



OBBR Office of Biorepositories
and Biospecimen Research

Developing caHUB's Tissue Collection Standard Operating Protocols (SOPs)

James A. Robb, MD

Consulting Pathologist, OBBR, NCI, DHHS
Governor, College of American Pathologists





Selection of Biospecimens Work Group

#1

OBBR Office of Biorepositories
and Biospecimen Research

Recommendations from 5 nationally recognized US surgical pathologists

- **Editor of a leading pathology journal**
- **Chairs of College of American Pathologists' (CAP) Surgical Pathology and Cancer Committees**
- **Member of ASCO/CAP ER/PR & HER2 Guidelines development groups**
- **Outstanding surgical and molecular pathology national & international lecturer**



Selection of Biospecimens Work Group #2

OBBR Office of Biorepositories
and Biospecimen Research

Invitations sent to domain-expert surgical pathologists

19 organ working groups formed

Used TCGA squamous cell carcinoma tissue collection SOP as draft document

Each working group created tissue collection protocols

(79 pathologists)

Most common/needed cancer(s) in that organ



Selection of Biospecimens Work Group #2

OBBR Office of Biorepositories
and Biospecimen Research

Invitations sent to domain-expert surgical pathologists

19 organ working groups formed

Used TCGA squamous cell carcinoma tissue collection SOP as draft document

Each working group created tissue collection protocols

(79 pathologists)

Most common/needed cancer(s) in that organ

Normal tissue as distant to the cancer as possible in the resected specimen



Selection of Biospecimens Work Group #2

OBBR Office of Biorepositories
and Biospecimen Research

Invitations sent to domain-expert surgical pathologists

19 organ working groups formed

Used TCGA squamous cell carcinoma tissue collection SOP as draft document

Each working group created tissue collection protocols

(79 pathologists)

Most common/needed cancer(s) in that organ

Normal tissue as distant to the cancer as possible in the resected specimen

Normal tissue from non-neoplastic surgically removed specimens and rapid autopsies



Selection of Biospecimens Work Group #2

OBBR Office of Biorepositories
and Biospecimen Research

Invitations sent to domain-expert surgical pathologists

19 organ working groups formed

Used TCGA squamous cell carcinoma tissue collection SOP as draft document

Each working group created tissue collection protocols

(79 pathologists)

Most common/needed cancer(s) in that organ

Normal tissue as distant to the cancer as possible in the resected specimen

Normal tissue from non-neoplastic surgically removed specimens and rapid autopsies

Cold ischemia time (<20 min) and tissue formalin-fixation (24 +/- 8 hours) protocols using ASCO/CAP (in press) & CLSI (in voting) draft guidelines



Biospecimen Work Group Products #1

OBBR Office of Biorepositories
and Biospecimen Research

- **Tumor collection strategy:** a quantitative prioritization matrix using 9 criteria and a 3-tiered scoring system for each element was developed – levels playing field



Biospecimen Work Group Products #1

OBBR Office of Biorepositories
and Biospecimen Research

- **Tumor collection strategy:** a quantitative prioritization matrix using 9 criteria and a 3-tiered scoring system for each element was developed – levels playing field
 - **Criteria:** 1) Prevalence, 2) increasing incidence, 3) survival, 4) cost to society, 5) ease of collection, 6) size, 7) treatment by surgery, 8) pre-resection treatment, 9) need for new molecular tools for Diagnosis, Prognosis, Prediction, and Personalized Targeted Treatment



Biospecimen Work Group Products #1

OBBR Office of Biorepositories
and Biospecimen Research

- **Tumor collection strategy:** a quantitative prioritization matrix using 9 criteria and a 3-tiered scoring system for each element was developed – levels playing field
 - **Criteria:** 1) Prevalence, 2) increasing incidence, 3) survival, 4) cost to society, 5) ease of collection, 6) size, 7) treatment by surgery, 8) pre-resection treatment, 9) need for new molecular tools for Diagnosis, Prognosis, Prediction, and Personalized Targeted Treatment
 - **60 cancers** identified (of 850): NLM/SEER data used



Biospecimen Work Group Products #1

OBBR Office of Biorepositories
and Biospecimen Research

- **Tumor collection strategy:** a quantitative prioritization matrix using 9 criteria and a 3-tiered scoring system for each element was developed – levels playing field
 - **Criteria:** 1) Prevalence, 2) increasing incidence, 3) survival, 4) cost to society, 5) ease of collection, 6) size, 7) treatment by surgery, 8) pre-resection treatment, 9) need for new molecular tools for Diagnosis, Prognosis, Prediction, and Personalized Targeted Treatment
 - **60 cancers** identified (of 850): NLM/SEER data used
 - **Weighted against scientific demand** during launch phase



Biospecimen Work Group Products

#2

OBBR Office of Biorepositories
and Biospecimen Research

- **Cold Ischemia Time Strategy:** Transfer from surgeon to pathologist SOP



Biospecimen Work Group Products #2

OBBR Office of Biorepositories
and Biospecimen Research

- **Cold Ischemia Time Strategy:** Transfer from surgeon to pathologist SOP – **MUST BE IN PATHOLOGIST'S CONTROL!**



Biospecimen Work Group Products #2

OBBR Office of Biorepositories
and Biospecimen Research

- **Cold Ischemia Time Strategy:** Transfer from surgeon to pathologist SOP – **MUST BE IN PATHOLOGIST'S CONTROL!**
- **Fixation & Shipping Strategy:** formalin-fixed tissue to caHUB in 70% ethanol SOP → processing at caHUB



Biospecimen Work Group Products #2

OBBR Office of Biorepositories
and Biospecimen Research

- **Cold Ischemia Time Strategy:** Transfer from surgeon to pathologist SOP – **MUST BE IN PATHOLOGIST'S CONTROL!**
- **Fixation & Shipping Strategy:** formalin-fixed tissue to caHUB in 70% ethanol SOP → processing at caHUB
- **Qualification Strategy:** Tissue morphologic and molecular qualification SOP – used TCGA SOP as basis



Biospecimen Work Group Products #2

OBBR Office of Biorepositories
and Biospecimen Research

- **Cold Ischemia Time Strategy:** Transfer from surgeon to pathologist SOP – **MUST BE IN PATHOLOGIST'S CONTROL!**
- **Fixation & Shipping Strategy:** formalin-fixed tissue to caHUB in 70% ethanol SOP → processing at caHUB
- **Qualification Strategy:** Tissue morphologic and molecular qualification SOP – used TCGA SOP as basis
- **Blood Collection Strategy:** Collection and processing SOP



Biospecimen Work Group Products #2

OBBR Office of Biorepositories
and Biospecimen Research

- **Cold Ischemia Time Strategy:** Transfer from surgeon to pathologist SOP – **MUST BE IN PATHOLOGIST'S CONTROL!**
- **Fixation & Shipping Strategy:** formalin-fixed tissue to caHUB in 70% ethanol SOP → processing at caHUB
- **Qualification Strategy:** Tissue morphologic and molecular qualification SOP – used TCGA SOP as basis
- **Blood Collection Strategy:** Collection and processing SOP
- **caHUB Total Quality Management Plan BSS→caHUB→client**
In progress: Identification of all process steps with detailed monitoring as feasible and risk mitigation for all



Biospecimen Work Group Products #2

OBBR Office of Biorepositories
and Biospecimen Research

- **Cold Ischemia Time Strategy:** Transfer from surgeon to pathologist SOP – **MUST BE IN PATHOLOGIST'S CONTROL!**
- **Fixation & Shipping Strategy:** formalin-fixed tissue to caHUB in 70% ethanol SOP → processing at caHUB
- **Qualification Strategy:** Tissue morphologic and molecular qualification SOP – used TCGA SOP as basis
- **Blood Collection Strategy:** Collection and processing SOP
- **caHUB Total Quality Management Plan BSS→caHUB→client**
In progress: Identification of all process steps with detailed monitoring as feasible and risk mitigation for all steps
VOLUNTEERS: robj@mail.nih.gov
- **Quality Monitoring Strategy:** Key monitors for all critical steps in Biospecimen Source Site - caHUB process flow



Thank you!

Questions?

OBBR Office of Biorepositories
and Biospecimen Research

NIH Videocast: caHUB Public Meeting 2/19/10

<http://videocast.nih.gov/PastEvents.asp?c=0&s=31>

OBBR: <http://biospecimens.cancer.gov/default.asp>

BRN: <http://biospecimens.cancer.gov/researchnetwork/default.asp>

caHUB: <http://biospecimens.cancer.gov/cahub/default.asp>