College of American Pathologists

Comments to the
Office of Public Health and Science
U.S Department of Health and Human Services
on the
Advanced Notice of Proposed Rulemaking (ANPRM) entitled

October 26, 2011

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October 26, 2011

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Director, Office for Human Research Protections (OHRP)
Office of Public Health and Science, Office of the Secretary
U.S. Department of Health and Human Services
1101 Wooten Parkway
Suite 200
Rockville, MD 20852

Re: HHS-OHPS-2011-0005

Dear Dr. Menikoff:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the OHRP’s Advanced Notice of Proposed Rulemaking (ANPRM) entitled “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay and Ambiguity for Investigators.” Currently celebrating 50 years as the gold standard in laboratory accreditation, the CAP is a medical society serving more than 17,000 physician members and the global laboratory community. It is the world’s largest association composed exclusively of board-certified pathologists and is the worldwide leader in laboratory quality assurance. The College advocates accountable, high-quality, and cost-effective patient care. The CAP’s Laboratory Accreditation Program is responsible for accrediting more than 7,000 clinical laboratories worldwide. Our members have extensive expertise in providing and directing laboratory services and also serve as inspectors in the CMS-deemed CAP accreditation program. The CAP also provides laboratories with a wide variety of proficiency testing programs and has the responsibility to evaluate the accuracy of test performance and interpretation in more than 23,000 laboratories worldwide. The CAP is pilot testing a biorepository accreditation program. See http://www.cap.org/apps/docs/laboratory_accreditation/lap_info/biorepository_accreditation_program_checklist_sample.pdf

The CAP supports OHRP’s twin goals of enhancing human subject protections while streamlining the rules governing research. We hope that the CAP can serve as a resource to OHRP in its overhaul of the Common Rule, particularly as it relates to biospecimens used in research. The last decade has seen spectacular discoveries relating to genes and diseases, especially cancer. The material for the studies leading to these discoveries has been primarily paraffin blocks with embedded tissue—collected and maintained by pathologists. In addition to research, pathologists analyze biospecimens every day as part of patient care and routinely use biospecimens to conduct required laboratory QA/QC. The CAP membership therefore has significant expertise with the myriad uses of biospecimens and wants to ensure that any changes contemplated by OHRP would not impede continued use of biospecimens for these purposes.
SPECIFIC COMMENTS ON THE ANPRM

Consent and Biospecimens
The CAP fully supports the principle of informed consent for the use of biospecimens, as is reflected in our policy on the use of biospecimens (see Appendix.) At the same time, the CAP wants to ensure that the proposed biospecimen consent requirement will not have a negative impact on the ability of our members to fulfill their responsibilities as practicing pathologists. Our comments are for the purpose of educating OHRP about the roles that pathologists play with respect to specimens and some of the challenges they currently experience related to biospecimens. We also seek clarification regarding the intended scope of the proposed changes, and make recommendations to avoid an unintended negative impact on the conduct of activities that pathologists must undertake to ensure the availability of accurate, reliable, and innovative tests that benefit patient care.

As noted above, pathologists interact with specimens in many ways, but are primarily involved— in the laboratory setting—with the evaluation and diagnosis of blood, body fluids or tissue specimens. These evaluations usually have prognostic implications. Once these evaluations are completed, there are, in many instances, residual specimens remaining.

The pathologist is the laboratory’s custodian of these residual specimens. Some portion must be retained, for varying lengths of time, in compliance with federal and state laboratory practice laws. Residual specimens are also needed by clinical laboratories to conduct quality assurance-quality control (QA-QC) activities mandated by the federal Clinical Laboratory Improvement Amendments (CLIA) and implementing regulations, 42 C.F.R. Part 493, as well as by the CAP Laboratory Accreditation Program (LAP). For example, the CAP LAP requires that all new lots of regents be checked against previous lots before being placed into use. A residual patient sample is required to perform this check. Clinical laboratories run immunohistochemistry (IHC) controls daily for laboratory blood and tissue assays and instrument validation studies.

Third party accrediting organizations, such as CAP, also depend on the availability of residual specimens to administer “proficiency testing”—which is a CLIA-mandated means by which a clinical laboratory demonstrates its ability accurately to perform laboratory testing. Finally, residual specimens are integral to the development and validation of new assays developed in-house by clinical laboratories (so called laboratory developed tests or LDTs). The CDC, for example, has recognized the problem of insufficient materials for quality assurance test validation, proficiency testing, etc. (See http://www.cdc.gov/genomics/events/file/print/10year/42_GeT-RM_ab.pdf)

The CAP does not believe any of the above-described uses of biospecimens constitute “research” as that term is defined in the Common Rule. 45 C.F.R. 46.102. Specifically, these uses are not undertaken as part of a “systematic investigation . . .designed to develop or contribute to generalizable knowledge.” Rather, they are for the purpose of enabling clinical laboratories to provide quality testing as part of clinical care of patients. The CAP therefore requests that the Notice of Proposed Rulemaking specifically exempt these uses of biospecimens from the research definition and clarify that they are not subject to the Common Rule.

In addition to the above-described uses of specimens by clinical laboratories, pathologists receive requests from researchers, both within their own institution and from external sources, for access to residual samples for research. As the pathologist does not interact with the patients
from whom these tissue samples were derived, he or she has no ability to ensure that consent for future research uses was properly obtained at the time of collection. The CAP believes clarity is required on the specific entity or persons who should have the obligation to ensure that appropriate consent was obtained for the research use. Pathologists should have no liability should the researcher or front-line provider responsible for patient intake fail to ensure that adequate consent was obtained prior to initiating a research study.

ANSWERS TO SPECIFIC QUESTIONS

Consent and Biospecimens
Question 23: Under what circumstances should it be permissible to waive consent for research involving the collection and study of existing data and biospecimens...? Should the rules for waiving consent be different if the information or biospecimens were originally collected for research purposes or non-research purposes?

Please see above discussion re: QA/QC uses. The CAP believes that any activities with biospecimens for purposes of CLIA or other regulatory compliance should be excluded from the definition of research and that consent for such uses should therefore not be required.

Question 47: Should there be a change to the current practice of allowing research on biospecimens that have been collected outside of a research study (i.e. “left-over” tissue following surgery) without consent, as long as the subject’s identity is never disclosed to the investigator?

CAP policies on informed consent state that such potential future uses of specimens should be clearly covered by the text of the informed consent document. These uses should be part of the general surgical consent or general facility consent for treatment.

Question 48: What, if any, are the circumstances in which it would be appropriate to waive the requirement to obtain consent for additional analysis of biospecimens?

While we are not offering specific answers to this question (except for identifying biospecimen-related activities that should not be considered research in the first instance), we want to underscore the importance of continued access to biospecimens by pathologists for both research and non-research uses, as well as the pathologist’s inability to ensure that consent has been properly obtained. While the pathologist by default becomes the “custodian” for such specimens, the pathologist cannot control the consent process as he or she generally does not typically interview the patient prior to specimen collection or surgical procedure that would result in a tissue or body fluid specimen. Instead, the pathologist must rely on the entity collecting the specimen in the first instance – whether that is the treating physician or the sponsor of the initial study in which a specimen was collected – to ensure that consent was properly obtained. The pathologist would in the vast majority of instances be unable to go back to the contributor of the specimen and get the necessary consent. The CAP is therefore concerned about the implications of the consent requirement on the pathologist if the upstream entity did not get proper consent.

OHRP should clarify on whom the burden falls with respect to obtaining consent for research uses when such consent would be required by the proposed policies. CAP believes that the responsibility to ensure consent (or seek waiver from an IRB) rests with the researcher, and the pathologist should not be held to have breached the regulations for mere provision of a
specimen that may turn out to have been obtained without proper consent. From an operational perspective, tracking of patient consent or opt in/out processes for use of patient data and samples is generally handled at the level of EHR systems, not in laboratory information systems (LIS’s). Pathologists often do not have access to the EHR, only to the interface to input information into the EHR.

Question 49: Is it desirable to implement the use of a standardized, general consent form to permit future research on biospecimens and data? Are there other options that should be considered, such as a public education campaign combined with a notification and opt-out process?

The CAP would support the use of a standardized, general consent form, as it will increase the likelihood that the institutions and health care providers that collect specimens in the first instance obtain consent for their future research use. Furthermore, it is essential that the new consent forms be short enough to include on the surgical consent form (a practice not currently allowed by many IRBs); otherwise proper consent for the research use of residual specimens derived from surgical procedures will be extremely difficult to obtain.

Under the ANPRM, biospecimens collected before the implementation date would be grandfathered, but institutions would need to implement a standardized general consent for use of tissue for research. While some cancer centers have implemented such measures, many hospitals have not wanted to put scarce resources into doing so. We would urge OHRP to mount an educational campaign on the importance of such a universal consent.

Question 50: What is the best method for providing individuals with a meaningful opportunity to choose not to consent to certain types of future research that might pose particular concerns for substantial numbers of research subjects beyond those presented by the usual research involving biospecimens? How should the consent categories that might be contained in the standardized consent form be defined (e.g. an option to say yes-or-no to future research in general, as well as a more specific option to say yes-or-no to certain specified types of research)? Should individuals have the option of identifying their own categories of research that they would either permit or disallow?

As noted above, pathologists generally do not have contact with the patients who provide their biospecimens and therefore we would defer on the optimal methods of providing consent to those who regularly interface with patients. However, the CAP policy on the “Informed Consent for Donation of Biospecimens” states that that the informed consent process should always include the ten items below.

1. The specific biospecimen(s) to be donated, or a general reference to the biospecimens from an identified procedure;
2. The uses that might be made of the donated biospecimen, including the primary (intended) use, possible secondary uses, and any limitations on use;
3. Any substantial risks to the donor associated with the donation;
4. The fact that a potential donor who does not give consent will not suffer adverse consequences;
5. The fact that neither the donor nor the donor’s family will have any claim to the results of research or to products which may result from use of the biospecimen, or a statement of the rights that the donor or family will have in the results of any research or in any resulting products;
6. The fact that the pathologist and/or laboratory may be compensated for the costs of procuring, storing, processing, and distributing the biospecimen (if such is in fact the case);
7. The policy on disclosure to the patient or family of any information that is learned from review of the biospecimen;
8. The policy on protecting the privacy interests of the patient;
9. The manner and duration of storage, including, where applicable, a statement to the effect that the biospecimen may be retained indefinitely as part of a biorepository; and
10. Possible methods of disposition of the biospecimen (including incineration).

The CAP policy, which was written in the context of the existing Common Rule requirements, also states that informed consent documents reference all additional possible foreseeable uses for the biospecimens including research. Additionally, it stipulated that “disclosure should be made in a manner that is understandable to a reasonable lay person” and “in the case of a biospecimen donation specifically made for research purposes,” that the informed consent document should “cover the following topics: the intended procedures and uses of the biospecimens in the context of the protocol; and the policy governing handling of the discovery of unanticipated clinical information about the donor secondary to the processing of material for the protocol. Further, if the biospecimen is donated for use by a specific researcher or at a specific institution, the consent form should address ownership of the biospecimen.” Lastly, the policy states that any tissue that may end up being “excess” and used for research purposes should be embargoed and “remain available to be returned for additional diagnostic evaluation if necessary. If any excised tissue may be used for research after a diagnosis is reached, the pathologists should make sure that the informed consent form grants permission for this use.” Given that the policy assumes the current regulatory regime, it may need to be revisited when OHRP finalizes any changes to the Common Rule with respect to biospecimens.

Question 52: Should the new consent rules be applied only prospectively, that is, should previously existing biospecimens and data sets be “grandfathered” under the prior regulatory requirements? If so, what are the operational issues with doing so?

HHS should clarify that the requirement for consent would apply only prospectively – for biospecimens collected after implementation of a final rule. Thousands of biospecimens have been gathered under current rules, and there is no practical way to ascertain their consent status or re-consent the donors of such specimens, which were generally gathered according to institutional policies and in many cases were part of research currently subject to IRB approval. If requirements for informed consent were retrospective for biospecimens, important pathology research related to the molecular underpinnings of cancer as well as many other important disease states would be in jeopardy.

From a practical standpoint, pathologists do not generally have direct access to patients and thus are hindered from obtaining direct informed patient consent. Such direct patient contact by pathologists would entail the pathologist contacting patients retrospectively after their procedures, and often a great many years after to allow for long-term follow-up. Long-term follow-up is of course a highly desirable aspect of many clinical and translational research studies. It would also be impossible to obtain informed consent for patients who have died or from patients with inaccurate contact information due to relocation. From a scientific standpoint, such exclusions would introduce untenable bias into study designs.
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Question 53: In cases in which consent for future research use is not obtained at the time of collection, should there be a presumption that obtaining consent for the secondary analysis of existing biospecimens or identifiable data would be deemed impracticable, such that consent could be waived, when more than a specified threshold number of individuals are involved?.... If so, what threshold number should constitute impracticability? Is the number of potential human subjects the only measure of impracticability?

We do not propose a specific number but note that the option for consent waiver through an IRB should be retained for both retrospectively (pre-rule changes) and prospectively (post-rule changes) collected samples.

Deidentification

Question 56: DNA extracted from de-identified biospecimens can be sequenced and analyzed in other ways, with the results sometimes being linked to other available data that may allow a researcher to identify the persons whose specimens were being studied. How should Federal regulations manage the risks associated with the possibility of identification of such biospecimens? Should a human biospecimen be considered identifiable in and of itself? What are the advantages and disadvantages of considering all future research with biospecimens to be research with identifiable information?

Genomic data is potentially identifiable information. On the other hand, histochemical, immunohistochemical, ultrastructural and directed molecular testing (i.e. FISH, RT-PCR for limited set of markers) will not lead to identification of individual patients.

Question 57: Should some types of genomic data be considered identifiable and, if so, which types (e.g., genome-wide SNP analyses or whole genome sequences)?

The notion that any specimen can be identified by DNA analysis is technically true, but at this time would demand some specific effort and access to an appropriate database of such information (unless one was dealing some rare genetic abnormality affecting a very limited population). While it may be difficult to do this now as researchers generally do not have access to the deidentification key that links specific genetic material to a person’s identity/name, it is probably going to be fairly easy in ten years when these databases will likely exist. When they do become reality they will likely become part of one’s medical record and subject to HIPAA so placing the same security on any research applications of specimens would be appropriate.

Question 58: Should the new data security and information protection standards apply not just prospectively to data and biospecimens that are collected after the implementation of new rules, but instead to all data and biospecimens? Would the administrative burden of applying the rule to all data and biospecimens be substantially greater than applying it only prospectively to newly collected information and biospecimens? How should the new standards be enforced?

As physicians, the vast majority of pathologists has already been subject to the HIPAA Privacy and Security Rules since their inception and is thus already used to the existing HIPAA rules. CAP’s established policy on the Custodianship of Human Biospecimens and Their Derived Products,“ recognizes the importance of HIPAA compliance, stating that: “The responsibility to maintain diagnostic material also includes providing appropriate material for institutionally approved research when the patient has given informed consent to allow their biospecimens for research and the requirements of applicable privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA) are complied with....” However, in the absence of more clarity it is hard to assess the burden, either retrospectively or prospectively, but in general CAP favors a prospective approach to implementation of new regulatory requirements
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CONCLUSION

The CAP appreciates the opportunity to comment on this ANPRM and looks forward to working with OHRP as it to develop appropriate requirements for the research use of biospecimens. Should you have any questions on our comments, please contact Julie Cantor-Weinberg, Director, Public Health & Scientific Affairs (202) 354-7136/jweinbe@cap.org.
APPENDIX

I. CAP Policy on the Informed Consent for Donation of Biospecimens

Policy Synopsis
The College of American Pathologists supports donation of biospecimens for research, education, and transplantation. Donations of biospecimens for these purposes can advance medical knowledge, improve the quality of health care, and save lives. At the same time, respect for the rights of the donor requires that informed consent be obtained. The specific disclosures that must be made in order to ensure that consent is informed will depend on a variety of factors, including the context in which the donation is made, the use to which the biospecimen will be put, and the requirements of applicable law.

Policy
The College of American Pathologists supports donation of organs, tissues, cells and fluids ("biospecimens") for use in research, education, and transplantation. Donations of biospecimens for these purposes can advance medical knowledge, improve the quality of health care, and save lives. However, the College also believes that respect for the rights of the donor requires that informed consent be obtained before a biospecimen is donated. The specific elements that should be covered in the informed consent process will depend on the context in which the donation is made, the use to which the biospecimen is put, and applicable state law.

The need to obtain informed consent for the donation/use of biospecimens will arise in any of four different contexts:

1. Incident to a procedure specifically conducted for the purpose of recovering an organ or tissue from a living or deceased donor for transplantation;
2. Incident to a procedure specifically to obtain tissue for research, usually as part of a pre-approved protocol;
3. Incident to a diagnostic or therapeutic procedure performed for the benefit of the patient;
4. At autopsy, whether performed by consent of the family or by requirement of the state.

Certain disclosures should be made in all of these contexts. Additional considerations may apply depending on the specific context.

A. Basic Disclosures

Regardless of the context, the College believes that the informed consent process should, at a minimum, always include a description of the following:

1. The specific biospecimen(s) to be donated, or a general reference to the biospecimens from an identified procedure;
2. The uses that might be made of the donated biospecimen, including the primary (intended) use, possible secondary uses, and any limitations on use;
3. Any substantial risks to the donor associated with the donation;
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4. The fact that a potential donor who does not give consent will not suffer adverse consequences;

5. The fact that neither the donor nor the donor’s family will have any claim to the results of research or to products which may result from use of the biospecimen, or a statement of the rights that the donor or family will have in the results of any research or in any resulting products;

6. The fact that the pathologist and/or laboratory may be compensated for the costs of procuring, storing, processing, and distributing the biospecimen (if such is in fact the case);

7. The policy on disclosure to the patient or family of any information that is learned from review of the biospecimen;

8. The policy on protecting the privacy interests of the patient;

9. The manner and duration of storage, including, where applicable, a statement to the effect that the biospecimen may be retained indefinitely as part of a biorepository; and

10. Possible methods of disposition of the biospecimen (including incineration).

In addition, the informed consent process should cover any requirements imposed by governing law, the institution at which the donation is being made, or an applicable Institutional Review Board.

With respect to the second of these points, it should be noted that biospecimen material in excess of that needed for the initial intended purpose of the procurement, or deemed inappropriate for the initial intended purpose of the procurement, may be useful for other purposes such as research or teaching. For this reason, the College recommends reference in the documents to these possible additional uses. This reference need not be in tiered form, but all foreseeable possible uses should be mentioned.

With respect to the fifth point, a decision must be made regarding whether the donor will share in any commercial benefit associated with the donated biospecimen. Depending on what that decision is, appropriate disclosure should be made.

With respect to the sixth point, the College holds that the procurement and distribution of biospecimens for any use beyond the diagnostic evaluation should not be motivated by financial gain. Moreover, no pathologist should profit from the sale or transfer of biospecimens for which the pathologist has diagnostic responsibility. However, it is appropriate for the pathologist and/or laboratory to recoup the costs associated with the procurement, storage, processing, and distribution of biospecimens. If the pathologist intends to recoup such costs, that point should be included in the informed consent process.

Disclosure should be made in a manner that is understandable to a reasonable lay person. If practical, the donor (or guardian or next-of-kin) should be given a fair opportunity to ask questions. Consideration should be given to any cultural or religious concerns as needed. Consent should be given in a written document signed by the donor (or guardian or next-of-kin). The document should include a section in which any specific considerations raised by the donor may be expressed.

B. Additional Considerations In Specific Contexts
1. Incident To A Procedure Specifically Conducted For The Purpose Of Obtaining A Biospecimen For Transplantation

In this setting, permission is obtained for recovery of a biospecimen from a living or deceased patient for transplantation into a living recipient. In the majority of cases, the biospecimen in question will be suitable for transplantation. However, on occasion, the biospecimen may be found to be abnormal and may require a further diagnostic evaluation. On other occasions, it may be found to be unsuitable for transplantation. In these situations, the biospecimen none the less may be appropriate for future research.

In addition to the basic disclosures discussed in Part A above, the disclosures relating to consent for donation of a biospecimen for transplantation should cover the following topics:

1. Grant of access to the donor’s medical records by members of the clinical and administrative team for purposes of determining the suitability of the biospecimen for transplantation;
2. Permission to perform diagnostic testing associated with the transplantation process (e.g. histology, HIV testing, etc);
3. Discussion of whether and how the results of any diagnostic testing might be made available to the donor or the survivors of the donor;
4. Explanation of the rules governing release of information about the donor to the recipient, and release of information about the recipient to the survivors of the donor; and
5. A statement of policy on maintaining the confidentiality of information about the donor obtained in connection with the donation process.

The College is aware that, under presumed consent laws in some states, the pathologist is permitted, as a matter of state law, to procure certain organs for possible use in transplantation as long as the pathologist is not aware of any objections. While recognizing the importance of increasing the number of tissue and organ donations, the College believes that such an increase should not come at the expense of the informed consent of the donor or donor’s family.

Moreover, the College recognizes that, in some instances, pathologists have been found subject to liability under federal law for taking organs or tissues from a decedent without actual consent, even when they have acted pursuant to a presumed consent statute.

The College supports the rights of individuals to give informed consent to the donation of biospecimens for transplantation purposes when the donation is unlikely to cause health problems for the donor. The College also supports the rights of an individual to give informed consent during that individual’s lifetime to the donation of biospecimens for transplantation purposes upon death. For these reasons, the College supports state legislation which offers various mechanisms by which persons can consent during their lifetime to donation of biospecimens at their death. These mechanisms include driver’s license check-offs, advanced directives, and living wills. The College also supports legislation permitting health care powers of attorney that survive the death of the person giving the power of attorney. The College believes
that any pathologist who relies in good faith on any such instrument should be immunized from liability in connection with the recovery of biospecimens.

2. Incident To A Procedure Performed To Obtain A Biospecimen For Research, Usually As Part Of A Pre-Approved Protocol

In this setting, the patient is typically enrolled in a research protocol which requires acquisition of biospecimens for evaluation or banking as part of the protocol. The amount of biospecimen obtained may be in excess of that required for the protocol.

In addition to the basic disclosures discussed in Part A above, the consent form for donation of a biospecimen for research purposes should cover the following topics:

1. The intended procedures and uses of the biospecimens in the context of the protocol; and
2. The policy governing handling of the discovery of unanticipated clinical information about the donor secondary to the processing of material for the protocol.

Further, if the biospecimen is donated for use by a specific researcher or at a specific institution, the consent form should address ownership of the biospecimen. It should indicate what happens to the biospecimen if the principal investigator leaves the institution at which he or she is practicing. For example, is it the intent of the donor that the donated biospecimen stays with the researcher (regardless of where the researcher might move), or does it stay with the institution? There should be an indication of how the biospecimen will be handled if it stays with the institution.

3. Incident To A Diagnostic Or Therapeutic Procedure For The Benefit Of The Patient

Where a biospecimen is obtained incident to a diagnostic or therapeutic procedure performed for the benefit of the patient, consent to donation of excised tissue or other biospecimen will generally be covered in the consent form signed by the patient in advance of the procedure. The responsibility to obtain informed consent in this context will generally fall on the patient’s primary physician, the surgeon, or the institution at which the procedure is performed.

The CAP believes that achieving the diagnostic or therapeutic goal of the procedure is of primary importance. The pathologist, and only the pathologist, should determine how much tissue is needed for diagnostic purposes. Tissue that is not likely to be needed for diagnostic purposes but that may be used for research should, where possible, be held in “embargo” and remain available to be returned for additional diagnostic evaluation, if necessary. If any excised tissue might be used for research after a diagnosis is reached, the pathologist should make sure that the informed consent form grants permission for this use.

After completion of the diagnostic evaluation, tissue not embedded in paraffin blocks or made into glass slides should be handled in a manner described by the surgical permission form. The pathologist assumes a custodianship responsibility for the tissue blocks and slides for the period of retention of this material. Recognizing that paraffin embedded tissue may have future diagnostic value for the patient in the event that a pertinent diagnostic or prognostic test becomes available, the College believes that at least one block of diagnostic tissue should be preserved for the minimal retention time of paraffin blocks and should not be used for research,
education, quality control, or any other non-diagnostic activities. Relevant requirements of the CAP Laboratory Accreditation Program Checklist and similar document of applicable accreditation agencies must be complied with.

4. At Autopsy

Depending upon the circumstances of the autopsy, some tissue, often whole organs, may be obtained for further study or other purposes and may not be included with the body released to the funeral home. Other tissue, typically small biopsies ("stock jar") and paraffin blocks, will be retained for extended periods of time. The relevant considerations will be different depending on whether the autopsy is performed under signed consent by the family or conducted pursuant to statute or other legal authority.

4a. Autopsy Consented By Family

Where an autopsy is consented by the family, the consent form should cover any use of biospecimens that the pathologist might want to make. If the pathologist would like to retain and use tissue or organs for research, education, or other activities, the consent form should include a section on biospecimen donation.

The College believes that the next-of-kin should be allowed to restrict use of biospecimens except insofar as a restriction would run contrary to the wishes of the decedent expressed in writing while the decedent was alive. If retention or use of biospecimens is limited by the terms of the consent in a manner that the pathologist feels may significantly compromise the diagnostic evaluation, the pathologist should discuss this issue directly with the next of kin or the treating physician and should document that discussion and the implications of the requested restriction.

Procurement of tissue from a deceased patient for transplantation or as part of a research protocol or for a specific, pre-identified research protocol should not be performed under the scope of the autopsy permit. Rather, separate specific informed consents governing those contexts should be required.

A routine autopsy (including removal and examination of the thoracic, abdominal, and pelvic contents, the brain, eyes, and spinal cord) does not compromise the appearance of the body at a funeral. However, if there are diagnostic and/or other reasons to extend the dissection, such as altering the face or affecting the embalmability of the extremities, permission as deemed appropriate by the pathologist, should be obtained from the next of kin and noted in the autopsy permission form.

The consent form should address the ultimate disposition of any retained organ or tissue not returned with the body to the funeral home. The form should cover retention of organs and tissues by the pathologist’s institution (e.g., as part of a teaching collection), possible disposal by incineration, and return of the retained organs to the funeral home at a later time after the diagnostic evaluation has been completed, if requested in the consent form.

Autopsies of fetuses can raise special concern. They may evoke serious religious and emotional issues. Therefore, the pathologist should pay particular attention to state law which may implicate autopsies of fetuses and disposal of fetal material.
Where consent to biospecimen donation is obtained at autopsy, it is sometimes difficult to know whether consent has been obtained from the appropriate next-of-kin. It is possible, for example, that one child of the decedent may consent to autopsy and to donation of biospecimens but that another child is not in agreement. Or it may not be clear whether a particular individual has the authority to give consent. This uncertainty has the effect of discouraging pathologists from seeking donations of biospecimens at autopsy.

The College endorses legislation that immunizes pathologists from liability if informed consent to biospecimen donation has been obtained from one responsible next-of-kin. For example, where the decedent’s spouse has given consent, the pathologist should not be required to get permission from the children or from siblings. Where one child of the decedent has given informed consent to biospecimen donation, the pathologist should not be required to obtain consent from the other children of the decedent.

4b. Autopsy Required By Law
When an autopsy is required by law, no consent form governs the procedure. Therefore, retention of organs/tissues should be restricted to that needed for the diagnostic evaluation of the patient, and extra care is needed to assure that the family is informed of the need to retain these tissues. The pathologist should be mindful of any known religious views of the decedent which might be violated by retention of biospecimens. The Hmong religion, for example, strictly prohibits mutilation of the body. Although such religious views may sometimes have to be subordinated to state law for forensic purposes, the pathologist should be respectful of the religion of the decedent and try to do no more than what is required by law.

Any organs or tissues not needed for possible further diagnostic evaluation in the judgment of the pathologist should be returned with the body to the funeral home. If whole organs are to be retained for possible additional study, it is desirable that the family be informed of this retention. The retention should be documented in the autopsy report. The College endorses development by pathologists of local protocols indicating (a) how notification of the family should occur and (b) how retained organs and tissues are to be disposed of when no longer needed.

The College recommends that if, within 60 days of the autopsy date or the notification of the family of the tissue retention (according to local practices), whichever is later, the family has not contacted the autopsying facility requesting return of the retained biospecimens following evaluation, the pathologist should be allowed to determine the disposition and dispose of any retained tissue as he/she seems appropriate, in accordance with local laws and regulations.

The College advocates legislation which specifically immunizes the pathologist who acts in good faith and makes reasonable attempts to keep the family informed of his practices against liability of any form resulting from the retention of organs/tissue from the autopsy.

Conclusion
This policy is intended to promote the goal of obtaining biospecimens for research, education, and transplantation while at the same time honoring the fundamental ethical principle that a pathologist must “maintain a practice of compassion, human dignity, and respect toward patients, colleagues, and other health care professionals.” See CAP Principles of Ethical and Professional Conduct. (CAP Policy J), Principle 1.

Revision history

Revised August 1991
Reaffirmed August 1994
Revised August 1997
Reaffirmed August 2000
Revised August 2003
Revised May 2010