Alliance Biorepositories and Biospecimen Resource (ABBR)

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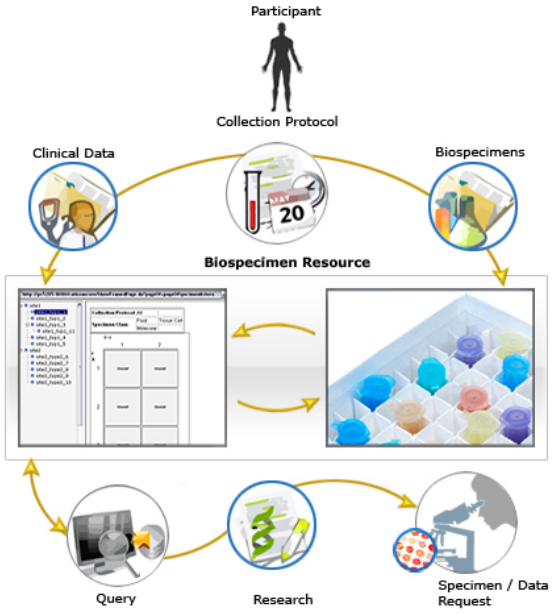
Presentation Objectives

- Become familiar with resources used to collect, process, and distribute biospecimens in the context of Alliance clinical trials.
- Understand the processes and considerations for biospecimen collection activities in Alliance clinical trials.



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ABBR / AFB Goals

- Facilitate collection, storage, processing, and distribution of biospecimens in the context of Alliance clinical trials.
  - Integral biomarker studies - **Mandatory**
  - Integrated correlative science studies **(Mandatory)**
  - Future / secondary correlative science studies

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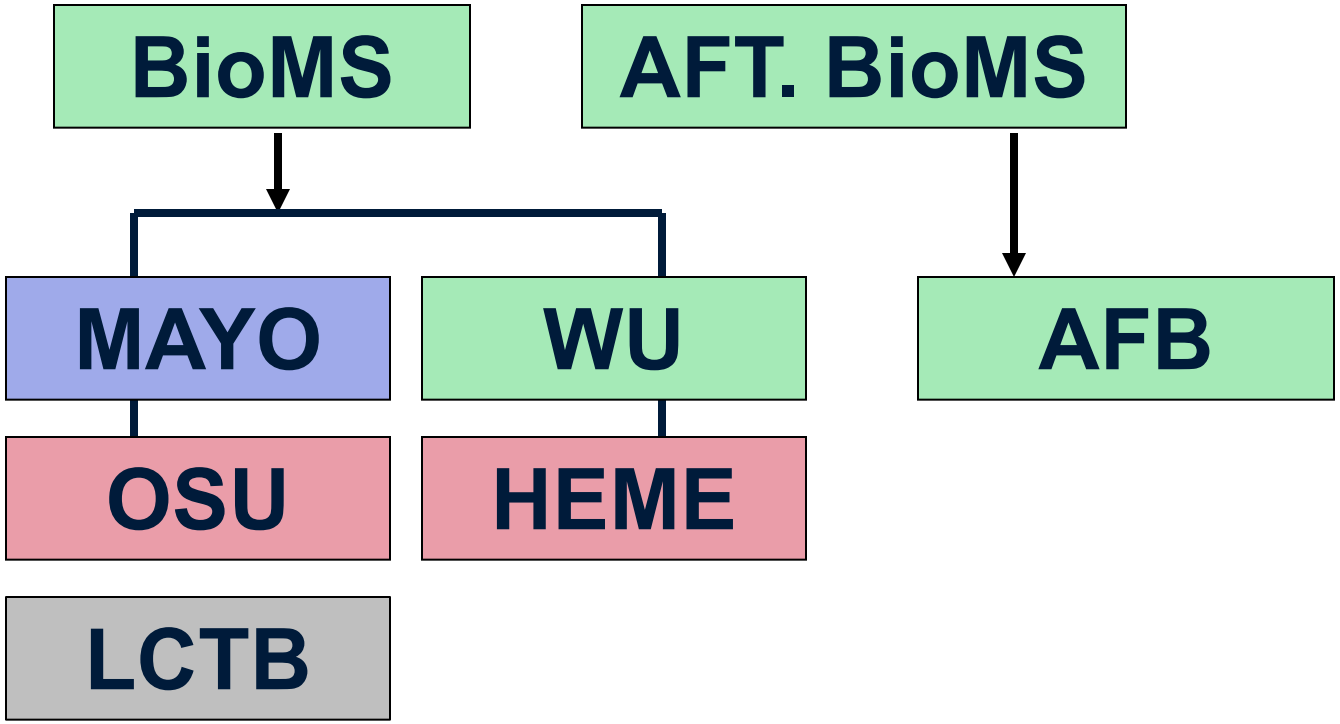
ABBR / AFB Organization



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ABBR Organization

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Biospecimen Collection Overview

- Protocol initiation
- Protocols and Procedures
- BioMS
- Collection kits
- Collection procedures
- Pathology tissue blocks
- Specimen labeling
- Shipping
- Feedback
- FAQs / FOPs

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Protocol Initiation

- Review the protocol.
- Review the Correlative Science Manual (CSM) – if applicable.
- Identify pathology contacts and be aware of institutional pathology policies (block release; slide cutting charges).
- Identify equipment / services that may be needed for on-site specimen processing (centrifuge; -70 freezer; dry ice).
- Order biospecimen collection kits- if applicable.
- Identify supplies needed for biospecimen collection and shipping (blood tubes; mailers).
- Confirm access to BioMS.
- Ask all questions and resolve issues (in writing) prior to first enrollment.

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Protocols and Procedures

- Trial protocol describes what biospecimens are to be collected, when to collect them, and how to collect them.
- The language and format of procedures in legacy protocols will vary; language in new protocols is more uniform.
- All AFT trials and future NCI Alliance trials will have a supplementary Correlative Science Manual (CSM).
  - Provides more detailed description of collection, processing, and shipping procedures.
  - May be updated for corrections and clarity without a formal protocol amendment.
  - Provides only the essential details for biospecimen collection, processing, and shipping for laboratory personnel.
  - Latest update is always available electronically on the AFT.BioMS or BioMS web site.
- Review and resolve procedural questions with Alliance / AFT study coordinator (in writing) prior to first enrollment.

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BioMS / AFT.BioMS

- Alliance **Bio**specimen **M**anagement **S**ystem (BioMS) tracks the collection, transport, and storage of biospecimens across Alliance biorepository and laboratory sites.
- BioMS and AFT.BioMS are identical but independent systems for NCI vs. AFT trials.
- RAVE tracks data; BioMS tracks physical biospecimens.
- Assistance / Instructions for using BioMS can be found on the BioMS web site (800 help desk; email; videos).
- URLs, emails, and phone numbers for BioMS help can be found both in the trial protocol and CSM (if applicable).
- Contact BioMS help only for BioMS related questions.
- BioMS **must** be used for all kit requests, biospecimen logging, and shipping.
- Confirm access and understanding of BioMS prior to first patient enrollment.

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BioMS / AFT.BioMS

- If applicable, kits should be ordered using BioMS.
- Once a participant is registered (i.e. OPEN), the participant will appear in BioMS.
- Access to trials and participants in BioMS is based on user-site association data.
- Search for registered participant based on trial and participant ID.
- Select appropriate collection time point.
- Register collection of biospecimens (include annotation data if required).
- Create a ‘shipment’ for the biospecimens and generate / print shipment manifest.
- Receive confirmatory email that biospecimens have been received and received quality of the biospecimen.

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Collection Kits

- Some complex trials provide biospecimen collection kits to facilitate biospecimen collection.
- Kits are trial- and time-point specific.
- Kits should be requested through the BioMS system.
- Please allow 7-10 days for kit delivery (overnight delivery can be provided at the site's expense).
- Do not order kits more than 60 days in advance, since: kits may be lost / discarded; some components of the kits may expire.
- Kits are recycled to minimize cost; please return all kits.
- Expired kit components may be replenished with identical institutional supplies.
- Cost to ship kits to site is paid for by the biorepository; cost to return biospecimen kit may or may not be pre-paid.

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Collection Procedures

- All collection procedures are harmonized and optimized to properly preserve biospecimens. Please follow all specific procedures.
- Review collection and- if applicable- processing procedures before enrolling patients.
- Contact the appropriate biorepository (not BioMS helpdesk) if there are questions or limitations in performing the required procedures.
- Pay particular attention to requirements regarding blood collection tube types and shipping container types.

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Pathology Tissue Blocks

- Although there are no national regulations that prohibit the release of pathology tissue blocks to an outside institution, some states or institutions may have regulations that require clinical sites to retain all pathology blocks.
- Sometimes a “regulation” is only a rumor. Please confirm policies concerning block release in writing.
- Blocks are always preferred over tissue cores and cut unstained slides for many reasons, but in some cases, a trial may allow for the submission of slides rather than a block.
- For cases with multiple blocks, collaborate with the pathology department to ensure the submission of a representative, adequate tissue block, as specified in the protocol.
- All blocks or slides must be submitted with a de-identified pathology report, labeled with the participant study number.

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Biospecimen Labeling

- All biospecimens received must be labeled according to protocol- this usually means study number, participant number, and date collected. If applicable, also label with biospecimen type (“serum”, “plasma”, “tumor”)
- Do not remove surgical pathology identifiers from primary surgical pathology blocks.
- If possible, slides cut from a surgical pathology block should be labeled with the study number and participant number, not the institutional surgical pathology number.
- Label slides, tubes, etc. directly with an indelible marker. Do not apply adhesive labels. Label all containers before freezing.
- Biospecimens with no or ambiguous labels will be discarded.

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Biospecimen Shipping

- If a kit is provided, use the collection kit as instructed to ship biospecimens to the biorepository or lab.
- Note that some kits provide for shipping at two temperatures (dry ice compartment and ambient compartment)- in these cases, ensure that they are properly assembled and that biospecimens are placed in the appropriate compartments.
- When shipping frozen biospecimens, be certain to include a sufficient amount of **dry** ice to keep biospecimens frozen for 24-28 hours.
- When kits are not provided, ensure that the shipping containers used are IATA compliant, properly labeled, and fit-for-purpose.
  - Adequate packing for glass tubes and slides
  - Absorbent materials for fluids
  - Cool packs for paraffin blocks shipped during summer months

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Biospecimen Receipt

- Upon receipt at the biorepository or lab, BioMS will message the sender, acknowledging the receipt and receipt condition of each biospecimen in the shipment.
- Questions concerning the received quality message should be directed to the specific biorepository or lab, not the BioMS helpdesk.
- Receipt data from BioMS (missing or inadequate biospecimens) is provided for IPEC reporting- please resolve any missing or inadequate submissions with the biorepository as quickly as possible.

Looking for help? Email bioms@alliancenctn.org
Or Phone 1(855)-55-BIOMS or 1(855)-552-4667

BioMS Public / BioSpecimen Management System - BioMS

BioMS Specimen Receipt Values

Created by George Bijoy, last modified on Sep 28, 2017

The following are the new Specimen Receipt values available in BioMS Release 2.5. Against, each one of these specimen quality receipt values, you can see a biorepository staff action and a comment to the CRA. The comment to the CRA will be communicated via email notification upon receiving the specimen at the Biorepository.

#	Status Value	Description	Applicable Specimen Types	Biorepository Staff Action	CRA Comment in Email
1	Acceptable	Sample is okay and meets requirements.	All	Accession and Store	None.
2	Alert-Cauterized	Tissue shows gross cauterization artifact.	Tissue	Accession and Store	Specimen is usable; in the future, please avoid cauterized tissue.
3	Alert-Damaged	Sample is physically damaged but still usable.	All	Accession and Store	Specimen is usable; in the future, please ensure proper packaging to avoid specimen damage
4	Alert-Hemorrhagic	Specimen shows gross hemorrhagic tissue	Tissue	Accession and Store	Specimen is usable; in the future, please avoid
18	Unacceptable-No ID	A sample has been received with no physical identification.	All	Reject; Do not accession; Destroy with Director approval	Specimen will be discarded. Contact the appropriate protocol coordinator to determine if a replacement specimen can be recollected and submitted. Please ensure that all future specimens are completely labeled, per protocol requirements.
19	Unacceptable - Not in shipment	Sample listed on BiomS packing slip is physically not in shipment	All	Reject; Do not accession	Contact the appropriate biorepository and/or BioMS help desk to resolve this conflict. Please ensure that all specimens are accounted for in future submissions.
20	Unaccceptable-QNS	Quantity not sufficient; Sample is too limiting to process and is unusable	All	Accession and Destroy with Director approval	Specimen quantity is less than requested and not usable. Please contact the appropriate protocol coordinator to determine if a replacement specimen can be recollected and submitted; ensure that the requested specimen quantity is collected in future submissions.
21	Unacceptable-Thawed	A sample intended to be received frozen has	All	Accession and	Contact the appropriate

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FAQs / FOPs

-Thanks -

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