Informed Consent Challenges: Biobanks & Return of Genetic Results

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Informed Consent Challenges

• Biobanks
  – Collect & store specimens, but vary in their design, scope, and nature of research they support
  – Pre-existing collections or prospective collections
    • Some collections predate informed consent
    • Others are used for research under waivers of consent

• Return of individual results from genetic research
  – Difficult to predict, thus communicate, what may be found
Informed Consent Challenge – Biobanks

- Various consent/notification approaches used by prospective biobanks
- No consent/notification
  - Samples collected for clinical use, and distributed deidentified for research under “waiver of consent”
- Opt-out
  - Typically doesn’t constitute a research grade consent
- Opt-in
  - Respects individual autonomy but in fewer samples than opt-out model
- Consents: tiered, broad, dynamic
Scaling Consent

• Large-scale biobanks becoming more common
• Institution-wide approaches
  – Front door consent
  – Registrar enabled consent
  – Electronic consent
• How to scale up and maintain the rigor around the consent process?
• How much emphasis should we place on consent alone?
Ongoing Education

• Various groups have suggested that summary results of research (aggregate results) should be provided to biobank participants
  – Options: newsletter, website, other outreach
  – Language should identify major findings & study limitations
  – Address this during consent – most want this but some don’t

• Rationale:
  – Demonstrate respect and reciprocity
  – Provide ongoing information after broad consent
  – Provide education about the research process
  – Build trust in research enterprise
Informed Consent Challenge – Results from Genetic Research

• Returning individual genetic research results
  1. Clinically relevant results with significant medical impact (focus area of research)
  2. Incidental/Secondary Findings discovered during the course of research – unfocused, could include anything

• Difficult to predict, thus communicate, what may be found
  – How do you discuss potential risks and benefits?
Return of Genetic Research Results – Consent Considerations

• Should be clear whether research results will be returned, and if so, under what situations
  – Medically actionable most common
• Many advocate that participants should be allowed to set preferences regarding the types of results that may be returned
• Participants should have the option *not to receive results* at the time of original consent & beyond
Return of Genetic Research Results – Consent Considerations

- Information is difficult to communicate, and can take a long time to cover
- Potential for this information to be overwhelming for participants
- Traditional informed consent isn’t well suited for this. Other potential options:
  - Consent for the potential of incidental finding, with more detail provided when participant recontacted
  - Select types of findings at time of consent
Genomic Result Management

- Use of web-based tools
- My46 enables individuals to manage their own genetic testing results
  - Set/revise result preferences
  - View result summary
  - View result report; geared towards healthcare providers

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Questions