are also used by physician assistant, physical therapy, and occupational therapy students in accredited programs at the Massachusetts College of Pharmacy and Health Sciences, the MGH Institute for Health Professions and Simmons University, under formal

collaboration agreements between HMS and those institutions. The AGP does not transfer donor bodies outside its own morgue and teaching laboratories. All AGP donors are embalmed, and the AGP does not support any work involving fresh tissues.

Several hundred students from Harvard and other institutions use the HMS anatomy labs over the course of a single year. Depending on the particular course, students in the labs may undertake dissection, may study prosections of different areas of the body prepared by HMS anatomy faculty, or both.

II. CHARGE AND SCOPE

This Panel is charged with assessing current practices and operations of the AGP to identify areas for improvement to conform to current best practices. The Panel consists of the following members:

- **Sally Aiken, M.D.**, Retired Chief Medical Examiner, Spokane County Medical Examiner's Office, Member of the Federal Forensic Sciences Standards Board
- **Robert McKeon, Ph.D.**, Associate Professor and Body Donor Program Director, Emory University School of Medicine
- **Brandi Schmitt, M.S.**, Executive Director of Anatomical Services, University of California Office of the President

Harvard's Charge letter asked this Panel to review the:

- Appropriateness of the AGP's operations and consent processes;
- Security and privacy practices in the operation of the AGP;
- Adequacy and appropriateness of data management in the operation of the morgue and the AGP, including designated periods for data retention;
- Screening, hiring, and supervision of morgue staff, including basic requirements for each position;
- Adequacy of current staffing of the morgue and the AGP;
- Physical environment of the working areas of the morgue, including adequacy of equipment and the location of staff members' and supervisors' offices in relation to the location(s) in which cadavers are handled;
- Reporting structure within HMS for the morgue and AGP;
- Tracking of cadavers through the cycle of educational use, from initial accession, to use in anatomy laboratories, to final disposition using external vendors;
- Ensuring the integrity of cadavers in the period of use within anatomy laboratories, including ensuring privacy and ensuring that dissected portions of cadavers are tracked so that they may be reunited at the end of their educational use;
- Security of morgue operations, including possible mechanisms of electronic and other surveillance of daily operations;
- Reporting of adverse events and quality improvement processes; and
- Screening and monitoring of external vendors for transport and disposition of cadavers.

III. PANEL REVIEW PROCESS

To meet these goals, the Panel's assessment process involved multiple stakeholder interviews, review of pertinent literature, standards, and AGP documents. The Panel visited the AGP facility in person in July 2023 to observe the facilities and processes and to conduct additional interviews. The Panel also evaluated floor plans, organizational charts, reporting structures and select job descriptions; and assessed contextual aspects of anatomy needs for professional programs. The Panel's review included key resources, best practices, and guidelines (see Appendix A) and standards set forth by an accreditation program (see Appendix B). Staff and faculty at HMS, including staff in the AGP, cooperated fully with the review process.

The following section of this report outlines the findings and recommendations that the Panel was asked to make, organized according to Harvard's charge letter. The Panel's recommendations are based on best practices that the Panel believes are beneficial to body donor programs operated by academic institutions.

IV. FINDINGS AND RECOMMENDATIONS

A. Appropriateness of the AGP's operations and consent processes

1. Policies and Procedures

Harvard University should develop and implement a comprehensive policy specific to the AGP that addresses all human specimens acquired or used for education and research. Processes to maintain an up-to-date Standard Operating Procedure Manual (the "SOPM") are also needed. Harvard University does not have a policy related to the AGP or to the care and use of human specimens donated or acquired for education and research. The development of a policy that reflects the values of Harvard University is strongly recommended. The policy should delineate roles and responsibilities for the AGP, including those of the governing board and operational committee described in Sections IV.G.1 & IV.G.2 of this report and set minimum standards for the donation, acquisition, tracking, use, care, and disposition of human specimens used by employees and students.

The AGP's SOPM was last updated in 2014. The Panel recommends that Harvard and HMS create new procedures and update existing procedures for all operational practices in the AGP. The SOPM should be reviewed to ensure that it covers required documentation of donor specimens and teaching collections, tracking of donor specimens and uses, the maintenance of accurate inventories of all human remains in the care of HMS, and training requirements (including the documentation of any training requirements). The Panel's recommendations that there be written policies and procedures to document donor use requests are set forth in Section IV.H.2 of this report. After the SOPM has been updated, the AGP should implement training specific to the updated SOPM for AGP staff members and other university stakeholders to ensure that it is put into practice.

The Panel recommends, at the minimum, that HMS and Harvard review the SOPM to consider updates for the following issues related to AGP operations:

- Health and safety (Personal Protective Equipment [PPE] use, hazardous chemical labeling, emergency exposure procedures);
- Training and training documentation;
- Records management;
- Eligibility and suitability assessments;
- Donor tagging and tracking;
- Donor specimen requests and related agreements;
- The use of personal vehicles for institutional business; and
- Medical device companies' use of laboratories and anatomical specimens (in relationship to HMS's Policy on Sponsorship, Gifts, Meals, and Access of Pharmaceutical Representatives to the HMS Campus).

The Panel also observed that AGP's adherence to and comprehension of relevant University-wide policies could be enhanced. The Panel's review and recommendations pertaining to employee and student training, and documentation of such training, are discussed in greater detail in Section IV.D.1 and Section IV.H.4 of this report.

2. Consent Process

The Panel recommends that the donation consent form, termed the Instrument of Anatomical Gift (the "Instrument"), be reviewed with guidance from the Office of the General Counsel. To the Panel's knowledge, the current version of the Instrument was implemented in 2022, while the prior version dates to 2003. The Instrument should be reviewed periodically, for example every three years, to ensure that it is consistent with programmatic and best practices (e.g., readability for lay persons, detail regarding potential timelines, teaching uses of donations, and the like).¹ Version control measures should be implemented. The Office of the General Counsel also should participate in the review to ensure that any definitions and practices described are consistent with the Massachusetts UAGA and other applicable laws. The Panel believes the

¹ As a matter of best practice, and in addition to conforming with all applicable laws, the document of gift should be readable to a layperson and describe the donor and the donor estate responsibilities. The document should clearly state the donation recipient and the intended users of the donation. It should include the following information that is made specific to the institution receiving the donation: preparation methodologies; possible uses and purposes for the donation including duration of use and possible long-term retention for teaching or research purposes; acquisition, use and storage of images, data, medical records, and test results or findings; any financial implications for donation including the financial status of the program itself, if commercialized product development will be supported and financial responsibilities that the donor's next of kin or estate may incur; final disposition and memorialization; and how to revoke the donation, as well as any options the donor may have for directing the donation (opting in to or out of specific uses or dispositions, if applicable). It should be signed and witnessed accordingly and provide some information on how the program will handle future changes to policies and procedures, if needed.

Instrument should be more specific and could be improved by including all relevant information in a single packet that is organized to flow from registration to disposition.²

More specifically, the Instrument contains three sections and a Donor Data Form that the Panel believes might benefit from additional update as laws in this space continue to evolve:

- **Section I, Consent and Authorization**, contains certain key disclosures, about preparation, access to health information and general information about uses, users (like Harvard's or another education institution's students and faculty). The Instrument would benefit from adding specific details such as including possible uses of data or images (which can be derived from medical records or captured during the use of the donor) and Harvard's practices pertaining to the secure storage of this information (if applicable).
- **Section II, Disposition**, includes options for the potential donor to choose from four methods of disposition, including: (1) cremation and interment arranged by HMS; (2) cremation with the return of cremated remains by HMS; (3) cremation with the pick-up of cremated remains by the donor's designee or next of kin; or (4) the return of remains for disposition without cremation. Important disposition disclosures that convey AGP practices are included in the footnotes. Instead, such information should be placed in a more prominent location within the Instrument. The Panel recommends that the Instrument should be revised to provide more specificity regarding how retained specimens will be tracked and disposed.
- **Section III, Declaration as to Remains**, includes a declaration statement, granting AGP the authority to effectuate the donation and to authorize cremation or burial. The Instrument would benefit from including specific examples of actions that might be taken by AGP. The donor is asked to sign on this page and two witnesses are to sign on the following page (i.e., the "Witness' Attestation" page). Instead, the Panel recommends that the donor initial each section individually which likely will encourage donors to review the contents of each section more carefully. The donor and witnesses should sign on the same page at the conclusion of the document, thus requiring the donor to apply their signature once in full consent and authorization of the terms of the donation, disposition, and declaration in its entirety. The panel also recommends that the witness process be reviewed to ensure that it serves the intended purpose and that the next-of-kin and designated contact descriptions are accurate.

² The document of gift should be accompanied by instructions on how to complete forms and information on the registration acknowledgement process. This packet should include information on eligibility and suitability criteria for donations and information pertinent to enacting the donation at the time of a registrant's death like notification and transportation details. Other forms that should be included in a registration packet of information are those that relate to the donor's medical history and the personal details needed to complete required paperwork like a death certificate and permit for disposition.

- **The Donor Data Sheet** is on the last page of the Instrument and prompts the donor to provide certain identifiable information such as their name and next of kin. (Use of the Donor Data Sheet and areas for improvement related to donor eligibility/suitability are discussed in greater detail in Section IV.A.3 below.)

More generally, the Panel believes there are opportunities to update and streamline donor communications templates and public-facing communications including the AGP website. Therefore, the Panel recommends that AGP engage internal stakeholders or third-party advisors, as needed, to provide editorial assistance for written materials that will be distributed to donors and their families, to ensure that these materials reflect current practices and are clear, concise, and compassionate. The AGP website can be expanded to include a dedicated donor memorialization page, with images of the existing donor monuments, student ceremonies, and any new memorialization efforts. The AGP website provides an opportunity to disseminate information about its processes and procedures, and other important pertinent details.

3. Registration Process

The Panel recommends the appointment of a Medical Director to advise on matters of donor eligibility and suitability. Within the anatomical gift field, donor eligibility usually refers to characteristics known about a potential donor in life that may preclude donation. Suitability for use is usually determined at the time of death through a series of assessment questions.

The Instrument has an attachment for donor information (i.e., the Donor Data Sheet), but does not include specific questions about health status at the time of donor registration. All individuals who submit a completed Instrument are registered and considered eligible by default. However, the Instrument advises that not all registrants will be accepted as donors at the time of their death, and the AGP website states that registrants with an infectious disease at the time of death, such as HIV, will not be accepted for donation.

The donor suitability procedures currently in place were originally developed by anatomy faculty and AGP staff and are implemented by the AGP staff; suitability is determined at the time of death by AGP staff, but these staff are not trained in clinical medicine and receive limited training to determine donor suitability. Suitability is determined when the AGP is notified that a registrant's death has occurred. HMS currently employs three full-time staff members in the AGP, and donor screenings are done by either the AGP Managing Director or the AGP Manager. If the AGP Manager has questions about the eligibility or suitability of donors, the final arbiter is the AGP Managing Director.

A Donor Qualification worksheet is completed by phone. Staff members report that they typically attempt to collect donor qualification information from health care providers, but for most registered donor deaths, information is obtained from a family member instead of from a clinical source. In review of a sample of AGP donor files, no donor medical records were identified, even though the Instrument includes a consent for release of medical records

consistent with a Massachusetts UAGA provision that a donor program can access medical records for suitability determination.³

For these reasons, the Panel believes that the AGP would benefit from the appointment of a Medical Director to advise on matters of eligibility and suitability. Best practice is for donation registration processes to include information about eligibility and should address capacity (mental capacity and age) to donate and standard donor characteristics that might prohibit donation, including the known presence of infectious disease, such as HIV, during life. The suitability procedures at the time of death should include screening (of family-provided information, and ideally of health care clinician-provided information or medical records) to ensure that a donor body is in suitable condition (typically, no trauma or conditions that may preclude the teaching of anatomy) and of a practical size and posture to allow for safe body handling and intended use. Another suitability purpose, which is partly recognized by current AGP practice and policy, is to determine if a donor had an infectious disease that would place those transporting, preparing, embalming, examining, or studying the body at risk. The current screening practices may need to be expanded for prions, respiratory viruses and emergent diseases. The Medical Director can assist with the development of decision trees for routine use by AGP staff.

B. Information security and privacy practices in the operation of the AGP

The Panel recommends further review and assessment of AGP information security processes to ensure proper safeguards for personally identifiable information stored in hard copy. Hard-copy registration and donation records are stored in the AGP offices. The hard copies contain donor personal information, and access is by key to the AGP offices and file cabinet(s). However, the Panel recommends improving practices to ensure more secure storage of any access keys and periodic security and privacy refresher training to any person with access to identifiable information.

The Panel finds that the privacy practices for information stored in the AGP electronic database are adequate. The AGP registry and donor database is customized on a FileMaker Pro platform that is hosted on a Harvard server. Access is password-protected and limited to the three current AGP staff members and a contract software developer. Technical support for the database is currently being brought in-house.

C. Adequacy and appropriateness of data management in the operation of the morgue and the AGP, including designated periods for data retention

The Panel recommends that AGP consult with Harvard's Archivist on how to identify potentially significant records and seek advice and training from a records specialist to develop a written record management plan specific to AGP. Currently, all registrant and donor records, regardless of their status, are retained indefinitely. The Panel recommends a written record management plan that accounts for the minimum retention periods as set forth in any

³ See Mass. Gen. Laws ch. 113A, § 22.

applicable laws, regulations, university policies, and donor consents (i.e., the Instrument). Inactive records for registrants should be culled on a periodic basis. Records can be destroyed once the applicable minimum retention periods have been met.

D. Screening, hiring and supervision of morgue staff, including basic requirements for each position

1. Employee Screening and Training

Given privacy considerations and the preciousness of the donor resources, as a matter of best practice and to the extent not occurring, the Panel recommends that staff receive routine training in ethical values and conduct and acknowledge their understanding of these responsibilities both at hire and annually thereafter. Going forward, the AGP should be sure that employees receive more detailed training, and that such training be documented. Training should cover, for example, relevant Harvard and HMS policies, safety practices, and record retention. Opportunity for professional growth should be made readily available, and AGP staff members should be encouraged to attend regional or national meetings regarding body donation or organizations with relevant content. Such opportunities would be consistent with the need for AGP staff to remain current on best practices and any changes to rules and regulations governing body donation and use and should be required. Employees with supervisory responsibilities should attend regular supervisor trainings so that they can effectively manage staff, including for training, compliance, and performance evaluations.

The Panel recommends that there be rigorous background checks and screening in the hiring process for AGP staff. The Panel recommends that all AGP potential hires be subject to thorough background checks, in accordance with current Harvard policy, to ensure the compatibility of the potential employee with the AGP mission and operations. Periodic re-screening of current AGP staff might also be considered. This process could include review of public-facing social media accounts, if consistent with Harvard's policies.

The Panel further recommends more formal training processes for the security supervisors who have responsibility for receipt of donors after hours. Donor bodies need to be received in a timely manner, soon after death which means they may arrive before or after business hours, including on weekends and holidays. Outside of business hours, supervisors from the University's external security vendor receive donors on behalf of the AGP (and AGP staff are on call). Training for this role should be formalized and include not only AGP procedures but areas relevant to occupational safety and health; alternative strategies to minimize the delivery of donor bodies after hours should be considered.

2. Position Requirements and Review

The Panel recommends that Harvard review and update job descriptions and job duties of the three current AGP employees. The Panel observed that job descriptions for each of the three positions are not up to date and should be revised to reflect the current responsibilities of each employee. HMS employs three full-time staff members in the AGP, i.e., a Managing Director, an AGP Manager, and a Staff Assistant who works in the morgue. The Staff Assistant and the AGP Manager report to the AGP Managing Director, who reports to a Senior Director for Finance and Administration in the PME.

- The Managing Director has supervisory, technical, administrative, financial, and compliance-related responsibilities. Currently, and historically, the Managing Director performs all embalming and determines the assignment of donors to courses and other specimen recipients.
- The AGP Manager's duties are primarily administrative, including handling all communications with the donor during the registration process and the next of kin at the time of the donor's death and all subsequent communication.
- The Staff Assistant's duties are primarily technical, related to care and tracking of donated bodies. The Staff Assistant position is currently filled by a temporary employee being trained by the Managing Director with the goal of transitioning this individual to permanent full-time employment. The temporary Staff Assistant is enrolled in Mortuary School and plans to become a licensed embalmer. It is possible that the Staff Assistant position might perform embalming for the AGP in the future.

The Managing Director and AGP Manager alternate weeks on call, primarily assisting families when an eligible donor dies and performing suitability screening.

The job descriptions for each of the above positions should be updated to reflect their current roles, responsibilities, and expected qualifications and training. For example, although the job description for the AGP Manager includes duties in preservation and technical morgue-based operations, and the job description lists experience as a licensed embalmer as a preferred qualification, the current AGP Manager is rarely in the morgue and does not fulfill such responsibilities. Similarly, the Managing Director position lists an Embalmer's license as a preferred qualification; the current Managing Director is licensed and the Panel believes this qualification, or commensurate education, should be required.

Furthermore, to the extent not already occurring, Harvard should ensure that employee annual performance reviews should be formalized and conducted by individuals with in-depth knowledge of AGP policy and procedures. Performance goals should be included and reviewed during each performance evaluation. The Panel's overall recommendations pertaining to the reporting structure and oversight are discussed in greater detail in Section IV.G.

E. Adequacy of current staffing of the morgue and AGP

The Panel recommends that the AGP consider hiring a dedicated anatomy laboratory technician. AGP staff currently perform some duties that would more typically be the role of laboratory technician in a gross anatomy teaching laboratory. A laboratory technician in such a role could support faculty donor use requests and perform class scheduling. Additional duties might include general maintenance of the laboratories, supply stocking, inventory and check-out for prosected remains, and chain-of-custody responsibilities for donors assigned to courses in the teaching laboratories. This would free APG staff time for other duties, such as efforts to improve its processes and procedures. Staff time will be needed to prepare records for archiving, to create and update procedures and to coordinate with different departments (e.g., Information Technology, Facilities, Human Resources, Environmental Health and Safety, Security, and members of the proposed operational committee and governing board that are discussed later in this report).

F. Physical environment of the working areas of the morgue, including adequacy of equipment and the location of staff members' and supervisors' offices in relation to the location(s) in which donors are prepared for study.

The Panel recommends that the current Staff Assistant be housed in office space outside of the morgue to minimize potential chemical exposure. The AGP facility is located on the HMS campus with lab and office space spread across different floors in the same building. The AGP Managing Director and the AGP Manager have offices located in an administrative area while the Staff Assistant uses a workspace that is in or near the embalming area. Instead, the Staff Assistant should be provided with a workspace on the morgue floor, away from the embalming area to reduce potential exposure to chemicals. Other than possible chemical exposure for the Staff Assistant, the Panel does not have concerns related to the AGP staff office locations.

The Panel recommends prioritizing the repair of the floor in the largest body storage freezer, which displays cracks, unevenness, and swelling from water damage. The AGP has three walk-in freezers for long-term storage. The main freezer has the largest storage capacity. There are also two smaller freezers available. The damage to the main freezer was first identified in 2022 and was likely caused by groundwater freezing, which resulted in ice buildup in the center floor. Continuing use of this main freezer in its current state poses a risk of injury for AGP staff and prevents staff from efficient transfer of bodies onto gurneys from storage racks. AGP staff should use alternative areas of storage until the floor in the main freezer is repaired. Other possible solutions for long term storage of embalmed bodies; for example, a walk-in cooler; should be considered.

The Panel also recommends removing any morgue equipment that is no longer used, in order to optimize the morgue and storage space; and that the AGP establish a comprehensive, coordinated maintenance plan. The Panel observed that certain pieces of equipment are no longer used. For example, a large piece of equipment is stored in the morgue space but not in use because of mechanical problems. If it were removed, the space could then be retrofitted for additional and secure storage, or another purpose. For instance, such additional space can

be used to store a body scale, eliminating the need for staff to estimate body weight. Accurate body weight information can help the AGP better determine how a donor body is best used or for safe maneuvering during dissection.

The AGP would benefit from an overarching plan for facilities maintenance as well as custodial services. The cleanliness in the morgue was acceptable during the site visit. The Panel noted that several different departments are responsible for different types of safety monitoring and maintenance (e.g., surgical lights above tables and certain tools are cleaned by AGP staff periodically, whereas custodial staff is responsible for general cleaning). While many of the services are currently being performed, the separation of the responsible parties into various departments under different authorities can cause challenges to maintenance efforts and consistent communication with AGP staff. The hiring of a laboratory technician, as noted above, could help provide more coordinated oversight of maintenance and custodial services within the teaching laboratories.

The student laboratories could benefit from upgrades. The anatomy laboratories were built 36 years ago and are showing wear. Many of the furnishings in the seven anatomy laboratories (stools, step stools and pegboards) are wooden, which can absorb the preservative fluids with carcinogenic properties. All wooden equipment should be replaced with solid surfaces that are non-absorbing and can be adequately sanitized. This can help reduce mold issues and improve overall cleanliness.

The Panel believes the general environment of the student dissection labs should be improved. The size of the laboratory space is satisfactory. Each room is of sufficient size for four dissection tables, and each table can comfortably be used by four students. Surgical lights above tables and tools are cleaned by AGP staff periodically, but more frequent cleaning of lights and autopsy tools is recommended. Custodial staff mops the floor on weekdays and performs general cleaning. The anatomy laboratories are monitored for formaldehyde, and reported monitoring results are under exposure limits. Ventilation is adequate, as confirmed by an interview with an Environmental Health and Safety representative but this could be better communicated to faculty and staff. Each anatomy room has a small sink with a single monocular eyewash station. Larger sinks with binocular eyewash stations at each are recommended. Emergency eyewash bottles should be available at multiple locations in each lab. There are a few emergency showers, widely spaced, available near the laboratories. More showers should be considered. Increasing the number and visibility of laboratory safety signage should also be considered.

G. Reporting structure within HMS for the morgue and AGP

The Panel recommends that the AGP Managing Director report directly to the Dean for Medical Education or a designee; and that the HMS implement a two-tiered oversight system: (1) a smaller operational committee and (2) a governing board.

The general placement of the AGP in the Harvard Medical School PME is a good fit for the program overall, however, the AGP has limited regular access to subject matter experts and would benefit from greater technical oversight.

As noted above, the AGP currently has three full-time staff positions. The AGP Manager and Staff Assistant report to the Managing Director. The Managing Director reports to the HMS Senior Director for Finance and Administration. There is an additional layer of reporting between the Senior Director for Finance and Administration and the Dean for Medical Education, and those in these intermediary positions do not have experience with body donation, anatomy, or other directly relevant subject matter. Access to other experts relies on individual recognition of matters where advisory services may be needed and on self-directed initiative to seek advice.

We recommend that the AGP report directly to the Dean for Medical Education or the Dean's designee. We further suggest the following:

1. Operational Committee

An operational committee should be created and should be responsible for ensuring regulatory compliance and adherence to best practices in body donation on a day-to-day basis. The operational committee should include supervisors who have directly relevant knowledge and are capable of providing supervision for the facilities, labs, and the morgue where AGP activities occur. Specifically, the Panel recommends that the operational committee members include:

- The AGP Managing Director
- A faculty advisor with anatomy expertise
- A PME leader such as the Dean for Medical Education or their designee (i.e., a member of the PME staff that reports directly to the Dean)
- Other AGP staff and subject matter experts, as needed

2. Governing Board

A governing board should be established and should be responsible for long-term oversight. The Panel recommends that a governing body meet annually, or more often as needed, to receive reports on the AGP, advise on long-term strategies, and provide subject matter expertise for new and ongoing items of interest. Examples of governing board members include:

- Dean for Medical Education or their designee
- AGP Managing Director
- Medical Director of AGP
- Faculty representative(s)
- Legal counsel from the Office of the General Counsel
- Anatomy laboratory manager

- Environmental Health and Safety officer
- Compliance officer
- Representative of Vice Provost for Research
- Biomedical ethicist
- Student end user representative
- Donor community representative

The Office of the General Counsel should be available to the governing board to advise and opine on the laws, rules, and regulations applicable to universities and to anatomical gifts. They should also be party to operational controls for all vendor agreements, facility agreements, consent forms, hold-harmless agreements, and other documents both standard and modified. To the extent not already occurring, the panel recommends that the AGP becomes a client to specific attorneys within the Office of General Counsel, who will serve as members of the governing body.

Other members of the governing board should be invited to participate as subject matter experts in applicable agenda items raised by the operational committee.

H. Tracking of cadavers through the cycle of educational use, from initial accession, to use in anatomy laboratories, to final disposition using external vendors

1. Tracking and identification

The Panel recommends that a consistent protocol be applied for donor identity verification at intake into the AGP; and, with IT assistance, that real-time donor and specimen location tracking shift entirely to an electronic system. The identity of all donors should be verified, by matching the identity tag on the donor with the accompanying paperwork and donor acceptance documents, upon receipt of the donor's body. Currently, donor tracking is accomplished through a database and is dependent on AGP staff manually entering changes in location of each body. The donor number is placed on the body tray upon arrival, just before the body is moved to temporary refrigerated storage in the receiving area. When the donor is moved to a new location, the donor number is used to identify the record, and the new location is entered by drop-down selection in the database. Hard-copy forms (e.g., Receipt of Donor Form, Morgue Donor Card, and Cadaver Identification Verification) are used to aid in tracking. The hard-copy forms are scanned and stored in the database.

The AGP database application has a module that can print the donor number along with a barcode onto a tag that can be scanned. The Panel recommends enhancing this system for full use in tracking all donor bodies and donor specimens. In conjunction with the barcode system, tracking can also be streamlined by adding a workstation near the teaching laboratories, which likely would promote tracking, location, and chain-of-custody work in real time.

The Panel recommends modifying the current donor and specimen coding numbering system. Each accepted donor is given a donor number. The donor numbers are generated

consecutively, and donor numbers are now in the 5,000s. The numbering system would have more meaningful utility, for example, by numbering donors by year and then in order that the donation is received within the year (e.g., 23-001 would be the first donation received in 2023). The donor number and the related barcode would be used as the key identifiers while the body is in the custody of the AGP, and these numbers would be synced back to the donor's identity in the AGP database.

The panel recommends that donor specimens that are retained for long term education and research be clearly labeled and tracked throughout storage, use and disposition; and, that all human remains including disassociated, prospected and legacy teaching collections with an unknown provenance be inventoried, assessed, and tracked while under the care of HMS until they are disposed or returned. The panel did not identify any institutional requirement or process to label and track donor specimens that are retained for long term uses. Best practices include the labeling and tracking of all donor specimens so that their location is known and traceable to the donor they originate from until such time as they are disposed in accordance with the donor's consent (the *Instrument*). Some current faculty have recognized that tracking and labeling should be part of the management process for these collections and have been using their own method. The panel believes that the methods for tracking and documentation are not sufficient in their current form and recommends that additional steps are implemented to request, review and document all specimens and to connect them to their source (the donor) going forward. Labeling, tracking and inventory responsibilities should be assigned to the AGP. The database should be enhanced to track these items whether they come from a known donor source or from an unknown (legacy) source. Consent disclosures need to be created to address disposition practices when specimens are not reunited with the donor before cremation. The AGP managing director has established a permitting procedure for the disposition of unidentified donor specimens and specimens that cannot be reassociated for a traditionally permitted disposition, and this will continue to be needed and should be compassionately explained in the *Instrument*.

The AGP also has a legacy collection of skeletons and bones. The panel has not investigated the collection held by AGP, but these types of collections are common in U.S. medical schools. Most were purchased as medical teaching specimens in a manner that was legal at the time but may not have been ethical. The panel recommends that the skeletons and bones be assessed by experts and that any regulatory requirements like those found in the Native American Graves Protection and Repatriation Act be applied, as needed. Because there are not regulations that apply to all human skeletal remains held in research and teaching collections, the panel also recommends that Harvard establish a protocol for storage, use and disposition to result in consistent and respectful procedures for all such human remains in its care; and explore opportunities to teach about consent and past transgressions related to how human remains have historically been obtained for research and education.

2. Requests for use of donors

The Panel finds that the AGP would benefit from ensuring a formal written standardized procedure for receiving, reviewing, and approving requests for use of donors. The current practice for obtaining specimens is that the requestor notifies the AGP Managing Director verbally or through email regarding the number of students or donor bodies needed. The primary requestor, often a course director, provides the dates of the course and a roster of students who will need access for the duration of the use. The Managing Director then selects donor bodies for assignment based on cards completed at the time of preparation and entered into the database under the “suggested use”. A search may then be done limited to the “suggested use” field to review which donors may be most suitable for the request. Course directors and specimen recipients generally receive limited donor data, such as age and birth gender. If the course is not a Harvard course, the AGP Managing Director initiates, or verifies the existence and execution of, an active service agreement. Donor assignments are tracked in the database.

There are no formal written procedures for receiving, reviewing, approving, and documenting requests for the use of anatomical material being used, nor any formal assessment of the appropriateness of requests for use of donors. There are no written materials developed or disseminated by the AGP to specimen recipients beyond the policies and procedures customarily appended as Exhibit B to the agreements executed with external institutions that will be receiving donor specimens.

3. Donor specimen contracts

The Panel recommends an assessment of whether the AGP Managing Director should serve as the signatory to agreements for the educational and/or research use of donor specimens.

According to interviewees, Harvard’s practice is to allow various individuals in divisions or departments to sign and effectively execute various types of agreements. The PME delegation of authority for approving agreements for the educational and/or research use of donor specimens, in practice, resides with the AGP Managing Director, as does the responsibility for maintaining records of contract changes and maintaining the record of the executed agreement. The Panel recommends Harvard consider whether such contracting responsibilities should continue to be delegated to the AGP Managing Director going forward, and if so, how legal review may be a required step in any contract revisions or renewals.

Regarding contracts generally, and to the extent not occurring, Harvard should ensure that there are proper processes for the AGP and the proposed governing board to request advice from the Office of the General Counsel on various agreements (including but not limited to vendor agreements, facility agreements, consent forms, and hold harmless agreements) or other issues of concern, as needed. A determination should be made as to which office is the official record holder and the appropriate record management plan should apply.

4. Donor use and student training

The Panel recommends a more formal discussion with students about regulations for anatomical gifts (e.g., consent considerations in the Massachusetts UAGA), policies or practices that govern the AGP, and comprehensive laboratory rules. HMS anatomy faculty have expertise and are widely recognized for their work integrating ethics and professional competencies into the anatomy curriculum. This is accomplished in part by incorporating information about ethics into the course. Participating faculty reach out to students, in some cases prior to the start of the course, encouraging them to share and express their feelings or concerns about human dissection through various modalities. Videos that include senior or previous students' perspectives about the anatomy course are available in at least some courses. Students are encouraged to participate in organizing a service of gratitude. Additionally, a short video with limited basic information (e.g., no food or drinks in the lab) is available for review. However, the Panel believes that students would benefit from a more uniform, formal, and structured discussion regarding all of these issues. The Panel reviewed the current available orientation materials provided from HMS courses. Consistent student orientation practices will be particularly helpful given the number of course instructors and students, representing a number of institutions, who use the HMS laboratories.

The Panel recommends that Harvard require all specimen recipients (including students) be routinely provided with standardized guidance on the AGP policies and respectful treatment of donors in the laboratory and attest to understanding the consequences of non-compliance and disrespectful treatment. Best practices would include documenting the acknowledgment of each participant having received relevant training, their responsibilities, and their understanding regarding consequences for violations. All those supervising others should be required to attest to understanding the terms of use and acknowledge their responsibilities for educating other participants (e.g., regarding appropriate behavior and parameters of donor use). Students should sign a standardized document confirming their understanding of Harvard's laboratory rules and regulations, with the applicable rules and regulations appended. The Panel believes that regular, standardized information dissemination and training creates a culture of compliance in which donors are inherently respected and honored. Course evaluations on the effectiveness of this training, and to determine perceptions about laboratory cleanliness and safety can serve as an opportunity to receive feedback.

- I. **Ensuring the integrity of cadavers in the period of use within anatomy laboratories, including ensuring privacy and ensuring that dissected portions of cadavers are tracked so that they may be reunited at the end of their educational use**

The Panel recommends that donor location reconciliation should be a regular activity, occurring at established time intervals and at a specific stage of the donor's residency in the AGP. The AGP staff members periodically reconcile donor locations (i.e., location of the body) with the database, but there is not an established schedule for these reconciliation activities. Currently, two AGP staff members, working together, perform inventory/reconciliation of

donors. For improved security, inventory practices should be subjected to verification by a supervisor or another third party. Discrepancies, if any, should trigger more frequent inventories and corrective action.

The Panel recommends that Harvard leverage the knowledge of anatomy faculty and integrate anatomy faculty into the process of securing remains at the conclusion of study and dissection; and, that storage of donor bodies ready for cremation be limited to the shortest duration practical. Although the Panel did not have concerns related to the extent of the anatomical faculty's current involvement in AGP disposition processes, the AGP program could benefit from their expertise and increased participation. Harvard's anatomy faculty are highly familiar with considerations related to donor bodies used in anatomy courses. For instance, anatomy faculty and lab manager staff can be more involved in the chain-of-custody process to be followed when confirming with witnesses that the body is complete, ensuring that a body is correctly identified by donor number, and that the body is sealed securely for transport to a crematory as soon as is feasible. A combined chain-of-custody form can be developed to accompany the secured body through release for cremation and return of the cremated remains to the AGP.

J. Security of morgue operations, including possible mechanisms of electronic and other surveillance of daily operations

The Panel recommends that: (1) ongoing projects that add and upgrade cameras in the morgue and anatomy laboratory areas be completed; (2) all key locks be re-keyed; and (3) any keys be assigned to specific individuals and kept in secure locations. Although the Panel recognizes that the security practices have been expanded and enhanced since the alleged criminal conduct was reported, these additional measures are needed to ensure a greater degree of security for the physical premises.

The AGP should assess and consider working with the current external security vendor to develop a process for review of keycard access to the facility. Harvard employs a private contractor to provide campus security, including security to the AGP. Keycard access to AGP facilities is limited to AGP staff, supervisors, and faculty. Anatomy laboratory access is limited to faculty and students who are enrolled at HMS, and other authorized students who are taking a specific course of study. Visitors are allowed only when accompanied by an individual with authorized access. There are several points of entry; most of these also have camera surveillance.

The Panel recommends that the process for reviewing keycard access should include periodic checks of keycard data at regular and random intervals, with comparison to camera views. Checks also should be triggered by defined unusual incidents such as keycard use at non-business hours. Keyed entries should be re-keyed and visitor access should be pre-approved. The Panel further recommends that individuals who are assigned supervisory responsibilities for AGP staff and operations be expressly delegated the responsibility of performing routine review of facility procedures pertaining to donor preparation, use and security.

K. Reporting of adverse events and quality improvement processes

AGP should develop a formal monitoring process for documenting any reported deviations from standards, subsequent investigations, and the outcome of such review. As discussed above, the Panel recommends updating existing AGP policies and procedures. As a part of this effort, AGP should develop a formal monitoring procedure for documenting deviations from standards. This should include documentation of any reports received, the resulting investigation details and the resolution/solution, if any.

This documentation should be periodically reviewed by the operational committee or governing board, and should trigger process improvement or corrective action, as needed. The Panel believes that implementing the processes outlined in this report and a monitoring process to track, review and perform root cause analysis of any deviations from standards would help prevent or mitigate potential compliance issues.

L. Screening and monitoring of external vendors for transport and disposition of donors and human remains

AGP should consider using a contracted body removal service that is operated under standardized terms and conditions negotiated with HMS. Currently, at the time of death and acceptance, the donor's next of kin are directed to contact a funeral home of their choice. If the next of kin inquires, the AGP provides the names of two funeral homes to the family for their consideration. The funeral home chosen then arranges for the removal and transport of the deceased donor from the place of death directly to HMS or to their mortuary before transporting them to HMS. The funeral home is responsible for generating the Death Certificate and Permit for Disposition. HMS provides a certain stipend to funeral homes for transport and administrative services. If the costs exceed this amount, then the next of kin or donor's estate is responsible for the additional costs.

Alternatively, the AGP could consider using the services of a contracted body removal agency. If Harvard opts to contract with a new body removal service vendor, this also will serve as an opportunity to establish a new master contract incorporating a variety of terms and conditions (e.g., fees based on a geographical area, response times, the use of background checks, insurance requirements, adherence to AGP admitting procedures, and/or site visits at AGP's election).

M. Additional Subjects for Consideration

The Panel believes that memorial services should be organized to consider the impact that donation and donors may have on the greater community. This includes the impact on families of donors; the beneficiaries of the donations (such as faculty, researchers, staff, and students); institutions and organizations; the broader education and research community; and the public at large. At their time of registration in the AGP, most donors choose cremation with burial at Harvard's expense. A non-denominational service is held each Fall at the cemetery. Family members of donors who choose either of the two alternative disposition methods (i.e., return

of cremated remains to designated individual or return of the body to designated next of kin) are not offered an opportunity at present to receive acknowledgement of the donor's gift or appreciation by Harvard, students, or faculty that benefit from their altruism.

The Panel suggests that the current student-organized memorial ceremony, now exclusive to certain Harvard students and faculty or to the families of donors that choose one type of disposition, should be open to all students and faculty, as well as the families and loved ones of all donors. This would allow families and community members to gain understanding directly from students about the value of the gift. If Harvard prefers that the student-organized memorial ceremony remains a private event, then the Panel encourages Harvard to create an alternative mechanism of acknowledgement that expresses gratitude to all donors for their gift, without regard to their chosen method of disposition discussed in the preceding paragraph.

The Panel suggests that in addition to providing a formal letter of gratitude and a small token of appreciation to the donors' families, Harvard consider creating a permanent memorial to all donors in an accessible location, preferably on or near the HMS campus.

V. CONCLUSION

This report summarizes the Panel's key findings and recommendations related to the AGP. The Panel recommends that AGP engage in process improvement efforts to review, develop, and revise policies and procedures specific to the AGP; implement an oversight and governance structure (i.e., an operational committee and governing board); enhance routine training given to AGP staff and other stakeholders; and assess the overall infrastructure (technological or otherwise) for areas of improvement. The Panel acknowledges that such improvement activities will be an ongoing effort involving multiple departments at Harvard. By leveraging the strengths of the faculty and institution, implementation will provide better support for the AGP program and staff. Enhancements to donor information and consent and development of equitable memorialization traditions will provide opportunities for positive community engagement.

APPENDIX A

Resources

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APPENDIX B

Newspaper articles in *The Boston Globe* from 6/16/23, “Medical School Body Donation Programs are Based on Trust with Little Outside Oversight,” and 6/22/23, “Opinion: The Scandal at the Harvard Morgue is not a Reason for More Government,” propose accreditation by the American Association of Tissue Banks (“AATB”) as a means to improve processes at the AGP to prevent future theft of body parts and to make the program more transparent.

As the two articles state, seven private enterprises are currently accredited, none of which is in Boston. It is important to note that none of these companies is housed in an academic institution, and none has a direct mission to deliver education and conduct research. Harvard-based body donation programs, like the one at HMS, do so to support education and research primarily in support of their internal mission. Many do so at a financial loss. In the case of the AGP, donations are currently accepted by individuals who register themselves prior to death and are used for teaching anatomy or surgical procedures to medical students, dental students, and students in related health care fields.

The Panel evaluated the AATB accreditation program and concluded that this accreditation program would not assist in meeting the pressing needs and challenges in the AGP. As demonstrated by the companies currently accredited by AATB, this accreditation is not a fit for most other programs that are based in universities with medical or health sciences schools and designed to train affiliated students and clinicians. The Panel also reviewed anatomy professional association guidance, best practices and policies from anatomy professional associations, along with peer reviewed manuscripts, and applicable university policies, documents and websites. Several associations present information specific to universities and ethical guidance applicable to all body donations. Although these are not accrediting agencies, the Panel believes that the practices outlined therein provided more appropriate guidelines for university-based anatomical gift programs. Recommendations included in this report are based on this guidance and best practices and, if implemented, will provide the AGP a means for improved oversight, governance, tracking, security, and transparency.