Background

- BRAC 2005: AFIP must be disestablished by September 2011
- NDAA 2008, section 722: The President shall establish and maintain a Joint Pathology Center (JPC) that shall function as the reference center in pathology for the Federal Government
- The Joint Pathology Center will provide, at a minimum, the following services:
  - Diagnostic pathology consultation services in medicine, dentistry, and veterinary sciences
  - Pathology education, to include graduate medical education (residency and fellowship programs), and continuing medical education
  - Diagnostic pathology research
  - Maintenance and continued modernization of the Tissue Repository and, as appropriate, utilization of the Repository in conducting the activities described above
- The Joint Pathology Center must be established within DoD and establishment must be consistent with BRAC law
Background

- Joint Pathology Center Working Group
  - Convened: March 2008
  - Reviewed eight courses of action and selected one
  - Course of action approved by Deputy Secretary of Defense
- Joint Pathology Center officially delegated by President of the United States to Department of Defense: April 2009
  - Mission officially delegated to Joint Task Force National Capital Region Medical (JTF CapMed) in December 2009

The Joint Pathology Center

VISION

The Joint Pathology Center is the federal government’s premier pathology reference center supporting the Military Health System (MHS), DoD and other federal agencies

MISSION

The Joint Pathology Center will provide world class diagnostic subspecialty consultation, education, training, research and maintenance/modernization of the tissue repository in support of the mission of the DoD and other federal agencies
The Five Pillars of the Joint Pathology Center

**Pathology Consultation**
- Full spectrum surgical pathology consultation utilizing state-of-the-art technology
- Telepathology Services
- Environmental/Biophysical Toxicology Service
- "one-of-a-kind" Veterinary Pathology Consultative Service

**Tissue Repository**
- Maintains and maintains the world’s largest tissue repository
- Utilizes material in support of clinical care
- Utilizes material in support of education
- Develops and maintains strategic plans for allocation of tissue for federal government research

**Pathology Research**
- Pathologist-driven research
- Support clinical research (TBI initiative, USMCI initiatives, etc)
- Utilizes tissue in support of other federal government priorities
- Veterinary Pathology research
- Utilizes Tissue Cohort Registries for research

**Pathology Education**
- Provides Graduate Medical education rotations and other support to federal government residencies and fellowships
- Offers robust online CME activities in collaboration with USU
- Provides Veterinary Pathology Residency for DoD
- Provides Support to Navy Oral Pathology Residency Program
- Supports Continuing Medical Education

**Strategic Partnerships**
- Augment and enhance capabilities through partnerships
- Partners with USU and other federal agencies
- Opportunities for partnering and support of Comprehensive Cancer Center and USMCI

World Class Support of the Mission (DOD, VA, HHS, other)

Consultation Mission

- Provide secondary pathology consultation to federal agencies
  - Primary stakeholders: Department of Defense and Veterans Affairs
  - Other stakeholders: other federal agencies
- Provide veterinary pathology consultation to federal agencies
Consultation

Pathology Subspecialties:
- Dermatopathology
- Veterinary Pathology
- Genitourinary Pathology
- GI/Hepatic Pathology
- Neuropathology
- Hematopathology
- Infectious Disease
- Bone/Soft Tissue Pathology
- GYN/Breast Pathology
- Oral/ENT Pathology
- Cardiovascular Pathology
- Pulmonary Pathology
- Environmental Pathology
- Nephropathology
- Molecular Pathology

Support Services:
- Environmental/Biophysical Toxicology Laboratories
- Cohort Registries and ACTUR
- Telepathology
- Veterinary Pathology Consultation
- Molecular Laboratories
- Histology/IHC/Special Stains Immunofluorescence
- Muscle Biopsy Interpretation
- Electron Microscopy
- Rad-Path Interpretation
- Administrative Support

Education and Research

Education
- Graduate Medical Education
  - Subspecialty rotations
  - Support of oral pathology residency
  - Support of dermatopathology fellowship
- Veterinary Pathology Residency
- Continuing Medical Education
  - Robust online offerings
  - Focus on MOC/Solo Pathologist
  - Develop large online digitized pathology case archive
- Support for Live Courses

Research
- Pathologist-driven research
- Utilization of Repository
- Support of Clinical Initiatives
- Utilization of Cohort Registries
- Utilization of ACTUR data
- Veterinary Pathology Research
- Collaborative efforts and Partnerships
- Opportunity for collaboration, support, and funding through existing processes
Tissue Repository

- **Maintenance**
  - Continue ongoing maintenance of holdings
  - Access to cases for continuity of clinical care
- **Modernization**
  - Continue current digitization project
  - Develop plan for organization/utilization of BRAC material
  - Environmental update of one building
- **Utilization**
  - Clinical Mission: utilization of cases for support of consultative mission
  - Education:
    - Slide digitization project for online digital slide repository
    - Utilization of material to develop online courses
    - Opportunity for utilization of digitized material for other courses
  - Research
    - Development of plan to fully utilize Tissue Repository
    - Opportunities for partnership

Develop plan for utilization of repository material in research:
- Develop carefully and deliberately
- Utilize Repository Consensus Findings (2005) and Asterand findings and recommendations
- Utilize findings and recommendations of IOM
- Engage strategic partners
- Ensure sustainability of repository material
Strategic Partnerships

- Focus on research and utilization of Tissue Repository
- Similar models within DoD and VA
- Collaboration and partnership within DoD, with VA and other governmental agencies
- Opportunity for collaboration and partnership for research with civilian academic community

Governance and Organizational Structure

- JPC aligned under Headquarters, Joint Task Force National Capital Region Medical (JTF CapMed)
- JTF CapMed:
  - Established in October, 2007
  - Commander: VADM John Mateczun
  - Joint (Triservice) organization providing military healthcare services for the national capital region
  - Currently in final stages of implementing integrated health care delivery system in the National Capital Region
  - World Class Health Care System
  - Will consist of Walter Reed National Military Medical Center, Fort Belvoir Community hospital, several Centers of Excellence, The Joint Pathology Center, and Headquarters, JTF CapMed
**Governance and Organizational Structure**

- Joint Pathology Center
  - Separate organization but closely aligned with world class academic medical center, WRNMMC.
  - Consists of four divisions and Office of Director
  - Board of Advisors comprised of senior subject matter experts from stakeholder agencies and services

**Budget and Facilities**

- **Budget:**
  - Funded by Department of Defense
  - JPC operating budget separate from hospitals and Centers of Excellence

- **Facilities:**
  - Forest Glen campus of Military Research Medical Command (MRMC)
    - Buildings 606 and 510: The Joint Pathology Center main functions
    - Building 161: Veterinary Pathology, Electron Microscopy and grossing lab
  - Bethesda Campus:
    - Histology: function integrated into hospital histology section: 6000 square feet of laboratory space with state-of-the-art technology
    - Molecular Laboratories: 3000 square feet of laboratory space (being renovated)
  - Andrews Air Force Base:
    - Environmental/Biophysical Toxicology Lab: 1600 square feet of lab (being renovated)
  - Opportunities in the future
Support of Stakeholders and Other Opportunities

- Support of Armed Forces Medical Examiner
- Support of Operations in theater:
- Other Federal Agencies
  - Major stakeholders
    - Department of Defense
    - Veterans Administration
  - Other Key Federal Stakeholders
    - NIH, CDC, PHS, IHS, FDA
    - Non-medical federal stakeholders
  - Organization allows for sufficient flexibility to address stakeholder current and future needs

Establishment

- Initial Operating Capabilities: 01Oct 2010
  - Office of Director: 21 administrative personnel to prepare for assumption of mission
- Start of mission: 01 April 2011
- Full Operating Capabilities: NLT Sept 2011
- AFIP and Army supporting as JPC establishes
- Ensure continuity of clinical mission during transition in support of stakeholders
The Joint Pathology Center: Overview of the Tissue Repository

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21 April 2011

Background

- Armed Forces Institute of Pathology
  - Established in 1862 as the Army Medical Museum
  - Specimen repository responsibility of Army
  - Base Realignment and Closure Act (BRAC) of 2005 closed the AFIP with the Tissue Repository becoming the responsibility of the Uniformed Services University of Health Sciences (USUHS)

  - Directed the establishment of a Joint Pathology Center within Department of Defense to include the Tissue Repository
  - Mission of the Joint Pathology Center officially delegated to Joint Task Force National Capital Region Medical (JTF CapMed) in December 2009
  - Responsibility for the Tissue Repository realigned under JTF CapMed
Background

- **AFIP Tissue Repository Consensus Panel:**
  - Convened in August, 2005 to discuss the present status and future prospects of the Armed Forces Institute of Pathology (AFIP) Tissue Repository.
  - Panel Comprised of representation from academia, industry, and the federal government

- **Summary of Panel Recommendations:**
  - The Repository should be maintained as a vibrant, living entity that permits appropriate access and will require management by expert professional staff.
  - Adequate financial and human resources are needed to maintain the Repository.
  - The Repository will require verification of diagnoses in order to validate and authenticate the tissue specimens.
  - A scientific review process should be instituted for obtaining materials from the Repository that should allow accessibility and responsiveness to the needs of the research community.
  - A Scientific Advisory Committee should be established to evaluate the operations of the Repository and make recommendations on its scientific, medical and ethical practices on a regular basis.

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Background

- **USUHS awarded a contract to Asterand, Inc. in September 2007 to provide the following:**
  - Assess the accuracy and completeness of databases
  - Analyze a representative sample of tissue samples, slides, and blocks for:
    - Physical presence of materials
    - Visual inspection for size, depth, and/or gross assessment
    - Pathologic diagnosis and annotation for disease or normal status
    - Immunohistochemistry for protein preservation
    - A research and commercial value of the repositories
  - Additional recommendations to improve the collection
Background

- Asterand conclusions:
  - The Central and BRAC repositories are in very good shape for their size and age
  - The databases support excellent retrievability and inventory control of individual cases
  - The databases do not easily support common database queries that are useful in biomedical research
  - Valuation: conservative estimate at 1.4 billion dollars and with improvements, 3.3 billion dollars
  - Recommendations

Background

- Defense Health Board review of the Joint Pathology Center concept of operations in January 2009.

“The Board strongly believes the Tissue Repository is an irreplaceable national and international treasure and resource from which significant potential in research and advances in medical care will result, particularly with recent developments in genomics and individualized medicine as well as initiatives to establish a human biobank.”

- Defense Health Board recommendations:
  - Clearly define access and usage limits
  - Thoroughly define the route of access for civilian sector research
  - Every effort must be made to guarantee that holdings are preserved, implements world-class modernization, and is appropriately utilized
Tissue Repository Holdings

- Facilities:
  - Buildings 606 and 510 on Forest Glen campus in Silver Springs, MD
    - Building 606
      - Approximately 32,000 square feet
      - Recently completely renovated with 10,681 square feet of administrative space (including 2600 square feet of "future laboratory space")
      - Climate and security controlled
      - Holdings: Tissue blocks from Central collection and BRAC material
    - Building 510
      - Approximately 15,000 square feet of warehouse space
      - Currently undergoing life safety renovation
      - Climate and security controlled
      - Holdings: glass slides and wet tissue
  - Other:
    - Frozen tissue to be stored at off-site facility
    - Material still being moved from AFIP to Repository; expected completion July 2011.

Tissue Repository Holdings

- Overall: Since 1917:
  - 7.4 million total cases with data stored in multiple databases
  - 31 million paraffin imbedded tissue blocks*
  - 55 million glass slides*
  - 500-700,00 wet tissue samples*
  - 18 freezers with frozen samples (still being catalogued)
  - Digitized collection (still being catalogued)
  - Tissue Microarray Assay (TMA) Library: 29 TMAs available
  - Other:
    - Medicolegal Holdings
    - Vast glass slide study set collections (still being catalogued)
    - Digitized radiologic images for AFIP Rad/Path Course

Tissue Repository Holdings

- **Collections:**
  - **The Central Repository:**
    - 3.2 million cases (through 2011)
    - Consists of largely of material submitted for clinical consultation by Department of Defense, Veterans Affairs, Other federal agencies and civilian contributors
    - Consists of tissue blocks, wet tissue, frozen tissue, and glass slides including special stains and immunohistochemistry
  - **Databases:**
    - Pathology Information Management System (PIMS)
    - PANLARS (legacy database 1970-1999)
    - SNDO (legacy database 1917-1969)

- **The Central Repository (Continued):**
  - Unique and rare collections:
    - Not well defined
    - By disease, consists of some of the largest collections in the world of neoplastic and non-neoplastic disease including infectious disease
  - Collection largely represents cases sent for secondary consultation i.e. unique and challenging cases
  - Collection includes cases from international contributors and underserved areas
Tissue Repository Holdings

– The BRAC Collection:
  • Collections from closed military hospitals to meet accreditation requirements for retention of specimens
  • Consists of largely glass slides and paraffin imbedded tissue blocks and associated pathology reports
  • Collections from 27 closed military bases from all over the world
    – Over 4.2 million cases
      ‣ Two thirds with associated case material (slides and/or blocks)
      ‣ One third with report only
    – Represent community hospital and academic medical center case material from military and civilian beneficiary populations
    – Includes material from care to local populations overseas
  • Database:
    – Case reports in PDF format searchable in separate data management system

Other Databases

➢ Automated Central Tumor Registry
  – Serves as umbrella function for Department of Defense Tumor Registry process
    • Clinical information fed from all military treatment facilities that have tumor registry capabilities
    • Data complete and valid from 1998-2008. Data from 2009 to present being validated
    • Software: CDC Registry Plus and prep plus applications
  – Research-quality database that allows for:
    • Outcome analysis and referral patterns
    • Trend analysis
    • Statistical reporting
    • Health care analysis
    • Epidemiology
    • Uniform data collection and tracking
Other Databases

- The Cohort Registries:
  - Separate database
  - Represents case material and clinical information submitted for specific ‘War Registries’ initiated by AFIP
  - 12 current registries including POW, Leishmaniasis, Agent Orange, OEF/OIF.
  - Cases submitted by VA and military treatment facilities and civilian facilities caring for these patients
  - Case material identified and submitted by AFIP and JPC pathologists
- Electronic Medical Records

Desired End State

- Informed by recommendations made by IOM Panel
- Open up the Tissue Repository broadly for use in medical research
- Ensure sustainability of Repository holdings
- Address competing priorities for specimens
- Ensure that specimens released for research are valid, viable, and of high quality
- Provide clinical data to enhance utility of specimens
- Develop a cost-neutral approach to utilization of the repository
Challenges and Opportunities

- **Challenges:**
  - Variability in collection and storage of specimens
  - Collected largely for clinical use → lack of clinical data for cases
  - Lack of paraffin imbedded tissue block submission to repository

- **Opportunities:**
  - Develop a process to fully open the repository to research that includes proper oversight and administrative functions
  - Identifying appropriate business model that ensures sustainability of the holdings
  - Identifying technologies needed for the repository
    - Laboratory Technologies:
      - ensure specimen quality and specimen utilization
    - Information Systems:
      - Opportunities to improve biomedical research quality of database while continuing to serve as clinical database
      - Opportunities to utilize existing databases
    - Other technologies

Questions for IOM Panel

- What should be the mission and vision of the Tissue Repository?

- Given the defined mission and vision of the Joint Pathology Center, should access to repository materials be limited to the federal government or open to a larger pool of potential users? What advantages and disadvantages should be considered in defining the potential users of the repository in research?

- What are the ethical and legal considerations regarding utilization of the Tissue Repository in support of clinical care and education?

- Should material currently deemed not usable for consultation, education, and research be stored indefinitely or should the JPC develop a plan for disposal of unusable or non-viable specimens and are there any legal considerations with disposal of said specimens?
Questions for IOM Panel

» Should the BRAC Collection of materials be maintained indefinitely?

» Can tissue collected for clinical use be used for research (i.e. from patients not specifically consented for use of tissue in research)?

» What are the ethical considerations regarding use of tissues originally submitted for clinical use for research and can this be accomplished within current accepted guidelines for clinical research?

Questions for IOM Panel

» The Tissue Repository currently contains consult material from both federal facilities as well as that submitted for consultation by civilian providers. Can tissue within the repository from civilian providers be utilized in the same manner as that from federal facilities?

» What considerations should be given to utilization for research of unique, one-of-a-kind, material within the central collection of the Tissue Repository?

» What existing or emerging technologies (either as an intrinsic function or through partnership) should be considered in developing a plan for utilization of the Tissue Repository in research and how would they potentially affect the mission of the JPC?
The Tissue Repository

Questions?