Biobanking, Stored Specimens, and Data 1: Consent

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Biobank

- An organized collection of biological material and associated information, which is collected and stored for research purposes
- This presentation focuses on human samples and data

Diversity of biobanks

- Geography: international, national, local
- Population: whole society, ethnic group, specific disease
- Associated data
- Identifiability

Other sources of human samples and data

- Individual research projects
- Collections of individual researchers
- Samples from clinical care

…. overlapping ethical issues for research and sharing

Why share samples and data?

- Optimal use of contribution by research participants
- Increase sample size
- Accelerate discovery
- Reduce duplication

‘The difficulty in procuring samples has been referred to as: “the rate-limiting step” for some genomic research, “a major roadblock to translational research and personalized medicine”, and “the number one roadblock to a cure (for cancer)”’ (Pereira 2013)

Why share samples and data?

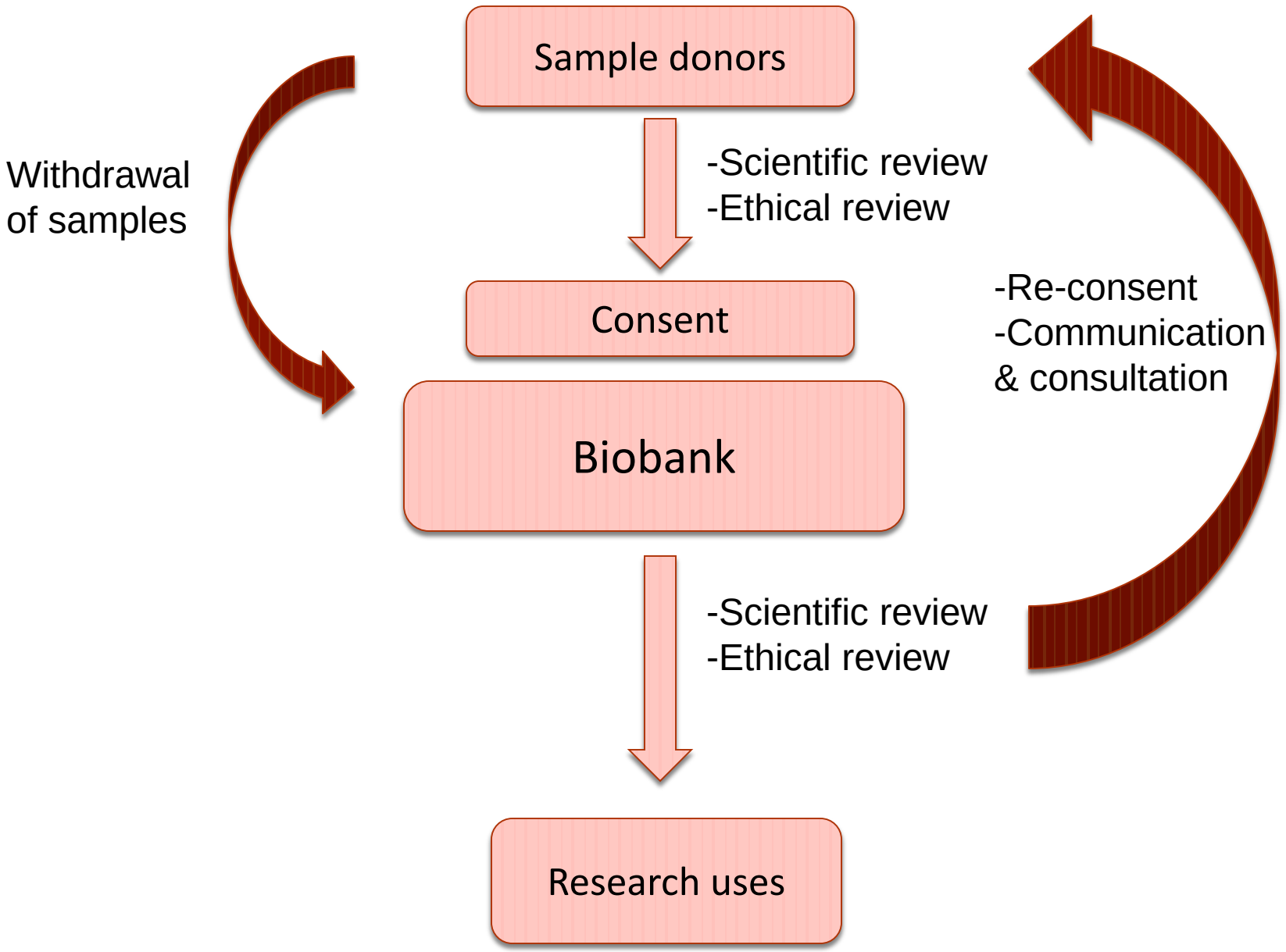
- Increasingly required, e.g.
  - NIH Genomic Data Sharing Policy for large scale genomic data
  - International Committee of Medical Journal Editors require data sharing statement for papers submitting clinical trial data

Ethical and regulatory challenges

- Consent
- Risks to participants
- Access, custodianship, and control of future research

Plan

- Presentation 1: Consent
- Presentation 2: Risks, benefits, and custodianship
- Case discussion: International specimen sharing


Sample donors
-Scientific review
-Ethical review
Consent
Biobank
-Scientific review
-Ethical review
Research uses
Withdrawal of samples
-Re-consent
-Communication & consultation

Consent

Consent 1: Prospective consent

- Obtaining consent for obtaining and storing specimens and data for future research projects

The challenge

- Research participants are typically told about the nature and purpose of the research
- For stored specimens and data this may be unknown

Consent options for future uses

Less burden, less control

More burden, more control

Consent type	Description
No consent	Do not obtain donor consent
Blanket	Consent to future research with no limitations
Broad	Consent to future research with specified limitations
Checklist	Donors choose which types of future studies allowed
Study specific	Consent for each specific future study

(Grady et al. 2015)

What do people want?

- Review of 30 studies with 33,000 respondents
- Most want to decide whether samples are used for research
- Willingness to donate usually not affected by details of research
- Exceptions:
  - Controversial topics (e.g. cloning)
  - Commercial research?
  - Specific populations (e.g. indigenous peoples)

(Wendler 2006)

- “Don’t just take my tissue and use it for diabetes; take my tissue and use it for diabetes to help the Native Hawaiians. That I can agree to…because we don’t have enough studies on us, the Native Hawaiians, so that we can get medicines that complement us.”

(Tauali’I et al. 2014)

Consent 2: Review of new studies

- Ethical review of new research uses ensures on-going respect for donors
- How should review be done?
- Easy case:
  - Donors gave consent to use in research
  - Donors can be identified

Approval of biobank research

Condition	If not met…
The research is valuable	Research cannot proceed
The research is ethically appropriate	Research cannot proceed
The research is consistent with the original consent	Require re-consent
Risks are minimal	Require re-consent
The proposed use does not conflict with donors' fundamental values	Require re-consent

Consistency with prior consent

- Often open to interpretation
- Key question:
  - Would a reasonable donor agree that the proposed use is included in the uses described in the consent?
- Checklists and tiered consent can lead to challenges in interpretation

Conflict with fundamental values

- Likely when proposed research seems to conflict with known values of some group
  - Moral objections to certain research, e.g. cloning
  - Group harms, e.g. propensity to addictive behavior
  - Concerns about distribution of benefits, e.g. commercial uses
- Community representation can help identify conflicts

Re-consent

- Respects donors' rights to decide what happens to their samples and data
- Various possible mechanisms, e.g. in-person, by letter, telephone
- Should emphasize the new aspects of the research
- Need not repeat the whole consent process

Hard case 1: No consent to research

- Samples may be collected for clinical purposes and later be identified as useful for research
- Donors did not consent to research use
- Can research be conducted, anyway?

Declaration of Helsinki

“For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.” (Paragraph 32.)

Hard case 2: De-identified samples

- Spectrum of identifiability:
  - Samples stored with personal information
  - Personal information linked to samples with code
  - No personal information

De-identified samples: Ethical considerations

- Some people think identifiable/non-identifiable distinction is significant
- May make a regulatory difference, e.g. in US
- But participants still care what happens to their samples and their values still deserve respect

  → 5 conditions for approval still apply, except…

…cannot re-consent

De-identified samples

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Should samples be de-identified?

- In favor:
  - Some say that consent is then not needed
  - Risks may be reduced

Should samples be de-identified?

But,

- Majority of people want to be asked about research, whether or not their samples are identifiable (Hull et al. 2008)
- Current technologies for genome analysis make identifiability a matter of degree

- Therefore, de-identification is not a great protection

Should samples be de-identified?

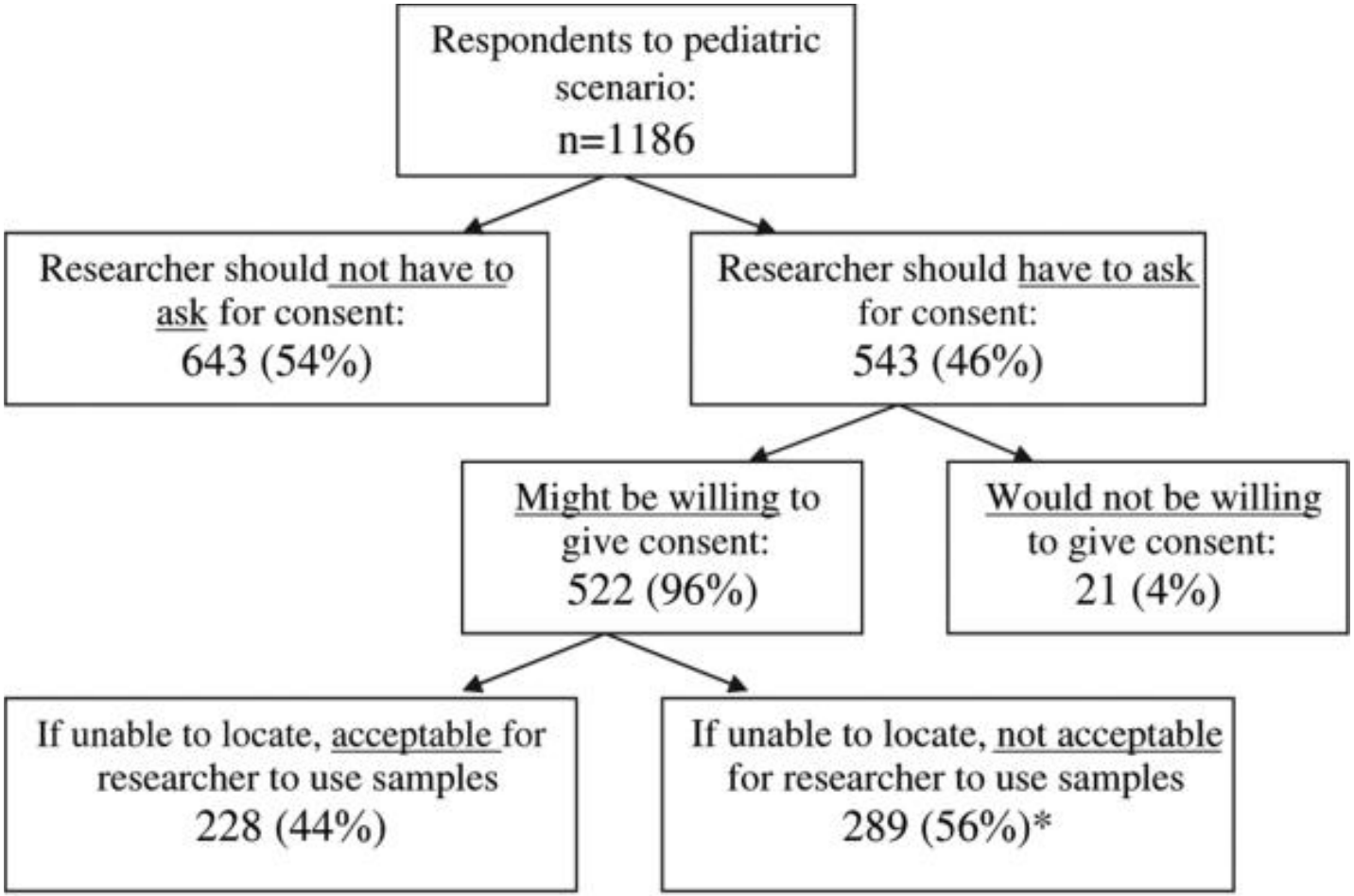
Plus,

- Scientific losses, e.g. not being able to go back to the medical record when new research questions arise
- Losses to participants, e.g. can’t receive incidental findings, can’t withdraw samples

Hard case 3: Pediatric samples and data

- Parents/guardians typically give consent to children participating in research
- If a child participant comes of age while in a study, she is asked for consent to ongoing procedures
- What about consent for new uses of her samples and data?

What do people want?



Goldenberg et al. 2009

Pediatric re-consent

- Shows respect for adults who have their own views about research participation
- Where obtaining consent is impractical it may still be permissible to waive consent

Withdrawal of samples

- Widely agreed that participants may withdraw from research at any time
- Does this include withdrawal of samples?
- If so, biobank should be able to arrange for destruction or return of biological materials, derived data, and personal information
- This does not include removal of individual data from studies or parts of studies that have been completed

Summary

- Broad consent to future use of samples and data is ethically acceptable
- More restrictive policies are also ethical, but there are trade-offs
- Additional ethical challenges
  - No initial consent to research
  - De-identified samples
  - Samples from children who reach adulthood
    - These challenges do not rule out doing research