Law and Ethics … the Legacy of AFIP National Tissue Repository

IOM-BSP-10-3 Review of the Appropriate Use of AFIP’s Tissue Repository Following Its Transfer to the Joint Pathology Center

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Law and Ethics ...

“In civilized life, law floats in a sea of ethics. Each is indispensable to civilization. Without law, we should be at the mercy of the least scrupulous; without ethics, law could not exist.”

Chief Justice Earl Warren
Supreme Court of the United States
ARMED FORCES INSTITUTE OF PATHOLOGY (AFIP) NATIONAL TISSUE REPOSITORY CONTAINS @:

- 7.8 MILLION CASES - DATA STORED IN MULTIPLE DATABASES
- 31 MILLION PARAFFIN-EMBEDDED BLOCKS (FFPE)
- 52 MILLION GLASS MICROSCOPE SLIDES
- 500,000-700,000 WET TISSUE SAMPLES

THESE TISSUE REPOSITORY MATERIALS DATE FROM 1917 THROUGH 2011.
THE AFIP RECEIVED THESE BIOSPECIMENS WHEN MILITARY AND CIVILIAN PATHOLOGISTS WORLDWIDE SENT TISSUE SPECIMENS TO THE AFIP’s EXPERT PATHOLOGISTS SEEKING 2ND OPINION DIAGNOSTIC CONSULTATIONS FOR THEIR PATIENT’S MEDICAL THERAPEUTIC INTERESTS.

OVER THE YEARS THE AFIP DEVELOPED VARIOUS REGULATIONS, POLICIES AND FORMS WHICH Addressed THE RECEIPT AND ACCESSIONING OF ALL OF THIS MATERIALS AS WELL AS THE SUBSEQUENT USE OF THESE FFPE SPECIMENS IN PATHOLOGY RESEARCH AND EDUCATION.

THE AFIP’S POLICIES DEVELOPED AND CHANGED AS SOCIETY’S LEGAL AND ETHICAL STANDARDS DEVELOPED AND CHANGED.
Legal and Ethical Issues – National Tissue Repository

- FORMALIN-FIXED, PARAFFIN-EMBEDDED (FFPE) ARCHIVAL TISSUES AND ASSOCIATED DIAGNOSTIC RECORDS REPRESENT AN INVALUABLE SOURCE OF INFORMATION ON DISEASES

- OLDER BIOSPECIMEN ARCHIVES CONTAIN MANY UNIQUE FFPE TISSUE SPECIMENS, RELATED GLASS MICROSCOPE SLIDES, AND ASSOCIATED MEDICAL RECORDS.

- MOST WOULD BE IMPOSSIBLE TO REPLICATE TODAY DUE TO CHANGES IN MEDICAL PRACTICE AND TECHNOLOGY.
NO SINGLE REGULATORY OR BIOETHICAL STANDARD ADDRESSED RESEARCH WITH ARCHIVED FFPE TISSUE SPECIMENS AND ASSOCIATED MATERIALS.

THE CHALLENGE IN APPLYING REGULATORY AND ETHICAL STANDARDS TO RESEARCH ON ARCHIVED FFPE TISSUES IS NOT DUE TO THE TISSUE SPECIMENS BUT FROM THE PERSONALLY IDENTIFIABLE HEALTH INFORMATION ASSOCIATED WITH THE SPECIMENS

THE PRIMARY ETHICAL PRINCIPLES WERE FIRST ARTICULATED IN THE 1948 NUREMBERG CODE CONCERNING HUMAN SUBJECTS RESEARCH PROTECTION:
- VOLUNTARY AND INFORMED CONSENT
- A FAVORABLE BENEFIT TO RISK ASSESSMENT
- RIGHT TO WITHDRAW FROM RESEARCH
THE 1964 DECLARATION OF HELSINKI AUGMENTED THE NUREMBERG CODE AND ADDED TWO IMPORTANT CONCEPTS:

1. THE INTERESTS OF RESEARCH SUBJECTS SUPERSEDE THOSE OF SOCIETY

2. EVERY CLINICAL RESEARCH SUBJECT SHOULD RECEIVE THE BEST TREATMENT AVAILABLE.
THE NATIONAL RESEARCH ACT OF 1974 ESTABLISHED TWO MODERN PILLARS OF HUMAN SUBJECTS RESEARCH OVERSIGHT:

1. THE INSTITUTIONAL REVIEW BOARD (IRB) TO EVALUATE AND APPROVE MOST KINDS OF RESEARCH INVOLVING HUMAN SUBJECTS

2. THE NATIONAL COMMISSION FOR PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH - INFLUENTIAL IN ESTABLISHING AN ETHICAL FRAMEWORK FOR THE PROTECTION OF VULNERABLE POPULATIONS
IN 1978, THE NATIONAL COMMISSION ISSUED THE BELMONT REPORT THAT ARTICULATED THREE MAIN PRINCIPLES OF BIOETHICS UPON WHICH IRB REVIEW OF HUMAN SUBJECTS RESEARCH IS BASED.

1. **RESPECT FOR PERSONS** - THE TENANTS OF VOLUNTARY PARTICIPATION, INFORMED CONSENT, AND THE PROTECTION OF PRIVACY.

2. **BENEFICENCE** - THE TENANTS THAT:
   - STUDIES SHOULD BE DESIGNED TO MINIMIZE RISK
   - THE RISKS OF RESEARCH MUST BE JUSTIFIED BY THE POTENTIAL BENEFITS
   - CONFLICTS OF INTEREST ARE MANAGED EQUITABLY

3. **JUSTICE** - THE TENANTS OF PROTECTING VULNERABLE SUBJECTS AND POPULATIONS AND INSURING THAT THE PEOPLE LIKELY TO BENEFIT FROM RESEARCH WERE NOT SYSTEMATICALLY EXCLUDED.
## Historical Overview: The Belmont Report – April 18, 1979

### Ethical Principles and Guidelines for the Protection of Human Subjects of Research

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TODAY HUMAN SUBJECTS RESEARCH IN THE UNITED STATES IS PRIMARILY GOVERNED BY THREE FEDERAL REGULATIONS.

1. FEDERAL POLICY FOR THE PROTECTION OF HUMAN SUBJECTS

- DEPARTMENT OF DEFENSE: 32 CFR PART 219
2. FOOD AND DRUG ADMINISTRATION (FDA) DID NOT ADOPT THE COMMON RULE.


DEPARTMENT OF DEFENSE SPECIFIC LEGAL AND ETHICAL STANDARDS:

10 USC 980 (1984) - LIMITATION ON USE OF HUMANS AS EXPERIMENTAL SUBJECTS [DEPARTMENT OF DEFENSE].

§ 980. Limitation on use of humans as experimental subjects

(a) Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless—
(1) the informed consent of the subject is obtained in advance; or
(2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance. …

DOD DIRECTIVE 3216.02 (25 MAR 2002) – PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DOD-SUPPORTED RESEARCH.

It is the policy of the Department of Defense that:

4.1. Protection of Human Subjects in Research. The rights and welfare of human subjects in research supported or conducted by the DoD Components shall be protected. This protection encompasses basic respect for persons, beneficence, and justice in the selection of subjects.

4.2. Informed Consent. In general, . . . no DoD Component may conduct or use appropriated funds to support research involving a human being as an experimental subject without the prior informed consent of the subject.
Legal and Ethical Issues – National Tissue Repository

- **BIOREPOSITORIES AND IDENTIFIABILITY OF TISSUE**

- **PRIVACY ISSUES** ARISE WHEN THE PERSONALLY IDENTIFIABLE INFORMATION ASSOCIATED WITH THE FFPE TISSUE BIOSPECIMENS RENDER THE DONOR IDENTIFIABLE.

- FFPE TISSUES FROM BIOREPOSITORIES ARE MORE LIKELY TO HAVE BEEN COLLECTED FOR DIAGNOSTIC OR SURGICAL PURPOSES AND LACK A SPECIFIC CONSENT FOR RESEARCH OR SURGICAL CONSENT WAS OBTAINED WITH A VAGUE REFERENCE TO RESEARCH.

- IN THE CASE OF OLDER FFPE TISSUES, THERE MAY BE NO CONSENT AT ALL BECAUSE THE SPECIMEN WAS OBTAINED PRIOR TO THE CURRENT REGULATORY GUIDANCE.
IN 1999, THE NATIONAL BIOETHICS ADVISORY COMMISSION DEFINED FOUR CATEGORIES WHICH ADDRESS THE ISSUES CONCERNING PERSONALLY IDENTIFIABLE HEALTH INFORMATION ASSOCIATED WITH FFPE TISSUES.

1. **UNIDENTIFIED BIOSPECIMENS** - BIOSPECIMENS THAT LACK ASSOCIATED PERSONALLY IDENTIFIABLE INFORMATION THAT CAN BE RETRIEVED BY THE REPOSITORY.

2. **IDENTIFIED BIOSPECIMENS** - BIOSPECIMENS LINKED TO PERSONALLY IDENTIFIABLE INFORMATION IN SUCH A WAY THAT THE DONORS COULD BE IDENTIFIED BY NAME, PATIENT NUMBER, OR CLEAR FAMILY RELATIONSHIP BY THE REPOSITORY.

3. **UNLINKED BIOSPECIMENS** (MORE COMMONLY KNOWN AS **ANONYMIZED BIOSPECIMENS**) - BIOSPECIMENS THAT HAVE BEEN STRIPPED OF ANY PERSONALLY IDENTIFIABLE INFORMATION THAT WOULD ALLOW THEM TO BE TRACED BACK TO THE ORIGINAL DONORS.

4. **CODED BIOSPECIMENS** - BIOSPECIMENS THAT HAVE ALL PATIENT IDENTIFIERS REMOVED AND REPLACED BY A CODE PRIOR TO BEING PROVIDED TO THE RESEARCHERS.
INFORMED CONSENT

INFORMED CONSENT IN RESEARCH IS A PROCESS DESIGNED TO EDUCATE POTENTIAL HUMAN SUBJECTS AS TO THE NATURE OF A RESEARCH PROJECT: PROCEDURES, DURATION, BENEFITS, AND POTENTIAL RISKS, IN A LANGUAGE EASILY UNDERSTOOD.

IF THE RESEARCH INCLUDES GENETIC SEQUENCING, THE POTENTIAL RISKS TO THE DONOR SHOULD ALSO BE ADDRESSED.

THIS PROCESS ENABLES INDIVIDUALS TO MAKE AN INFORMED DECISION TO PARTICIPATE IN THE RESEARCH STUDY.
INFORMED CONSENT

AN AFFIRMATIVE DECISION BY THE RESEARCH SUBJECT IS DOCUMENTED BY AN IRB-APPROVED AND SIGNED INFORMED CONSENT DOCUMENT.

FFPE TISSUES OBTAINED FROM BIOREPOSITORIES WILL GENERALLY REQUIRE INFORMED CONSENT IF ACCOMPANYING PERSONALLY IDENTIFIABLE INFORMATION IS REQUESTED (IDENTIFIED BIOSPECIMENS).

A RESEARCHER MAY NEED THIS INFORMATION IN ORDER TO CONTACT THE DONORS FOR ADDITIONAL PERSONALLY IDENTIFIABLE INFORMATION AND/OR DESIRES ACCESS TO THEIR MEDICAL RECORDS AS PART OF A LONGITUDINAL STUDY.
INFORMED CONSENT IS GENERALLY NOT REQUIRED FOR UNIDENTIFIED, ANONYMIZED, OR CODED FFPE BIOSPECIMENS WHEN NO ADDITIONAL PERSONALLY IDENTIFIABLE INFORMATION IS, OR WILL BE, REQUESTED.

WHEN TISSUES ARE OBTAINED FROM BIOPSIES OR SURGICAL PROCEDURES, A GENERAL SURGICAL CONSENT FORM IS TYPICALLY OBTAINED INDICATING THAT THE BIOSPECIMENS MAY BE USED FOR RESEARCH.

THIS IS GENERALLY NOT REGARDED AS INFORMED CONSENT FOR RESEARCH IF ACCOMPANYING PERSONALLY IDENTIFIABLE INFORMATION IS REQUESTED.
INFORMED CONSENT IS TYPICALLY OBTAINED FOR A SPECIFIC RESEARCH STUDY.

HOWEVER, BIOREPOSITORIES GENERALLY OBTAIN BROADER INFORMED CONSENT SPECIFYING THAT THE DONATED TISSUE CAN BE USED FOR UNSPECIFIED FUTURE RESEARCH STUDIES.

THE INFORMED CONSENT DOCUMENT MUST ALSO CLEARLY COMMUNICATE THE DONOR’S OPTION TO WITHDRAW FROM THE STUDY.
THE COMMON RULE STATES THAT HUMAN SUBJECTS RESEARCH IS PRESUMED TO REQUIRE INFORMED CONSENT, BUT THAT THIS REQUIREMENT CAN BE WAIVED OR ALTERED, WITH IRB APPROVAL, IF ALL FOUR OF THE FOLLOWING CONDITIONS SET FORTH IN 45 CFR PART 46.116(D)/32 CFR PART 219.116(D) ARE MET:

1. THE RESEARCH INVOLVES NO MORE THAN MINIMAL RISK TO PARTICIPANTS
2. THE WAIVER OR ALTERATION OF CONSENT WILL NOT Adversely Affect THE RIGHTS AND WELFARE OF PARTICIPANTS
3. THE RESEARCH COULD NOT PRACTICABLY BE CARRIED OUT WITHOUT THE WAIVER OR ALTERATION, AND
4. WHENEVER APPROPRIATE, PARTICIPANTS WILL BE PROVIDED WITH ADDITIONAL PERTINENT INFORMATION AFTER PARTICIPATION.
CERTAIN RESEARCH SUBJECTS BELONG TO PROTECTED POPULATIONS AND ARE NOT ELIGIBLE FOR A WAIVER OF CONSENT AS SET FORTH IN 45 CFR PART 46.201;46.301;46.401/32 CFR PART 219.201;219.301;219.401.

THESE “PROTECTED” GROUPS INCLUDE:
- MINOR CHILDREN LESS THAN 18 YEARS OF AGE
- PRISONERS
- PREGNANT WOMEN
- FETUSES AND PRODUCTS OF LABOR AND DELIVERY
- PEOPLE WITH DIMINISHED CAPACITY TO GIVE CONSENT INCLUDING SOCIOLOocialLY VULNERABLE POPULATIONS
- MENTALLY OR PHYSICALLY CHALLENGED INDIVIDUALS.

WHEN CONDUCTING RESEARCH ON ARCHIVED SPECIMENS, IT IS CRITICAL TO CONSIDER THESE CATEGORIES.
THE COMMON RULE AND THE IRB

THE IRB IS ONLY CONCERNED WITH HUMAN SUBJECTS RESEARCH, AND PRIOR TO REVIEW OF A PROTOCOL THE IRB WILL DETERMINE:

1. IF THE RESEARCH INVOLVES HUMAN SUBJECTS, AND, IF IT DOES,
2. WHETHER THE RESEARCH IS EXEMPT FROM THE COMMON RULE.

THE IRB IS ONLY RESPONSIBLE FOR REVIEW OF RESEARCH PROTOCOLS IF QUESTION 1 IS ANSWERED IN THE AFFIRMATIVE AND QUESTION 2 IS ANSWERED IN THE NEGATIVE.
THE COMMON RULE AND THE IRB

IN ORDER TO MAKE THIS DECISION, THE MEANING OF SEVERAL KEY TERMS, AS DEFINED UNDER THE COMMON RULE, MUST BE UNDERSTOOD.

HUMAN SUBJECT AS A LIVING INDIVIDUAL FROM WHOM AN INVESTIGATOR CONDUCTING RESEARCH OBTAINS EITHER:

1. DATA THROUGH INTERVENTION OR INTERACTION WITH THE INDIVIDUAL, AND/OR
2. THE INDIVIDUAL’S PERSONALLY IDENTIFIABLE INFORMATION.

NOTE: THIS DIFFERS FROM THE CONCEPT OF PERSONAL INFORMATION AS DEFINED UNDER HIPAA.
THE COMMON RULE AND THE IRB

THE EXEMPTION MOST RELEVANT TO FFPE TISSUES IS THAT CONCERNING PUBLICLY AVAILABLE OR UNIDENTIFIED BIOSPECIMENS [45 CFR PART 46.101(B)(4)/32 CFR PART 219.101(B)(4): RESEARCH INVOLVING EXISTING DATA, DOCUMENTS, RECORDS, PATHOLOGICAL BIOSPECIMENS, OR DIAGNOSTIC BIOSPECIMENS, IF THESE SOURCES ARE PUBLICLY AVAILABLE OR IF THE INFORMATION IS RECORDED BY THE INVESTIGATOR IN SUCH AS MATTER THAT SUBJECTS CANNOT BE IDENTIFIED, DIRECTLY OR THROUGH IDENTIFIERS LINKED TO THE SUBJECTS.
THE HIPAA PRIVACY RULE

THE MOST CONFUSING REGULATION RELEVANT TO RESEARCH WITH FFPE TISSUE BIOSPECIMENS IS THE ISSUE OF PERSONALLY IDENTIFIABLE INFORMATION.

THE COMMON RULE PROVIDES A CONCEPTUAL DEFINITION WHILE THE HIPAA PRIVACY RULE PROVIDES A PRESCRIPTIVE DEFINITION OF PERSONALLY IDENTIFIABLE INFORMATION.

THE HIPAA PRIVACY RULE DOES NOT COVER BIOSPECIMENS THEMSELVES, BUT RATHER THE PERSONALLY IDENTIFIABLE INFORMATION LINKED TO THE BIOSPECIMENS.
THE HIPAA PRIVACY RULE

HIPAA PRIVACY RULE DEFINES *INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION* AS A SUBSET OF HEALTH INFORMATION, CREATED OR RECEIVED BY A COVERED ENTITY OR EMPLOYER AND RELATED TO PAST, PRESENT, OR FUTURE PHYSICAL OR MENTAL HEALTH OR CONDITION OF AN INDIVIDUAL; THE PROVISION OF HEALTH CARE TO AN INDIVIDUAL; OR THE PAST, PRESENT, OR FUTURE PAYMENT FOR PROVISION OF HEALTH, AND THAT IDENTIFIES THE INDIVIDUAL OR THERE IS A REASONABLE BASIS TO BELIEVE THE INFORMATION CAN BE USED TO IDENTIFY THE INDIVIDUAL.
THE HIPAA PRIVACY RULE

A FURTHER DELINEATION IS THE CONCEPT OF PROTECTED HEALTH INFORMATION (PHI), WHICH IS DEFINED AS INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION TRANSMITTED BY ELECTRONIC MEDIA, MAINTAINED IN ELECTRONIC MEDIA, OR TRANSMITTED OR MAINTAINED IN ANY OTHER FORM OR MEDIUM. PHI SPECIFICALLY EXCLUDES EDUCATIONAL RECORDS.

A COVERED ENTITY IS DEFINED AS A HEALTH PLAN, A HEALTH CARE CLEARINGHOUSE, OR HEALTH CARE PROVIDER WHO TRANSMITS HEALTH INFORMATION IN ELECTRONIC FORM IN CONNECTION WITH A TRANSACTION FOR WHICH THE DHHS HAS ADOPTED A STANDARD.
ACCORDING TO THE HIPAA PRIVACY RULE, DE-IDENTIFIED PHI IS HEALTH INFORMATION THAT DOES NOT IDENTIFY AN INDIVIDUAL AND FOR WHICH THERE IS NO REASONABLE BASIS TO BELIEVE THAT THE INFORMATION CAN BE USED TO IDENTIFY AN INDIVIDUAL.

UNDER HIPAA, PHI CAN BE DE-IDENTIFIED EITHER BY REMOVING 18 KEY IDENTIFIERS OR BY USING A METHOD FOR STATISTICAL VERIFICATION OF DE-IDENTIFICATION.
A COVERED ENTITY CAN USE OR DISCLOSE A DONOR’S PHI FOR RESEARCH BY OBTAINING A PRIVACY RULE AUTHORIZATION.

A PRIVACY RULE AUTHORIZATION IS AN INDIVIDUAL’S SIGNED PERMISSION THAT ALLOWS A COVERED ENTITY TO USE OR DISCLOSE THE DONOR’S PHI FOR THE PURPOSES, AND TO THE RECIPIENT OR RECIPIENTS, AS STATED IN THE AUTHORIZATION.

AN AUTHORIZATION DIFFERS FROM AN INFORMED CONSENT IN THAT THE AUTHORIZATION FOCUSES ON PRIVACY RISKS AND STATES HOW, WHY, AND TO WHOM THE PHI WILL BE USED AND/OR DISCLOSED FOR RESEARCH.
AN INFORMED CONSENT FORM PROVIDES RESEARCH SUBJECTS WITH A DESCRIPTION OF THE STUDY AND ITS ANTICIPATED RISKS AND BENEFITS, AND A DESCRIPTION OF HOW THE CONFIDENTIALITY OF RECORDS WILL BE PROTECTED.

A PRIVACY RULE AUTHORIZATION CAN BE COMBINED WITH AN INFORMED CONSENT DOCUMENT TO PARTICIPATE IN RESEARCH.

THE HIPAA PRIVACY RULE REQUIRES AUTHORIZATION FOR THE USE OR DISCLOSURE OF PHI.
AUTHORIZATION IS NOT REQUIRED IF THE BIOSPECIMEN HAS BEEN DE-IDENTIFIED OR IF ONE OF THE FOLLOWING FOUR CONDITIONS IS MET:

1. DOCUMENTATION THAT AN IRB OR EQUIVALENT PRIVACY BOARD HAS WAIVED THE AUTHORIZATION REQUIREMENT IN ACCORDANCE WITH THE CONDITIONS SPECIFIED IN THE COMMON RULE;

2. THE USE OF PHI IS SOLELY TO PREPARE A RESEARCH PROTOCOL OR FOR SIMILAR PURPOSES PREPARATORY TO RESEARCH, THAT THE RESEARCHER WILL NOT REMOVE ANY PHI FROM THE COVERED ENTITY, AND THAT ACCESS TO THE REQUESTED PHI IS REQUIRED FOR PREPARING OF THE RESEARCH PROTOCOL AS SPECIFIED IN THE COMMON RULE;

3. THE USE OR DISCLOSURE OF PHI IS SOLELY FOR RESEARCH ON DECEDEENTS, THAT THE REQUESTED PHI IS NECESSARY FOR THE RESEARCH, AND AT THE REQUEST OF THE COVERED ENTITY DOCUMENTATION OF DEATH OF THE INDIVIDUALS IN QUESTION IS PROVIDED AS SPECIFIED IN THE COMMON RULE;

4. A DATA USE AGREEMENT IS ENTERED INTO BY THE RESEARCHER AND THE COVERED ENTITY, PURSUANT TO WHICH THE COVERED ENTITY MAY DISCLOSE A LIMITED DATA SET TO THE RESEARCHER FOR RESEARCH PURPOSES AS SPECIFIED IN THE COMMON RULE.
ANOTHER POINT OF CONFLICT CENTERS ON THE DIFFERENCE BETWEEN INFORMED CONSENT AND AUTHORIZATION.

THE COMMON RULE IS INTERPRETED AS ALLOWING THE INFORMED CONSENT DOCUMENT TO SPECIFY THAT DONATED TISSUE MAY BE USED FOR RESEARCH NOT ANTICIPATED AT THE TIME OF COLLECTION.

IN CONTRAST, THE PRIVACY RULE REQUIRES THAT AN AUTHORIZATION BE TIED TO A SPECIFIC RESEARCH PROTOCOL AND DOES NOT AUTHORIZE FUTURE UNSPECIFIED USE OF THE REQUESTED PHI.
RESEARCH USING FFPE TISSUES FROM DECEASED PERSONS IS AN AREA OF CONFUSION.

THE COMMON RULE IS SILENT ON RESEARCH INVOLVING BIOSPECIMENS AND ASSOCIATED PERSONALLY IDENTIFIABLE INFORMATION OBTAINED FROM DECEASED INDIVIDUALS.

THE COMMON RULE DEFINITION OF HUMAN SUBJECTS AS “LIVING INDIVIDUALS” IS GENERALLY INTERPRETED TO MEAN THAT SUCH BIOSPECIMENS ARE NOT COVERED.
THE HIPAA PRIVACY RULE DOES SPECIFICALLY COVER DECEASED INDIVIDUALS AND REQUIRES THAT CERTAIN ASSURANCES BE OBTAINED FROM THE RESEARCHER IN REGARDS TO THE USE OR DISCLOSURE OF PHI FROM DECEASED INDIVIDUALS.

THESE ASSURANCES ARE:

1. THAT THE USE AND DISCLOSURE OF PHI IS SOLELY FOR RESEARCH
2. THAT THE PHI IS NECESSARY FOR THE RESEARCH, AND
3. THAT DOCUMENTATION OF DEATH OF THE INDIVIDUALS IN THE STUDY BE PROVIDED, IF REQUESTED BY THE COVERED ENTITY.
RETENTION POLICIES – LOW LONG AND HOW MUCH

THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA), 42 CFR 493.1105 (B) PROVIDES THAT LABORATORY FACILITIES RETAIN PATHOLOGY SPECIMEN BLOCKS FOR AT LEAST 2 YEARS FROM THE DATE OF EXAMINATION.

IN CONTRAST, THE COLLEGE OF AMERICAN PATHOLOGISTS (CAP) MANDATES THE RETENTION OF FFPE BLOCKS FOR A MINIMUM OR 10 YEARS.

SOME STATE REGULATIONS REQUIRE EVEN LONGER RETENTION TIMES.
THESE REGULATIONS ARE NOT INTENDED TO DISCOURAGE RESEARCH USING FFPE TISSUES, BUT RATHER TO ENSURE THAT PATIENT MATERIAL IS AVAILABLE TO CONFIRM DIAGNOSIS, APPLY FUTURE ANALYTICAL TESTS, SUPPORT PATIENT PARTICIPATION IN CLINICAL TRIALS REQUIRING ACCESS TO ORIGINAL CASE MATERIAL, AND FOR LEGAL PURPOSES.

NEVERTHELESS, THERE ARE NO SPECIFIC RECOMMENDATIONS ON HOW MUCH CASE MATERIAL SHOULD BE RETAINED.
KEY POINT - RETAIN SUFFICIENT FFPE TISSUE TO ALLOW A PATHOLOGIST TO CONFIRM OR ALTER THE ORIGINAL DIAGNOSIS, AND TO ANALYZE THE TISSUE FOR DIAGNOSTIC OR PROGNOSTIC MARKERS THAT MAY BECOME KNOWN IN THE FUTURE.

IF SEVERAL BLOCKS ARE AVAILABLE, IT IS CERTAINLY ADVISABLE TO SAVE ONE REPRESENTATIVE BLOCK IN PRISTINE CONDITION.

IF A SINGLE BLOCK IS AVAILABLE, RETAINING ONE-THIRD TO ONE-HALF OF THE BLOCK CONTAINING THE LESION IN QUESTION WOULD SEEM PRUDENT.
AN ADDITIONAL CONSIDERATION CONCERNS THE USE OF FFPE BLOCKS TO PREPARE TISSUE MICROARRAYS (TMA), FOR WHICH A CORE PUNCH IS TAKEN FROM THE BLOCK RATHER THAN A WHOLE SECTION.

IN THIS CASE, IT IS IMPORTANT NOT ONLY TO RETAIN A SUFFICIENT FRACTION OF THE LESION FOR FUTURE ANALYSIS, BUT ONE SHOULD ALSO BE CAREFUL THAT THE CORE PUNCH(ES) DOES NOT OBSCURE THE BOUNDARY OF THE LESION OR COMPROMISE THE PATHOLOGISTS’ ABILITY TO APPRECIATE THE RELATIONSHIP BETWEEN THE LESION AND THE ADJACENT TISSUE.
RETROACTIVE CONSENT – PRACTICAL??

A PRACTICAL SUGGESTION OF ATTEMPTING TO OBTAIN RETROACTIVE CONSENT FOR IDENTIFIED SPECIMENS THAT ARE GREATER THAN 10 YEARS OLD HAS BEEN PROPOSED IN THE LITERATURE.
PERHAPS THE BEST PERSPECTIVE FOR OLDER ARCHIVAL SPECIMENS IS SUMMARIZED IN A QUOTE FROM RICHARD ASHCROFT OF THE IMPERIAL COLLEGE OF MEDICINE, LONDON, UK WHICH ADDITIONALLY QUOTES WILLIAM STEMPSEY OF LOYOLA UNIVERSITY:

“IN AREAS OF MORAL COMPLEXITY AND CHANGE, WE GAIN NOTHING BY JUDGING OUR PAST ACTIONS WITH OUR NEW-FOUND WISDOM OF HINDSIGHT AND IN THE LIGHT OF OUR HARD-WON CONSENSUS. IN PARTICULAR, THE RE-USE OF EXISTING ARCHIVES GATHERED IN THE PAST IS ESSENTIAL, AND MUST BE MANAGED EFFECTIVELY, AS A MATTER OF RESPECT TO PAST PATIENTS AND MINIMIZING THE BURDEN ON CURRENT PATIENTS. BUT, AT THE SAME TIME, HAVING MADE OUR DECISION ABOUT THE ETHICAL STANDARDS WE NOW WISH TO APPLY TO PATHOLOGICAL RESEARCH, WE MUST STICK TO IT IN COLLECTING NEW SAMPLES AND CONSTRUCTING NEW ARCHIVES.”
OBTAINING INFORMED CONSENT FOR EXISTING DATA SETS IS CONSIDERED IMPRACTICAL UNDER THE FOLLOWING CONDITIONS:

1. THE SIZE OF THE POPULATION BEING RESEARCHED IS EXTREMELY LARGE
2. A LARGE PROPORTION OF INDIVIDUALS HAVE LIKELY RELOCATED OR DIED SINCE THE PERSONALLY IDENTIFIABLE INFORMATION WAS ORIGINALLY COLLECTED
3. OBTAINING INFORMED CONSENT IS LIKELY TO INTRODUCE BIAS INTO THE RESEARCH
4. OBTAINING INFORMED CONSENT IS LIKELY TO CREATE THREATS TO PRIVACY BY HAVING TO LINK OTHERWISE DE-IDENTIFIED DATA WITH NOMINAL IDENTIFIERS
5. THERE IS A RISK OF INFLICTING PSYCHOLOGICAL OR SOCIAL HARM BY CONTACTING INDIVIDUALS OR THEIR FAMILIES

6. IT WOULD BE DIFFICULT TO CONTACT INDIVIDUALS DIRECTLY IF THE RELATIONSHIP WITH THE RESEARCHER OR REPOSITORY NO LONGER EXISTS

7. IT WOULD BE DIFFICULT TO CONTACT THE INDIVIDUALS THROUGH PUBLIC MEANS, SUCH AS ADVERTISEMENTS OR NOTICES

8. IF IN ANY OF THE ABOVE CIRCUMSTANCES THE REQUIREMENT FOR ADDITIONAL FINANCIAL, MATERIAL, HUMAN, OR OTHER RESOURCES TO OBTAIN CONSENT WOULD IMPOSE AN UNDUE HARDSHIP ON THE RESEARCHER OR ORGANIZATION.
BIOREPOSITORIES SHOULD HAVE ESTABLISHED POLICIES FOR ACCESS TO FFPE TISSUES AND THEIR ASSOCIATED CLINICAL DATA THAT ARE CONSISTENT WITH FEDERAL REGULATIONS, ETHICAL PRINCIPLES, STATE REGULATIONS (WHERE APPLICABLE), AND THE NATURE OF THE INFORMED CONSENT (IF ANY) ASSOCIATED WITH THE FFPE TISSUES.

BIOREPOSITORIES MUST SET UP OR HAVE ACCESS TO AN IRB.

REPOSITORY RESEARCHERS WILL NEED TO FOLLOW INTERNAL REGULATIONS OR SIGN A “USAGE AGREEMENTS” THAT ESTABLISH PROVISIONS FOR PROTECTING PERSONALLY IDENTIFIABLE INFORMATION, AND FOR THE USE, DISPOSITION, AND SECURITY OF THE BIOSPECIMENS AND THEIR ASSOCIATED DATA.
THE USAGE AGREEMENT MAY ALSO SPECIFY TERMS FOR THE PUBLICATION OF STUDY RESULTS AND THE PROPRIETARY RIGHTS ASSOCIATED WITH THE BIOSPECIMEN. THE USAGE AGREEMENT MAY ALSO BE CALLED A MATERIAL TRANSFER AGREEMENT (MTA) OR A DATA USAGE AGREEMENT.

THE AFIP TISSUE REPOSITORY EXPERIENCE (1919-2011)

- 1862 - AFIP ESTABLISHED AS THE ARMY MUSEUM.

Circular No. 5.

Surgeon General's Office,
Washington, D. C., June 9, 1862.

It is intended to prepare for publication the Medical and Surgical History of the Rebellion.

The Medical portion of this work has been committed to Assistant Surgeon J. J. Woodward, United States Army, and the Surgical part to Brigade Surgeon John H. Brinton, United States Volunteers.

All medical officers are therefore requested to co-operate in this undertaking by forwarding to this Office such sanitary, topographical, medical and surgical reports, details of cases, essays, and results of investigations and inquiries as may be of value for this work, for which full credit will be given in the forthcoming volumes.

Authority has been given to both the above named gentlemen to issue, from time to time, such circulars as may be necessary to elicit the desired facts, and the medical officers are desired to comply with the requests which may thus be made of them.

It is scarcely necessary to remind the medical officers of the regular and volunteer services that through the means in question much may be done to advance the science which we all have so much at heart, and to establish landmarks which will serve to guide us in future.

It is therefore confidently expected that no one will neglect this opportunity of advancing the honor of the service, the cause of humanity, and his own reputation.

William A. Hammond,
Surgeon General, U. S. Army.
1881 – LETTER FROM SURGEON GENERAL BARNES TO SECRETARY OF WAR ROBERT T. LINCOLN, SON OF THE PRESIDENT:

THE ARMY MUSEUM AND LIBRARY CONTAINED 51,500 VOLUMES AND 57,000 PAMPHLETS, WHILE THE 22,000 SPECIMENS OF THE MUSEUM WERE “UNIQUE IN THE COMPLETENESS WITH WHICH BOTH MILITARY SURGERY AND THE DISEASES OF ARMIES ARE ILLUSTRATED.” THE COLLECTIONS “ALTHOUGH ORIGINALLY FOUNDED CHIEFLY FOR PURPOSES OF MILITARY MEDICINE, HAVE PROVED TO HAVE MANIFOLD USES IN CONNECTION WITH THE GENERAL PROGRESS OF MEDICAL SCIENCE IN THE UNITED STATES, ESPECIALLY IN RELATIONS TO THE PUBLIC HEALTH, USES WHICH ARE PERHAPS OF EQUAL IMPORTANCE TO THE NATION.”
SINCE 1862 THE AFIP HAS COLLECTED AND ANALYZED TISSUE FROM ACTIVE DUTY SERVICEMEMBERS AND VETERANS AS WELL AS THEIR FAMILY MEMBERS.

WHILE NOT SPECIFICALLY NOTED IN ANY TRADITIONAL REGULATORY GUIDANCE, THE DEPARTMENT OF DEFENSE AND THE DEPARTMENT OF VETERANS AFFAIRS CERTAINLY HAVE KEEN INTEREST IN THE TISSUE AND ASSOCIATED MEDICAL RECORDS OF THE MILLIONS OF SERVICEMEMBERS WHOSE TISSUE HAS BEEN CONTRIBUTED TO THE AFIP NATIONAL TISSUE REPOSITORY.

INTERNAL DOD/MILITARY SERVICE POLICIES ADDRESS ACTIONABLE MEDICAL INFORMATION.
Legal and Ethical Issues – National Tissue Repository

- **EARLY 20TH CENTURY** - AFIP WAS VERY ACTIVE IN BROADENING THE HORIZONS OF PATHOLOGY

- **6 APRIL 1917** - SERIES B ACCESSIONS SPECIMENS INCLUDE ALL TISSUE SAMPLES RECEIVED AFTER 6 APRIL 1917 AND THESE TISSUES FORM THE BASIS FOR THE NATIONAL TISSUE REPOSITORY TODAY.
Legal and Ethical Issues – National Tissue Repository

- WORLD WAR II – 1941 - 1945

Figure 77.—Schematic representation of the flow of pathological materials during World War II. A. Continental network, to and through Histopathologic Centers on the way to the Institute. B. Worldwide flow to and from the Medical Museum.
THE 1948 NUREMBERG CODE.
Legal and Ethical Issues – National Tissue Repository

- GENERAL ORDER NO. 32 (6 JUL 1949) – ARMY INSTITUTE OF PATHOLOGY BECOMES THE ARMED FORCES INSTITUTE OF PATHOLOGY.

### Table III

**Sources of Autopsy and Surgical Cases Accessioned by the Armed Forces Institute of Pathology during the Calendar Year 1949**

<table>
<thead>
<tr>
<th>Contributor</th>
<th>Autopsy</th>
<th>Surgical</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armed Forces</td>
<td>3,434</td>
<td>10,966</td>
<td>14,420</td>
</tr>
<tr>
<td>Veterans Administration</td>
<td>7,707</td>
<td>7,206</td>
<td>14,913</td>
</tr>
<tr>
<td>Civilian Physicians*</td>
<td>957</td>
<td>2,739</td>
<td>6,696</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>12,098</td>
<td>23,931</td>
<td>36,029</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Month</th>
<th>Armed Forces</th>
<th>Veterans</th>
<th>Other Sources**</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>726</td>
<td>1394</td>
<td>495</td>
<td>2605</td>
</tr>
<tr>
<td>February</td>
<td>1039</td>
<td>931</td>
<td>619</td>
<td>2589</td>
</tr>
<tr>
<td>March</td>
<td>1373</td>
<td>1122</td>
<td>659</td>
<td>3154</td>
</tr>
<tr>
<td>April</td>
<td>1459</td>
<td>818</td>
<td>587</td>
<td>2864</td>
</tr>
<tr>
<td>May</td>
<td>1303</td>
<td>1322</td>
<td>517</td>
<td>3202</td>
</tr>
<tr>
<td>June</td>
<td>1287</td>
<td>1179</td>
<td>505</td>
<td>2971</td>
</tr>
<tr>
<td>July</td>
<td>1052</td>
<td>1497</td>
<td>144</td>
<td>3043</td>
</tr>
<tr>
<td>August</td>
<td>1256</td>
<td>1469</td>
<td>646</td>
<td>3373</td>
</tr>
<tr>
<td>September</td>
<td>1677</td>
<td>1700</td>
<td>336</td>
<td>3713</td>
</tr>
<tr>
<td>October</td>
<td>1449</td>
<td>1395</td>
<td>502</td>
<td>3346</td>
</tr>
<tr>
<td>November</td>
<td>1217</td>
<td>1057</td>
<td>636</td>
<td>2910</td>
</tr>
<tr>
<td>December</td>
<td>600</td>
<td>1171</td>
<td>500</td>
<td>2271</td>
</tr>
</tbody>
</table>

- Totals 14,420 14,913 6,696 36,029
- Per cent of total 40 41 19 100

*Includes cases contributed by civilian physicians and a small number of cases from U. S. Public Health Service and other governmental agencies such as the Federal Bureau of Investigation.

**A total of 40,670 cases were received by the Armed Forces Institute of Pathology during 1949; 461 of these were either being processed for accessioning or were held pending arrival of additional information or material.

**Includes material from civilian physicians and a small number of cases from U. S. Public Health Service and from other governmental agencies such as the Federal Bureau of Investigation.
Legal and Ethical Issues – National Tissue Repository

- GENERAL ORDER NO. 32 (6 JUL 1949) – ARMY INSTITUTE OF PATHOLOGY BECOMES THE ARMED FORCES INSTITUTE OF PATHOLOGY.
- ARMY REGULATION 40-410 (15 FEB 1950) – ARMED FORCES INSTITUTE OF PATHOLOGY.
Legal and Ethical Issues – National Tissue Repository

- 1964 DECLARATION OF HELSINKI

- THE NATIONAL RESEARCH ACT OF 1974

- 10 USC 176 (1976) – ARMED FORCES INSTITUTE OF PATHOLOGY.

- 1978 – BELMONT REPORT ISSUED
Legal and Ethical Issues – National Tissue Repository

- ARMY REGULATION 40-31 (415 SEP 1980) - ARMED FORCES INSTITUTE OF PATHOLOGY AND ARMED FORCES HISTOPATHOLOGY CENTERS.

- 10 USC 980 (1984) - LIMITATION ON USE OF HUMANS AS EXPERIMENTAL SUBJECTS [DEPARTMENT OF DEFENSE].

- ARMY REGULATION 40-31 (4 JUN 1993) - ARMED FORCES INSTITUTE OF PATHOLOGY AND ARMED FORCES HISTOPATHOLOGY CENTERS.

- DOD DIRECTIVE 5154.24 (10 APR 1992) - ARMED FORCES INSTITUTE OF PATHOLOGY.

- DOD DIRECTIVE 5154.24 (28 APR 1996) - ARMED FORCES INSTITUTE OF PATHOLOGY.

- DOD DIRECTIVE 5154.24 (3 OCT 2001) - ARMED FORCES INSTITUTE OF PATHOLOGY.

- DOD INSTRUCTION 5154.30 (18 MAR 2003) - ARMED FORCES INSTITUTE OF PATHOLOGY OPERATIONS.
Legal and Ethical Issues – National Tissue Repository

Universities/Medical Schools/Hospitals:
- Johns Hopkins Hospital
- University of Maryland
- Georgetown University
- Harvard University
- Mayo Clinic
- Children’s National Medical Center
- Georgetown University
- Columbia University
- University of Pennsylvania
- University of Michigan
- University of Cincinnati
- University of Washington
- University of California, Lawrence Livermore
- Temple University
- University of Kansas
- Loyola University
- Carilion Medical Center

AFIP’s Alliances
Broadening outreach, AFIP is extending its knowledge to establishments all over the world to make the medical community stronger. Hospitals, universities, organizations, companies and government institutions benefit greatly from AFIP’s consultation, education and research. Recently, here’s who is profiting from AFIP’s range of services.

Organizations:
- Henry M. Jackson Foundation
- Charles Louis Davis DVM Foundation
- TRUE Research Foundation
- The Peace Corps Office of Inspector General
- American Red Cross

Government Institutions:
- U.S. Department of State
- Naval Health Research Center, Silver Spring
- National Aeronautics and Space Administration
- Uniformed Services University of the Health Sciences
- The National Capital Consortium
- National Marine Fisheries Service
- World Health Organization
- Center for Disease Control and Prevention
- National Zoological Park
- Department of Veterans Affairs
- Department of Defense Health Affairs
- National Institutes of Health

Industry:
- NanoViricides Inc.
- Calabrant Systems
- Bristol-Meyers Squibb
- Pharmaceutical Research Institute
- GlaxoSmithKline
- Novartis Pharmaceuticals
Unique Registries at AFIP
The Department of Environmental and Infectious Disease Sciences maintains war-related datacenter Registries of anatomic pathology material from former POWs dating back to 1945, Vietnam War/Agent Orange veterans, Kuwait/Persian Gulf War veterans. Three additional registries are related to the Global War on Terrorism—Leishmaniasis, a disease-specific registry to monitor leishmaniasis cases from Southwest Asia, the Afghanistan Service Registry for military personnel deployed there, and the Operation Iraqi Freedom Registry. All registries are being consolidated into the International Toxicology Data Center making over 19,000 reports instantly retrievable.

Other registries in the department are the Breast Explant Registry database to archive and study data on silicone breast explants and bioimplantable materials, the Depleted Uranium Registry to analyze and monitor uranium exposure within all the armed services, the International Tissue and Tumor Repository for Chronic Arseniasis Registry, the Registry on Military Medical Geology to study and characterize geological and environmental factors and their distribution on the development of health problems, Tissue Reaction to Drugs, and the Registry on Chemical Warfare Agents.

The registries collaborate with the NCI, DoD, national and international organizations including the VA, UNESCO, the US Geological Survey, the Navy Bureau for Medicine, and the Army Corps of Engineers Environmental Lab.
Legal and Ethical Issues – National Tissue Repository

- AFIP REGULATION 40-1 (1 MAY 2009) – RETENTION, LOAN, AND DISPOSITION OF ACCESSIONED CASE MATERIALS.
- AFIP REGULATION 40-1 (1 FEB 2007) – RETENTION, DISPOSITION AND MAINTENANCE OF ACCESSIONED CASE MATERIALS.
- [AFIP REGULATION 40-1 (17 JUN 2002) – RETENTION AND DISPOSITION OF ACCESSIONED CASE MATERIALS.]
AFIP Regulation 40-1

1 May 2009

* AFIP Regulation 40-1

HEADQUARTERS
ARMED FORCES INSTITUTE OF PATHOLOGY
WASHINGTON, DC 20306-6000

AFIP Regulation 40-1

1 May 2009

Medical Services
RETENTION, LOAN, AND DISPOSITION
OF ACCESSIONED CASE MATERIALS

1. PURPOSE. This regulation establishes the policies and procedures for determining the retention, loan, and disposition of microscopic glass slides, tissue blocks, formalin-fixed tissue specimens, and other associated case materials that are accessioned into the repository of the Armed Forces Institute of Pathology (AFIP). It also establishes the policies and procedures under which the various pathology departments can maintain case materials within their departments for research and educational purposes, and procedures for processing requests for loan and/or copies of archival materials maintained by the AFIP, from both AFIP/contractor professional staff and from personnel or organizations outside the Institute.

2. APPLICABILITY. This regulation applies to all personnel handling, processing, or using accessioned case materials, whether assigned or attached for duty to, receiving training from, or volunteering services at the AFIP, or employed by the American Registry of Pathology (ARP), or under contract to the AFIP or ARP. This regulation applies to the loan and/or release of archival materials maintained by the Department of Repository Services. AFIP Repository Services materials consist of accessioned case and Base Realignment and Closure (BRAC) files, to include patient demographic and diagnostic data in databases, glass slides, paraffin blocks, and preserved wet tissue specimens. It does not apply to the archival materials maintained by the Armed Forces Repository of Specimen Samples for the Identification of Remains (AFRSSIR) nor the National Museum of Health and Medicine.

3. REFERENCES.


*This regulation supersedes AFIP Regulation 40-1, Retention and Disposition of Accessioned Case Materials, dated 1 February 2007 and replaces AFIP Regulation 40-4, Requests for Copies and/or Loan of Archival Materials, dated 12 December 1997.
AFIP Regulation 40-1


4. Department of Defense Directive 6040.41, Medical Records Retention

5. Department of Defense Instruction, 5154.30, Armed Forces Institute of Pathology Operations

6. Army Regulation 40-3, Medical, Dental, and Veterinary Care.

7. Army Regulation 40-31, BUMEDINST 6510.2F and AFR 160-55, Armed Forces Institute of Pathology and Armed Forces Histopathology Centers.

8. Army Regulation 40-38, Clinical: Investigation Program.

9. Army Regulation 40-66, Medical Record Administration and Health Care Documentation.

10. AFIP Regulation 40-9, Case Accessioning, Processing, and Storage.

11. AFIP Pamphlet 40-24, Technical Instruction for the DOD Clinical Laboratory Improvement Program

12. AFIP Regulation 40-68, Quality Assurance Administration

13. AFIP Regulation 70-1, Research and Investigation Program.


RESPONSIBILITIES:

a. Accessioned cases and associated materials are the property of the AFIP, not the individual pathology departments, staff members, ARP, or consultants. All case materials received at the AFIP that are to be reviewed for any purpose by the various pathology departments or by individual pathologists or scientists are considered to have been received in furtherance of an official AFIP mission and will be accessioned. Exceptions to this policy can only be granted by the Director, AFIP.

b. All accessioned case material is ultimately maintained and accounted for by the Department of Repository Services. The department currently consists of the Case Materials Accountability...
No individual may remove any AFIP material, including but not limited to accessioned material, from the AFIP operational locations without the written permission of the Director, AFIP, or duly authorized designee. Written permission may be granted only for the purpose of presenting the accessioned material at an educational conference when the actual material is required, other pre-authorized purposes, or any purpose required by law or regulation. When such permission is granted, the accessioned material will be signed out of the Repository by the Requestor so it can be recorded in PIMS for tracking purposes and packaged for transport by Repository personnel or Educational Department personnel. The Requestor will be required to maintain the strict confidentiality of any PHI and sign the material back into the Repository when the purpose for which it was signed out has been completed so it can be recorded in PIMS. This requirement does not preclude the transportation of accessioned material between the operational locations of the AFIP. Any questions regarding removal of materials should be directed to the Associate Chair, Department of Repository Services.

7. LOAN OF CASE MATERIAL.

a. Requests for loan of case material will be evaluated and processed based on the type of request received as follows:

(1) Internal requests for copies and/or loan of material from AFIP/contractor staff members.

(2) Outside requests from other DOD or federal agencies.

(3) Requests for copies and/or loan of patient materials from other outside organizations accompanied by a HIPAA-compliant authorization from the patient or his/her legal representative to whom the material pertains, or a properly issued court order or subpoena. All subpoenas not accompanied by a written patient/legal representative’s authorization will be reviewed by the AFIP Legal Counsel.

(4) Requests received under the Freedom of Information Act (FOIA). All these requests will be immediately forwarded to the AFIP FOIA Officer upon receipt.

(5) Requests received from professional, non-federal individuals or organizations for loan, use, or copies of archival materials for research and/or educational purposes that are not accompanied by a patient authorization(s) and are generic in nature, usually requiring a data base search be performed. All requests not accompanied by a written patient/legal representative’s authorization will be reviewed by the AFIP Legal Counsel.

b. Department of Repository Services will process requests from the above categories of requesters in accordance with their internal standard operating procedures and this regulation as applicable.
8. REQUESTS FOR MATERIALS MAINTAINED BY THE AFIP REPOSITORY.

   a. Internal requests for a retrieval listing from the AFIP database can be submitted to the Pathology Data Division in writing, by phone, or in person.

      (1) Requestors can complete AFIP Form 103-R, Request for Diagnostic Retrieval (Appendix A), or Pathology Data Division personnel will complete the form based on information provided by the requestor. All requests must be approved by the Associate Chair, Department of Repository Services or Chief, Records Repository Division. If the requestor requires a printout of material from another department, he/she should also coordinate the request with that department chair and obtain his/her signature on the request form.

      (2) Retrievals can be provided in one of three formats depending on the needs of the requestor. They can contain statistics only; a complete listing of all cases to include AFIP accession number, patient demographic, contributor information, diagnoses, and pathologic material available; or a listing of anonymized patient information and diagnoses. Requests for a complete listing of cases to include patient identifying information must have been reviewed and approved by the Institute’s IRB.

      (3) The requestor must specify time periods to be searched; i.e., 1990 to present. Listings on cases accessioned to the AFIP prior to 1970 will contain more limited information than those accessioned after 1970. If a requestor desires a listing of cases accessioned both after and prior to 1970, two searches must be run and two listings will be provided.

      (4) Retrieval listings containing any PHI cannot be released outside the Institute without appropriate authorization as detailed in paragraph 8d.

   b. The Records Repository Division serves as the central point for the coordination of routine internal retrieval requests for material from both the Records and Materials Repositories. Requests from AFIP/ARP staff members for materials and files maintained by Repository Services will be processed as follows:

      (1) Material may only be requested and maintained in the various pathology departments in accordance with this regulation.

      (2) The requestors’ requesting PHI data for research and education purposes must have an authorized identification code. These codes are coordinated through the IRB and if necessary and the Institutional Animal Use Committee (IACUC). The IRB reviews all research requests pertaining to the use of human subjects while the IACUC reviews all requests pertaining to the use of animals and if approved assigns an identification code to the protocol. Requests will also be processed for legal and quality assurance purposes. These requests should be coordinated through The AFIP Legal Counsel or Office of Quality Assurance, as required.

      (3) Requestors must complete AFIP Form 46-R-E, Case Material Control System Request (Appendix B). Forms can be obtained from the Records Repository. Requestors must
AFIP Regulation 40-1

1 May 2009

Director, NMHM or designate; the AFIP Legal Counsel; and at least five other scientific members as nominated by the Director, DAP and appointed by the Director, AFIP. The Director, DAP, will serve as chair. Votes will be taken and recorded. A majority vote will indicate approval or disapproval.

(a) If the request is disapproved, the Chief, Division of Research Administration, will inform the applicable chair(s) and prepare a letter to the requestor for the signature of the Director, DAP, indicating the reason for disapproval.

(b) If a request is considered in the service category and is approved, the applicable department chair(s), Associate Chair, Department of Repository Services, and the requestor will be informed by the Chief, Division of Research Administration. A bill and agreement for the use of pathologic material will be developed in coordination through with AFIP Legal Counsel and forwarded to the requestor. Upon receipt of payment and the signed agreement, the Associate Chair, Department of Repository Services, will inform the applicable department chair(s) and ensure the funds are appropriately distributed based on the services provided. Material requested will be prepared by the department and forwarded to the Associate Chair, Department of Repository Services, for release. The Associate Chair, Department of Repository Services, will ensure all material is anonymized prior to release while keeping an internal accounting of the accession numbers from which the material was derived.

(c) If the request is determined to be a collaborative research effort, and is approved, the Chief, Division of Research Administration, will inform the applicable chair(s) and prepare a letter to the requestor informing him/her of the approval. A copy of the research proposal will be requested if not already received, as will a memorandum stating the requestor’s willingness to pay for services provided. An AFIP point of contact will be appointed by the department chair. Upon receipt of the protocol, it will be processed in accordance with the procedures as outlined in AFIP Regulation 70-1, Research and Investigation Program. However, no material that has been set aside as involved in potential or actual litigation may be released.

9. PRIVACY ACT GUIDELINES WHEN CONDUCTING RESEARCH USING MEDICAL RECORDS.

a. Medical information and associated materials are protected by the Privacy Act, 5 U.S.C. 552a. Qualified individuals may have access to medical information and associated materials covered by this Act for research and study when approved by the AFIP Research Committee and the AFIP IRB as applicable in accordance with AFIP Regulation 70-1.

b. Information abstracted from AFIP records will be treated as confidential, and the identities of the patients, photographs, or other identifying information will not be used in any publication or released without the consent of the patient or authorized legal representative.

c. All identifying information will be removed from abstracts or reproduced records to be used in studies conducted outside the AFIP except when there is a valid patient/legal
Legal and Ethical Issues – National Tissue Repository

- AFIP REGULATION 40-3 (21 JAN 2009) – AFIP SPECIAL HANDLING CASES.
- AFIP REGULATION 40-3 (1 FEB 2007) – AFIP SPECIAL HANDLING CASES.
- [AFIP REGULATION 40-3 (3 JAN 2006) – AFIP SPECIAL HANDLING CASES.]
- [AFIP REGULATION 40-3 (1998) – AFIP SPECIAL HANDLING CASES.]
Legal and Ethical Issues – National Tissue Repository

- [AFIP REGULATION 40-4 (1 MAR 1994) – REQUESTS FOR AND/OR LOAN OF REPOSITORY, RESEARCH AND EDUCATIONAL.]
Legal and Ethical Issues – National Tissue Repository

- AFIP REGULATION 40-8 (1 FEB 2009) – VETERANS AFFAIRS PATHOLOGY REVIEW PROGRAM.
- [AFIP REGULATION 40-8 (1 MAR 2007) – VETERANS AFFAIRS PATHOLOGY REVIEW PROGRAM.]
- [AFIP REGULATION 40-8 (1995) – VETERANS AFFAIRS PATHOLOGY REVIEW PROGRAM.]
Legal and Ethical Issues – National Tissue Repository

- AFIP REGULATION 40-9 (23 JAN 2009) – CASE RECEIPT, ACCESSIONING, PROCESSING, AND STORAGE.
- AFIP REGULATION 40-9 (15 MAR 2007) – CASE RECEIPT, ACCESSIONING, PROCESSING, AND STORAGE.
- [AFIP REGULATION 40-9 (21 SEP 2005) – CASE RECEIPT, ACCESSIONING, PROCESSING, AND STORAGE.]
HEADQUARTERS
ARMED FORCES INSTITUTE OF PATHOLOGY
WASHINGTON, DC 20306-6000

Medical Services
CASE RECEIPT, ACCESSIONING, PROCESSING, AND STORAGE

The purpose of this regulation is to establish the policies and procedures by which the AFIP accepts cases for accessioning into the AFIP Repository and to set forth the guidelines by which these cases are to be handled from the time of case receipt and accessioning, through pathology department and laboratory processing, to final case resolution and permanent storage.

CHAPTER 1 – APPLICABILITY, SCOPE, AND GENERAL POLICIES

Purpose and Scope
Applicability
References
General Policies
Responsibilities

CHAPTER 2 – CASE RECEIPT, ACCESSIONING, AND DELIVERY

Receipt of Cases
Case Acceptance
Preparing Cases for Accessioning
Accessioning of Cases
Case Updates
Deaccessioning of Cases
Case Pick-Up and Delivery Service

CHAPTER 3 – ACTIVE AND INACTIVE CASE PROCESSING

Acknowledgement of Cases
Departmental Case Processing
Interdepartmental Case Processing/Transferring Responsibility for a Case
Requesting Laboratory Tests and Acknowledging Laboratory Materials
Evaluation and Selection of Reference Laboratories
Grossing of Formalin-Fixed Specimens
Final/No-Final Reporting of Cases
Preparing the Case Folder and Associated Materials for Permanent File
Returning Inactive Case Materials to Permanent File

This regulation supersedes AFIP Regulation 40-9, dated 15 March 2007.
CHAPTER 4 – CIVILIAN CASE BILLING POLICIES AND PROCEDURES

Civilian Case Billing Policies 4-1
Billing Procedures 4-2

CHAPTER 5 – ADMINISTRATIVE QUALITY REVIEW AND CODING

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Performance of Administrative Quality Review 5-2
Coding of Diagnoses 5-3
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CHAPTER 6 – PERMANENT FILING AND STORAGE

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Filing and Storage of Pathology Materials 6-2
Filing and Storage of Pathology Case Files 6-3
Requesting Inactive Case Materials from the Repositories 6-4

APPENDICES

AFIP Form 274-R, Contributor Case/Material Processing Request A
AFIP Form 288-R, AFIP Request for Consultation B
DD Form 2870, Authorization for Disclosure of Medical or Dental Information C
AFIP Form 49, Acknowledgement of Military Health System Notice of Privacy D
Practices
AFIP Form 50-13-R, Board of Veterans Appeals Case E
AFIP Form 34A-R, Sequence Folder Cover F
Sample Letter Returning Deaccessioned Case to Contributor G
Institute Practice Guidelines H
AFIP Form 45, Intradepartmental Consultations I
AFIP Form 45, External Consultations J
AFIP Form 102-R, Incomplete Records Discrepancy Checklist K
CHAPTER 1
APPLICABILITY, SCOPE, AND GENERAL POLICIES

1-1. PURPOSE AND SCOPE.

a. This regulation establishes policies and procedures for the initial handling and processing of all case documentation and associated materials sent to the Armed Forces Institute of Pathology (AFIP) from contributors worldwide for the purposes of consultation, education and/or research and which are accessioned into the AFIP (Repository). It covers the time from initial receipt of cases from contributors to the time the cases are forwarded to the Repository for permanent storage.

b. This regulation is not meant to serve as a step-by-step guide for using the Pathology Information Management System (PIMS), the AFIP’s computerized case tracking system. This regulation also does not pertain to the use of accessioned case materials in research or educational projects after the case has been finalized in PIMS. For policies and procedures regarding the use of case material for research or education, reference AFIP Regulation 70-1.

c. Finally, this regulation does not pertain to the DoD DNA Repository, and the collections of the National Museum of Health and Medicine of the AFIP.

1-2. APPLICABILITY. This regulation applies to all AFIP personnel and associated staff working within the AFIP who handle accessioned case materials. This includes all active duty military personnel, American Registry of Pathology personnel, contractors, federal civilian personnel, and all fellows, students, visiting scientists, American Red Cross volunteers, and temporary hires.

1-3. REFERENCES.

a. AFIP Regulation 40-1, Retention and Disposition of Accessioned Case Materials.

b. AFIP Regulation 40-3, AFIP Special Handling Cases.

c. AFIP Regulation 40-4, Requests for Copies and/or Loan of Archival Materials.

d. AFIP Regulation 40-8, Veterans Affairs Pathology Review Program (VAPRP).

e. AFIP Regulation 40-14, Electronic Consultation Service.

f. AFIP Regulation 40-16, Health Information Privacy.


h. AFIP Regulation 40-68, Quality Assurance Administration.

i. AFIP Regulation 70-1, Research Protocol Submission Guidelines, Approval Processes, and Continuous Monitoring Requirements.
1-4. GENERAL POLICIES.

a. All material accessioned into the AFIP becomes the property of the United States Government. No one staff member has an exclusive right to or exclusive control of the material. Examination and/or access to these materials is a privilege which is controlled ultimately by the Director, AFIP, through publication of regulations and policy letters.

b. All pathologic case folders and associated pathologic materials must be maintained in the central repository unless in active use for either consultation or approved educational or research purposes. See AFIP Regulation 40-1, Retention and Disposition of Accessioned Case Materials, for guidance concerning the requirements for maintaining inactive case materials outside the central repository.

c. No individual may remove any AFIP material, including but not limited to accessioned material, from the AFIP operational locations without the written permission of the Director, AFIP, or duly authorized designee. Written permission may be granted only for the purpose of presenting the accessioned material at an educational conference when the actual material is required, other pre-authorized purposes, or any purpose required by law or regulation. When such permission is granted, the accessioned material will be signed out of the Repository by the Requestor so it can be recorded in PIMS for tracking purposes and packaged for transport by Repository personnel or Educational Department personnel. The Requestor will be required to maintain the strict confidentiality of any Protected Health Information and sign the material back into the Repository when the purpose for which it was signed out has been completed so it can be recorded in PIMS. This requirement does not preclude the transportation of accessioned material between the operational locations of the AFIP. Any questions regarding removal of materials should be directed to the Associate Chair, Repository Services.

d. To ensure strict accountability of accessioned case materials and in order to conform to the requirements of the Privacy Act and the Health Information Portability and Accountability Act (HIPAA), only the Information Release Office within the Records Repository Division, the AFIP Legal Counsel, and designated personnel within the Office of the Armed Forces Medical Examiner are authorized to release repository materials or copies of accessioned case files to organizations or personnel outside of the AFIP (except to the original contributor of the material). See AFIP Regulation 40-4, Requests for and/or Loan of Repository, Research, and Educational Materials, for further guidance regarding the release of accessioned case materials outside the AFIP, as well as procedures regarding submission of retrieval requests to the repositories for in-house research and educational purposes.

e. All cases for which a written or telephonic opinion is formally expressed for the purpose of diagnosis by anyone acting in their capacity as an AFIP staff member must be accessioned. Material sent to the AFIP for research and/or education, and which will be permanently stored within the AFIP, must also be accessioned.

1-5. RESPONSIBILITIES. All personnel handling accessioned case material within the AFIP are responsible for ensuring that the material is accurately accounted for and all movement tracked within the Pathology Information Management System (PIMS). Additional responsibilities of various sections and personnel are as follows:
2-2. CASE ACCEPTANCE.

a. The following types of cases are not accessioned at the AFIP:

(1) Non-federal cases known to be in litigation are not accepted. An exception to this policy may be granted only with the express written approval of the Director, AFIP.

(2) The AFIP accepts cases from civilian pathologists; and in certain circumstances, the AFIP will also accept consultation cases from clinicians, or from patients if those cases are submitted in coordination with a pathologist or other health care provider. In any case where a pathologist or a health care provider is not sending the pathology material to the AFIP as a consultation, i.e. the patient is sending the material to the AFIP and requesting a consultation without any involvement of a pathologist or other health care provider, then the AFIP will either decline to accept the case or request that the patient contact the original pathologist or another health care provider and have that pathologist or other health care provider request a consultation.

(3) Cases in which the submitted pathology material does not match the number on the submitted pathology report; quantity and types of material do not match the forwarding paperwork; or where there is a discrepancy in the patient’s name between the paperwork and materials, are not accepted. CMAD personnel will contact the contributor for clarification and will hold the case until the appropriate material is received.

(4) Cases that are sent in with only cytology material will not be accepted. Cytology cases submitted with surgical pathology material will be screened by the Director of Advanced Pathology. The Director will determine if the case will be accepted and processed.

(5) Pediatric autopsy cases from civilian contributors will not be accepted.

(6) Civilian cases will be returned to the contributor unopened for non-payment of delinquent invoices over 120 days. Triage personnel will check all packages received from civilian sources against the daily civilian suspension list and return those from contributors on the list to the applicable delivery service. The Business Office will ensure the suspension list is kept up-to-date.

c. Cases not accepted for accessioning by the AFIP that have been opened are appropriately repackaged and returned to the contributor by the CMAD, along with a letter explaining the reasons for returning the case.

b. All contributors are to be encouraged to use the AFIP Form 288-R, AFIP Request for Consultation (Appendix B), to submit cases to the AFIP. The use of this form assists in ensuring that all information required to quickly and efficiently accession a case is provided. Civilian cases will not be accessioned without a completed and signed AFIP Form 288-R. If a civilian case is received without a completed and signed AFIP Form 288-R, the contributor will be contacted by CMAD staff and the contributor will be notified of the requirement. Failure by the civilian contributor to send a completed and signed AFIP 288-R will result in the case being returned to the contributor. The AFIP pathology branch that the case would be accessioned to
Legal and Ethical Issues – National Tissue Repository

- AFIP REGULATION 40-16 (23 JAN 2009) – HEALTH INFORMATION PRIVACY.
- AFIP REGULATION 40-16 (1 JUL 2005) – HEALTH INFORMATION PRIVACY.
- [AFIP REGULATION 40-16 (16 MAY 2005) – HEALTH INFORMATION PRIVACY.]
Legal and Ethical Issues – National Tissue Repository

Legal and Ethical Issues – National Tissue Repository

- AFIP REGULATION 70-1 (CH 2, 6 FEB 2006) – RESEARCH AND INVESTIGATION PROGRAM.
- AFIP REGULATION 70-1 (CH 1, 20 JAN 2006) – RESEARCH AND INVESTIGATION PROGRAM.
- AFIP REGULATION 70-1 (7 JUN 2005) – RESEARCH PROGRAM.
- [AFIP REGULATION 70-1 (FEB 1994) – RESEARCH AND INVESTIGATION PROGRAM.]
Legal and Ethical Issues – National Tissue Repository

- AFIP MANUAL 40-2 (2010) – INVESTIGATOR’S HANDBOOK.
- [AFIP MANUAL 40-2 (JAN 1992) – LABORATORY ANIMAL CARE AND USE MANUAL.]
Legal and Ethical Issues – National Tissue Repository

- AFIP MANUAL 40-40 (1 NOV 2010) – ARMED FORCES INSTITUTE OF PATHOLOGY CONTRIBUTORS’ MANUAL.
- AFIP MANUAL 40-40 (21 JAN 2009) – ARMED FORCES INSTITUTE OF PATHOLOGY CONTRIBUTORS’ MANUAL.
- AFIP MANUAL 40-40 (2 APR 2007) – ARMED FORCES INSTITUTE OF PATHOLOGY CONTRIBUTORS’ MANUAL.
- AFIP MANUAL 40-40 (1 JUL 2004) – ARMED FORCES INSTITUTE OF PATHOLOGY CONTRIBUTORS’ MANUAL.
- AFIP MANUAL 40-40 (15 OCT 2001) – ARMED FORCES INSTITUTE OF PATHOLOGY CONTRIBUTORS’ MANUAL.
- [AFIP MANUAL 40-40 (25 SEP 1995) – ARMED FORCES INSTITUTE OF PATHOLOGY CONTRIBUTORS’ MANUAL.]
The purpose of this manual is to assist our contributors in submitting cases to the Armed Forces Institute of Pathology (AFIP). Following these guidelines will ensure expeditious processing of cases and timely rendering of consultation reports. This manual also describes the AFIP's policy for retention of pathologic materials.

### Chapter 1: Introduction to the AFIP and its Missions

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### Chapter 2: Who Can Submit Cases to the AFIP

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<td>Department of Veterans Affairs</td>
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<td>Other Federal Goverment Agencies</td>
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### Chapter 3: Case Submission Requirements and Response Time

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*This manual supersedes AFIP Manual 40-40, dated 2 April 2007*
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<td>Mailing Instructions</td>
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<td>Where to Direct Inquiries and Obtain Information</td>
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<td>Educational Course Offerings</td>
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<td>Customer Service Hotline</td>
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</table>
CONTRIBUTOR'S CONSULTATION REQUEST FORM
ARMED FORCES INSTITUTE OF PATHOLOGY

PATIENT INFORMATION (Required)

<table>
<thead>
<tr>
<th>LAST NAME</th>
<th>FIRST</th>
<th>MIDDLE INITIAL</th>
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<th>SOCIAL SECURITY NO.</th>
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<th>Female</th>
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</tbody>
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MATERIALS FORWARDED

- Clinical Information (req’d)
- Formalin Fixed (Wet Tissue)
- Frozen Tissue
- Surgical Path Report (req’d)
- Autopsy Protocol
- X-rays
- Slides (req’d)
- Rpt of Investigation (AFME)
- Photos
- Blocks
- Rpt of Toxicologic Studies (AFME)
- Other

FIXATIVE (Required)

- Formalin
- B5
- Glyo-Fixx
- Alcohol (eg: Omnimix*, Safe-Fix*, Histochoice*) (*TM)
- Frozen
- Immunofluoresence
- EM
- Other
- Zenkers, Bouins, etc.

REGISTRIES/SERS

- SERS
- POW
- Kuwait/Persian Gulf
- Iraqi Freedom
- Enduring Freedom (Afghanistan)
- Agent Orange
- Depleted Uranium
- Leishmaniasis
- Embedded Metal Fragments
- Chemical Agent (nerve)
- Other

CASE IDENTIFICATION

Specific Biopsy Site or Organ (Required)

SPECIMEN IDENTIFICATION

Specimen Containers must be labeled with two identifiers.

Contributor’s Accession No(s)

Requested Department

CONTRIBUTOR'S WORKING DIAGNOSIS: (Differential diagnosis and questions should be entered in “Comments and Requests” Section)

CLINICAL HISTORY: Include: Location, Size, Symptoms, Duration, Physical and Laboratory Findings, Type and Date of Operation(s) and/or other Treatment.

(Continue in “Comment and Requests” section)

CONTRIBUTOR'S INFORMATION

CONTRIBUTOR'S NAME

NAME OF FACILITY

BUSINESS ADDRESS

CITY

STATE

ZIP CODE

COUNTRY

TELEPHONE

FAX

EMAIL

This form may be reproduced by the contributor or requested from AFIP.

AFIP Form 288-R (October 2010)
IMPORTANT

Have you enclosed a legible summary of the clinical findings, laboratory data, operative findings or report, and specific treatment? Cases selected for inclusion in specific registries often require additional information. Clinical or gross photos, pertinent X-rays, CT scans, MRI scans, echograms, angiograms, and similar diagnostic studies add substantially to the educational value of the case. They are highly desired by some departments and required by others.

COMMENTS AND REQUESTS:

AFIP RETENTION POLICY

1. MICROSCOPIC SLIDES SUBMITTED WITH EACH CASE ARE RETAINED PERMANENTLY. Under certain circumstances original slides may be returned to the Contributor if requested by the Contributor and approved by the Chair of the Department that would review the case. If slides are returned, then each slide will be digitized at the expense of the Contributor.

2. Blocks are retained for a minimum of ten (10) years, unless return is requested by the Contributor at the time the case is submitted. Contributors may request return or loan of blocks at some later time. If blocks are returned, then AFIP will retain representative diagnostic material.

3. Other pathologic material, X-rays, CT scans, MRI scans, echograms, angiograms, photographs, and similar diagnostic studies may be retained for education and research or discarded.

SIGNATURE OF CONTRIBUTOR

DATE REQUEST FORWARDED (YYYYMMDD)

PRIVACY ACT STATEMENT


2. PRINCIPAL PURPOSES: Medical information received in the course of the consultative process is used to form a database for education and research in pathology. Other patient information is used for filing and retrieval of consultation records. Information concerning the contributor is used to maintain contributor mailing lists.

3. ROUTINE USES:
   a. In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use as follows:
   b. Pathology consultation records are tracked in the Pathology Information Management System database for filing and retrieval of records, medical research, and statistical purposes. Individual consultation records may be released to the contributing medical care provider (physician, veterinarian), when required by law or as otherwise permitted by 45 C.F.R. 164.
   c. The DoD 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices also apply to this system.
   d. Pathology consultation records contain individually identifiable health information. The DoD Health Information Privacy Regulation (DoD 6025.18-R) issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information. DoD 6025.18-R may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this Privacy Act Notice.

4. PROVISION OF INFORMATION: The provision of patient information requested on this form is voluntary. However, if the information is not furnished, a consultation may not be possible. If so, the material submitted may be returned at the discretion of the AFIP without a consultation.
# CONTRIBUTOR’S CONSULTATION REQUEST FORM

**ARMED FORCES INSTITUTE OF PATHOLOGY-AMERICAN REGISTRY OF PATHOLOGY**

<table>
<thead>
<tr>
<th>NAME OF PATIENT (Last, First, Middle) (Required):</th>
<th>AFIP Accession Number (Previous, if known):</th>
</tr>
</thead>
<tbody>
<tr>
<td>SEX:</td>
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<tr>
<td>AGE:</td>
<td></td>
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<tr>
<td>DATE OF BIRTH (Month, Day, Year):</td>
<td></td>
</tr>
<tr>
<td>PATIENT’S SOCIAL SECURITY NUMBER (Required):</td>
<td></td>
</tr>
</tbody>
</table>

**MATERIALS forwarded:**

- [ ] Clinical Information (req’d)
- [ ] Clinical Pathology
- [ ] Surgical Path Report (req’d)
- [ ] Rpt of Investigation (AFME)
- [ ] Slides (req’d)
- [ ] Rpt of Toxicologic Studies (AFME)
- [ ] Blocks or Wet Tissue
- [ ] X-rays
- [ ] Frozen Tissue
- [ ] Photos

**RACE:**

- [ ] American Indian or Alaskan Native
- [ ] Asian or Pacific Islander
- [ ] Black
- [ ] White
- [ ] Not Known

**ETHNICITY:**

- [ ] Hispanic
- [ ] Not of Hispanic Origin

**CATEGORY:**

- [ ] Federal/Military
- [ ] Case solicited by
- [ ] Department or contributed specifically for value to AFIP for teaching, research or follow-up
- [ ] SERS Cases
- [ ] Other

**REGISTRIES:**

- [ ] POW
- [ ] Kuwait/Persian Gulf
- [ ] Agent Orange
- [ ] Geriatric
- [ ] Other

**CASE IDENTIFICATION:**

- [ ] Specific Biopsy Site or Organ (Required)
- [ ] Surgical Path/Autopsy Accession No. (s)
- [ ] Cytology Accession No. (s)

**FIXATIVE (Required):**

- [ ] Formalin
- [ ] B5
- [ ] Glyo-Fixx
- [ ] Alcohol (eg: Omnifix*, Safe-Fix*, Histochoice*) (*TM)
- [ ] Frozen
- [ ] Immunofluorescence
- [ ] EM
- [ ] Other

- [ ] Zenkers, Bouins, etc

**CONTRIBUTOR’S WORKING DIAGNOSIS:** (Differential diagnosis and questions should be entered in “Comments and Requests” Section)

**CLINICAL HISTORY:** Include: Location, Size, Symptoms, Duration, Physical and Laboratory Findings, Type and Date of Operation(s) and/or other Treatment.

(Continue in “Comments and Requests” section)

**NAME OF CONTRIBUTOR (Last, First, Middle Initial)**

**TELEPHONE NUMBERS**

**NAME OF FACILITY**

**EXTENSION**

**BUSINESS ADDRESS**

**TELEFAXMILE (FAX) NUMBER**

**STREET**

**OPERATIONAL HOURS**

**CITY**

**STATE**

**ZIP/Postal Code**

**COUNTRY**

**EMAIL**

AFIP Form 288-R (May 02) This form may be reproduced by the contributor or requested from AFIP.
IMPORTANT

Have you enclosed a legible summary of the clinical findings, laboratory data, operative findings or report, and specific treatment? Cases selected for inclusion in specific registries often require additional information. Clinical or gross photos, pertinent X-rays, CT scans, MRI scans, echograms, anglograms, and similar diagnostic studies add substantially to the education value of the case. They are highly desired by some departments and required by others. See attached info sheet.

COMMENTS AND REQUESTS:

AFIP RETENTION POLICY

Microscopic slides are kept on permanent file.

Blocks are retained for a minimum of five years, unless return is requested at the time that a case is accessioned. Blocks on cases judged to have educational or research value may be retained indefinitely.

Other pathologic material may be discarded when no longer used for education or research.

Further information can be obtained from the AFIP Contributors Manual available from the AFIP Research Office at (202) 782-2500 or at the website: http://www.afip.org/consult/manual/index.html.

If a civilian contributor (non-Federal) I certify to the best of my knowledge and belief that no litigation or claim of professional negligence involving the medical care of this patient has been, or is about to be, filed. ALL CONTRIBUTORS by their signature affirm that they have read THE FEDERAL PRIVACY ACT statement above.

SIGNATURE OF CONTRIBUTOR

DATE REQUEST FORWARDED (YYYYMMDD)

PRIVACY ACT STATEMENT


2. PRINCIPAL PURPOSES: Medical information received is considered during the consultative process and is used to form a database for education and research in pathology. Other patient information is used for filing and retrieval of consultation records. Information concerning the contributor is used to maintain contributor mailing lists.

3. ROUTINE USES:
   a. Pathology consultation files are used to provide a database for medical research and statistical purposes. When required by law or other official purposes, individual records may be released to the referring medical care provider (physician, veterinarian), to medical care providers treating the individual, to qualified medical researchers and students, and to other Federal agencies and law enforcement personnel when requested for official purposes involving criminal prosecution, civil court action, or regulatory orders.
   b. Pathology contributor mailing lists/files are used to publicize changes in policies and procedures pertaining to requests for consultative services and to disseminate information pertaining to continuing medical education courses or educational materials available at the AFIP.

4. NATURE OF DISCLOSURE: Disclosure of the requested information is purely voluntary; however, if the information is not furnished, consultation may not be possible, and material submitted may be returned without review.
Legal and Ethical Issues – National Tissue Repository

- AFIP PAMPHLET 70-1 (1 NOV 2004) INVESTIGATOR’S GUIDE – RESEARCH PROTOCOL SUBMISSION GUIDELINES, APPROVAL PROCESSES, AND CONTINUOUS MONITORING REQUIREMENTS.

- [AFIP PAMPHLET 70-1 (20 MAY 1996) INVESTIGATOR’S GUIDE – STEP-BY-STEP GUIDE TO THE RESEARCH PROTOCOL APPROVAL PROCESS.]
Legal and Ethical Issues – National Tissue Repository

- AFIP FORM 288-R (OCT 2010) – CONTRIBUTOR’S CONSULTATION REQUEST FORM.
- AFIP FORM 288-R (MAY 2002) – CONTRIBUTOR’S CONSULTATION REQUEST FORM.
Legal and Ethical Issues – National Tissue Repository

- DOD DIRECTIVE 3216.02 (25 MAR 2002) – PROTECTION OF HUMAN SUBJECTS AND ADHERENCE TO ETHICAL STANDARDS IN DOD-SUPPORTED RESEARCH.
- DOD INSTRUCTION 3216.01 (13 SEP 2010) – USE OF ANIMALS IN DOD PROGRAMS.
- DOD INSTRUCTION 6000.08 (3 DEC 2007) – FUNDING AND ADMINISTRATION OF CLINICAL INVESTIGATION PROGRAMS.
Legal and Ethical Issues – National Tissue Repository

- ARMY REGULATION 40-3 (1 SEP 1989) – CLINICAL INVESTIGATION PROGRAM.
- ARMY REGULATION 40-33 (16 FEB 2005) – THE CARE AND USE OF LABORATORY ANIMALS IN DOD PROGRAMS.
- ARMY REGULATION 70-25 (25 JAN 1990) – USE OF VOLUNTEERS AS SUBJECTS OF RESEARCH.
- ARMY – ACTIONABLE MEDICAL INFORMATION.
- SECNAVINST 3900.39D (6 NOV 2006) – HUMAN RESEARCH PROTECTION PROGRAM.
- MARINE CORPS ORDER 3900.18 (21 JAN 2011) – HUMAN RESEARCH PROTECTION PROGRAM (HRPP).
- AIR FORCE INSTRUCTION 40-402 (5 MAY 2005) – PROTECTION OF HUMAN SUBJECTS IN BIOMEDICAL AND BEHAVIORAL RESEARCH.
QUESTIONS????

Catherine M. With, MA, JD, LLM, LLM
Major, Judge Advocate, US Army
Legal Counsel
The Armed Forces Institute of Pathology (AFIP)
Washington, DC
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Blackberry: 703-855-0375
Email: catherine.with@gmail.com
Catherine.with@us.army.mil
Website: www.afip.org