H3Africa Consortium Meeting

Biorepository Users Working Group: MTA & Biospecimen release

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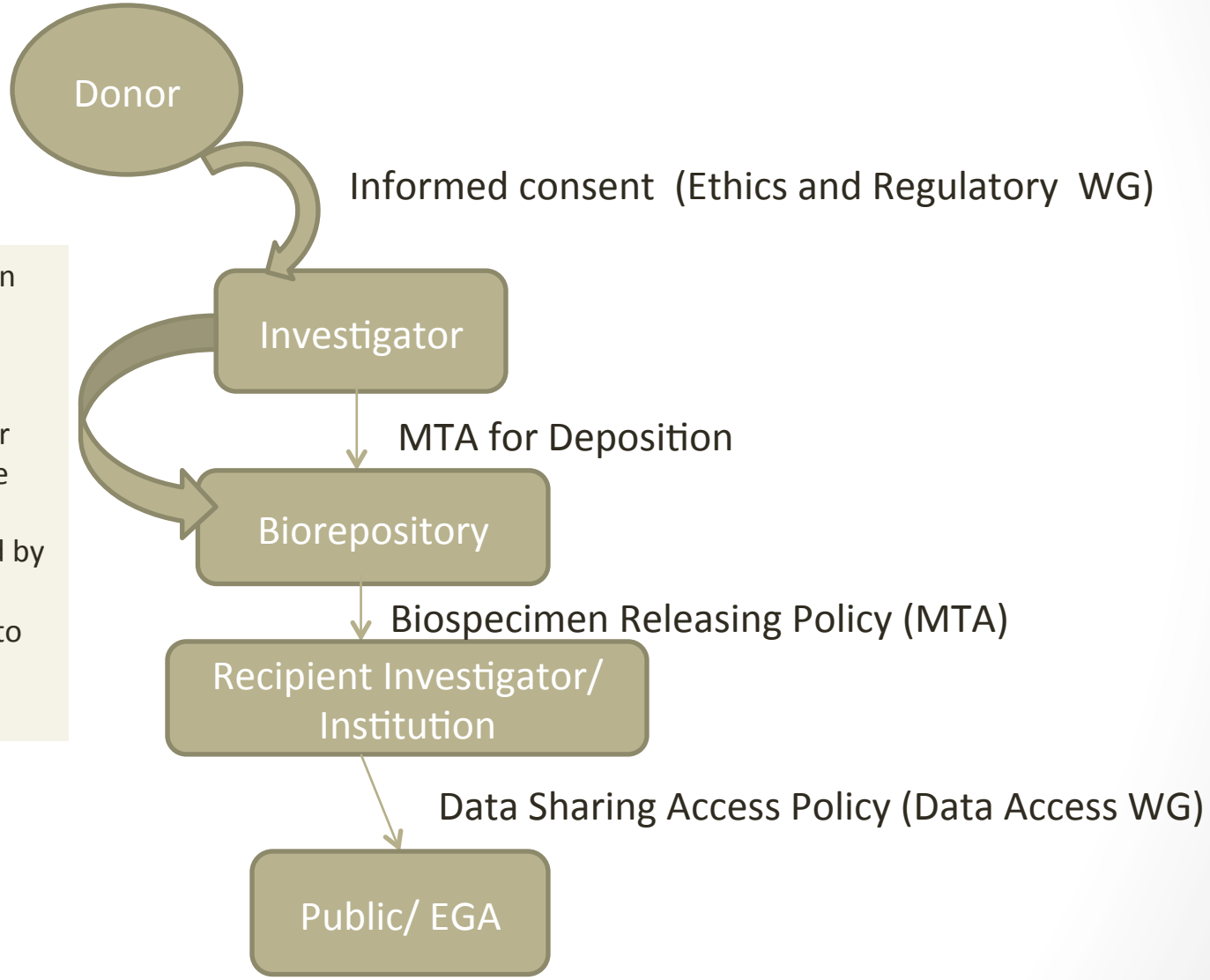
May 16-18, 2013

Accra, Ghana

Flow chart for H3Africa Biorepositories



Different deposition models:

- Retain portion of sample & send portion to bioR for distribution & safe storage.
- Sample processed by biorepository & portion returned to investigator.

Stakeholders

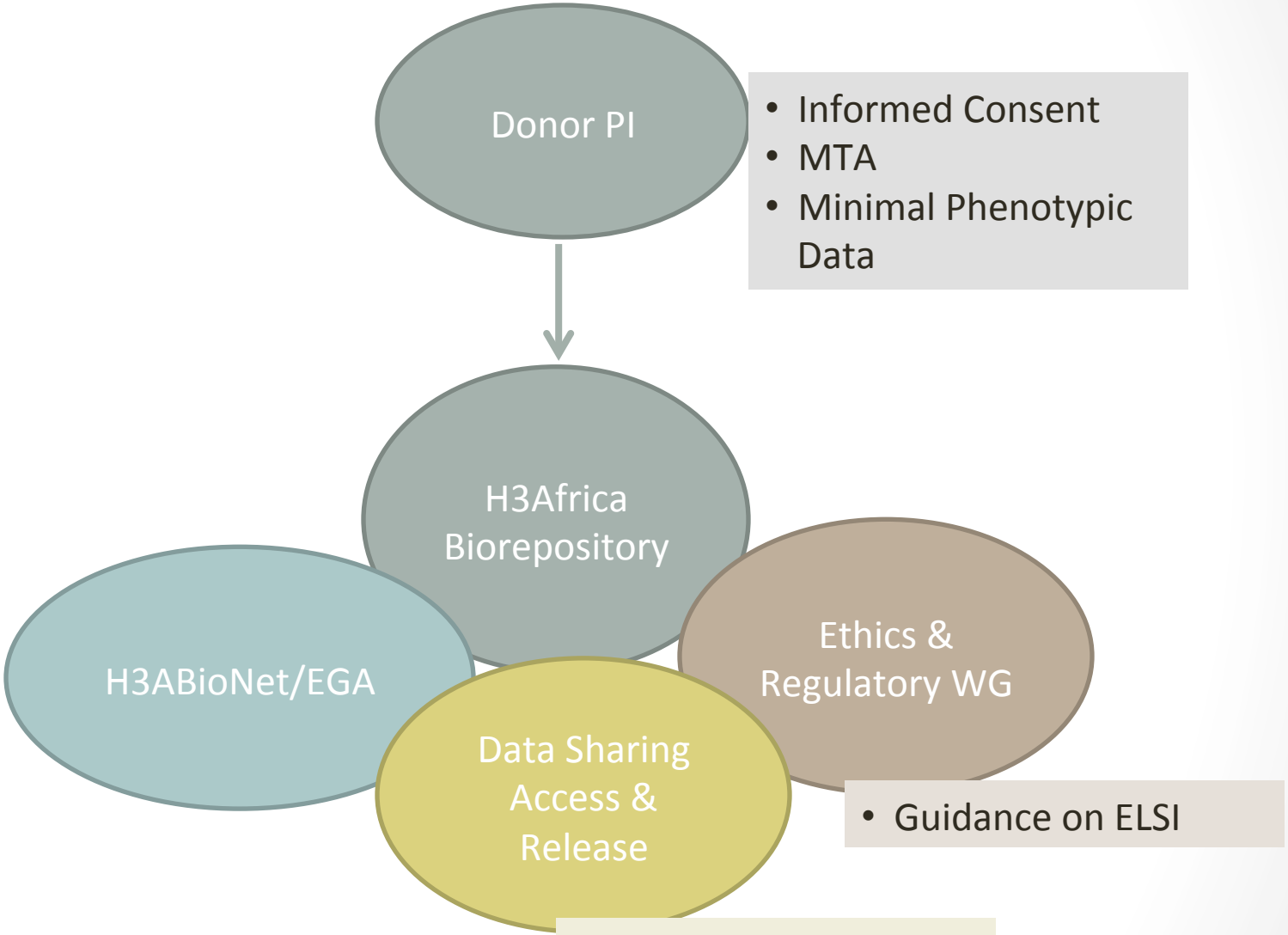
- Who has custodianship of the samples
  - Donor
  - Investigator/Institution
  - Funder
  - Biorepository
  - Scientific User
  - Ethicist/Politician/Government
  - Individual needing/receiving new early diagnostic tests and effective therapies

- **The dynamics of the stakeholder interactions will be influenced by the Informed Consent used by investigators.**
- **The Informed Consent must also include any restrictions on the use of the sample.**
- **The challenge is to BALANCE the interests of the stakeholders.**
- **Develop trust between different stakeholders.**

Governance

- Who will make decision about how the samples will be used
  - **Release policy applies only to the portion of the original biospecimen deposited in the Biorepository**
  - Who is able to receive and use the samples for research
  - For what uses
  - What restrictions apply to use
- How will these decisions be made
  - By donor/investigator/funder
  - By H3Africa Steering Committee (or sub-committee)
  - By H3Africa Biorepository
  - **By a Biospecimen Access Committee (panels of experts: Scientific, Ethical, Biobanking, etc)**
    - **Who sets membership of this group (internal/external)?**
    - **PIs could recues themselves from votes involving their own samples**
    - **Should there be representation from regulatory/governmental sector?**

Cross-talk


Donor PI
• Informed Consent
• MTA
• Minimal Phenotypic Data
H3Africa Biorepository
H3ABioNet/EGA
Ethics & Regulatory WG
Data Sharing Access & Release
• Guidance on ELSI
• Harmonization of access guidelines
• Sample Selection Website?

Regulatory Environment

- Ethical considerations
  - Community Advisory Boards (educating the community, appropriate language, community consensus)
  - Informed Consent
  - National Restrictions on use/distribution
- Transport across international boundaries
  - Shipping requirements and restrictions
  - Customs
  - Dealing through brokers

Patenting & Licensing rights

- The biorepository acts only as a custodian of the sample.
- The biorepository therefore doesn't make any claims to IP generated by academic research groups using specimens obtained from the biorepository. Who does have claims to IP?
- Permission for patenting and licensing will need to be granted by the Provider of the material?
- Patenting of materials themselves and knowledge gained from them is not clear cut.
- These questions need to be addressed in a Biospecimen Release Policy. This should be discussed by Ethics WG and Steering Committee.

Academic vs industry use – considerations for release of biosamples

- H3 Africa intent is to expand the infrastructure of biorepositories; develop best practice standards
  - Recovery of distribution fees will not sustain a biorepository
    - Value added activities may generate revenue to lower cost for H3Africa PIs/Users.
- Fee-for service activities; private agreements; revenue can be reinvested in infrastructure (H3 Africa samples held separate)
- Other government agency funding/NGOs
- Commercial Partnerships - structure and limitations
- Sensitivity to fears of biopiracy/biocolonialism
- “Deep pockets” of industry to speed research
- Industry operates within the regulatory/clinical trial environment and understands what it takes to bring a therapy to the marketplace/bedside.

MTA: An example of restricted use

The ORIGINAL MATERIAL described in the MTA is:

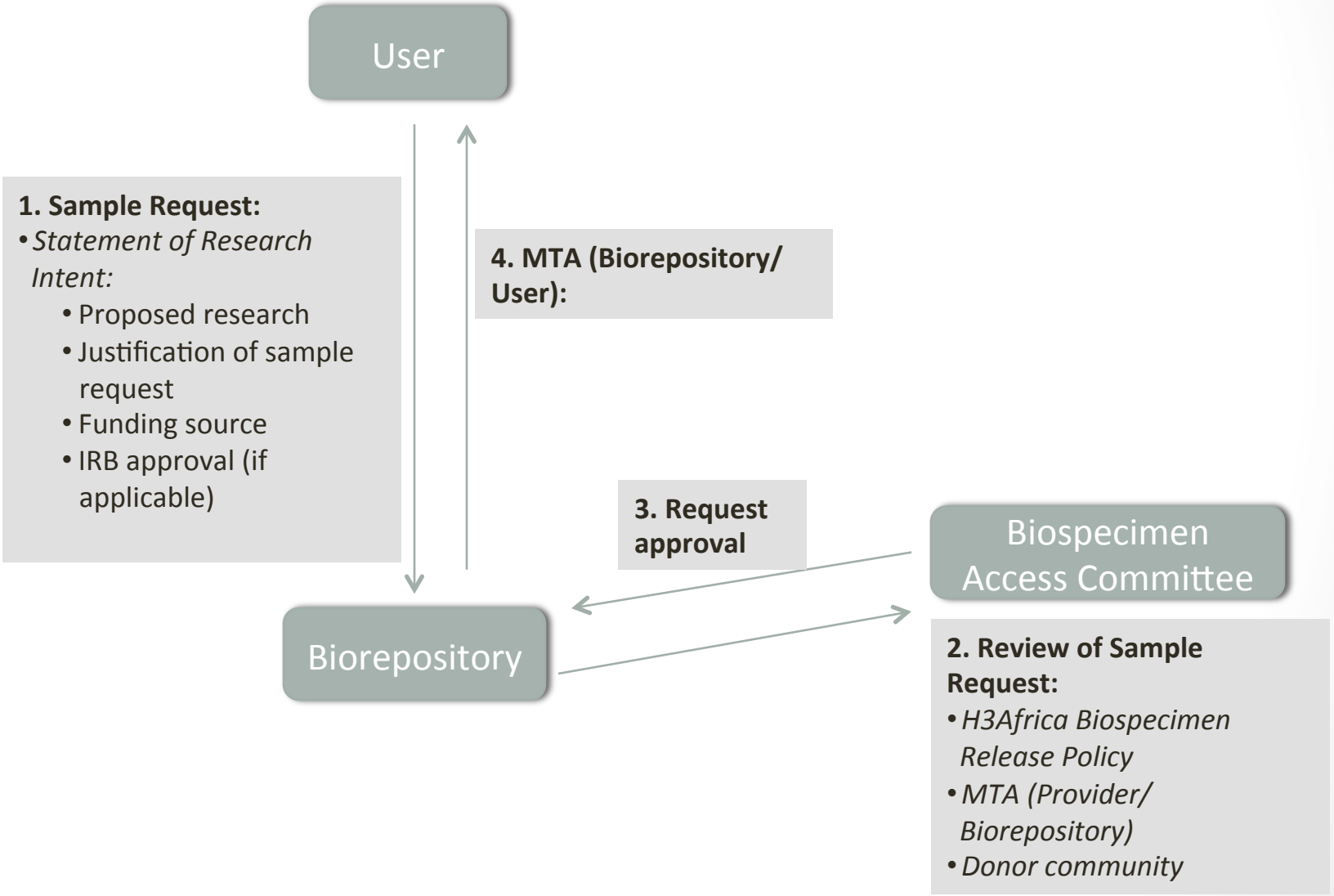
(The biorepository will complete this section depending on the MTA signed by the PROVIDER at the time the ORIGINAL material is deposited in the biorepository.)

☐ restricted to academic research only

☐ can be used for in-house research at academic or commercial institutions. The material CANNOT be redistributed, sold, or transferred to a third party. However, the results of the research (knowledge gained from the research) can be shared according to H3Africa Data Sharing Policies, published, or used to develop commercial products without restrictions.

☐ can be used for in-house research at academic or commercial institutions. Use of the ORIGINAL MATERIAL at a commercial institution is subject to a separate Licensing Agreement between the Biorepository and the RECIPIENT INSTITUTION. The material CANNOT be redistributed, sold, or transferred to a third party. The results of the research (knowledge gained from the research) can be shared according to H3Africa Data Sharing Policies.

Request for Biosample Release



Key Decisions for Development of MTA

- Governance/Stakeholders/Ownership.
- Limitations on use of samples
  - Academic
  - Commercial
  - Commercialization
  - Broad research scope or limited types of research
  - Licensing; who “owns” the IP
- Other ideas for sustainable sources of revenue to maintain repository

Coming Attractions for H3Africa Release of Samples

- Additional Discussion Points
  - Limited life of MTA/renewal options
  - Tiered Access to samples
  - Sliding Fee scale
  - Embargo periods before release of samples
  - Return of data as a condition of sample release

- Policy Statement for Release of Biospecimens for comment
  - September 2013 – depending on participation from H3Africa
- Draft MTA for comment
  - Before the October 2013 Meeting of H3Africa Consortium

And at last….

- This is all about YOUR input

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