Challenges of the Changing Face of Informed Consent: Human Specimen Research

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THEN
NOW
Models of Informed Consent

• Opt- In
  – Requires participant to actively give explicit permission for banking of specimens
  – Respects autonomy but may generate lower participation than opt-out

• Opt-Out
  – Requires participant to actively “opt-out” of having their specimens banked
  – May generate higher participation but may be deceptive depending upon how the option is presented
  – Some individuals may not understand or recognize opt-out option
Disease or Study Specific Consent

• Pros
  – Ensures consent for each study
  – Participants better informed
  – May be most appropriate for some research involving unique risks, research on stigmatizing diseases or for certain populations who might find broad consent unacceptable

• Cons
  – Restricts downstream uses and sharing; limits utility of resources
  – May necessitate additional consent or waiver if researcher later wants to use specimens for new purposes
  – May make decisions about adequacy of consent difficult
  – Potential burdens to researchers and participants
“Tiered Consent”

• Pros
  – Provides greater choice:
    • Eg., requests consent for:
      – Research on diseases under study yes/no
      – Other diseases yes/no
      – Permission for re-contact to participate in yes/no other studies

• Cons
  – Offers more choices for subjects but has many of the same limitations as disease-specific consent
  – Requires more rigorous tracking to ensure choices are honored; tracking and following over time can be very costly
Broad Consent for Future Use

• Pros
  – Allows flexibility in downstream uses
  – Allows for research uses that may not be able to be anticipated at the time of collection
  – Maximizes use of resources
  – Many participants find it acceptable
  – Relatively simple to administer

• Cons
  – Requires balance between being broad enough to permit flexibility vs. specific enough to be meaningful
  – Is it really “informed” consent? Participants unaware of specific uses; any discussion of research risks is vague
  – Some populations might not find it acceptable
Breadth of Consent

Under certain limited circumstances, the HHS and FDA Protection of Human Subjects Regulations at 45 CFR 46.116 and 21 CFR 50.25, respectively, permit an IRB-approved informed consent to be broader than for a specific research study. For example, when obtaining biological or tissue specimens from living individuals to create a repository established and maintained for research purposes, the IRB-approved informed consent document may include a description of the specific types of research to be conducted using the data and specimens maintained for the repository.

[http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp]
In addition, for future research that involves the study of individually identifiable information maintained for the repository, an IRB may determine that the original informed consent for the creation of the research repository satisfies the requirements of 45 CFR part 46 and/or 21 CFR part 50 for the conduct of future research, provided that the future research now being proposed was adequately described in the original informed consent. For some tissue repositories, the specific type of research that may be done in the future on donated biological and tissue specimens was unknown when the tissue was donated but sufficiently anticipated and described to satisfy 45 CFR part 46 or 21 CFR part 50. However, the informed consent information describing the nature and purposes of the research should be as specific as possible.

[http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp]
“Dynamic Consent”

• **Pros**
  - Provides for ongoing engagement of and communication with participants
  - Provides greater choice for participants
  - Participants can decide how much to share and for which projects; interaction tailored to meet individual needs

• **Cons**
  - May work better for certain types of projects than others
  - How well with this model work for certain populations?; need to ensure justice
  - Will participants be sufficiently vested?
  - Potential for additional bias?
  - Feasibility and costs of implementation
Choice of Model

• Is one model ethically superior to others?
  – “[a]s long as consent processes are equivalently effective in informing individuals about what they are consenting to, and as long as they do not unduly shape or undermine individuals’ ability to make genuinely voluntary choices, there is no philosophical or ethical imperative to use one kind of consent process over another.”


• Choice of model may be context-specific
Beyond Informed Consent

• How much can/should we rely on informed consent for future use of specimens and data?
• “Consent can’t do all the work”
• From consent to surrogacy¹
• Education, participant engagement and transparency important
• Need strong privacy protections and mechanisms for ensuring that uses of specimens are scientifically and ethically appropriate
• Good governance and oversight mechanisms are critical

¹Mongoven and Solomon, Genetics in Medicine, Feb. 2012
Summary and Conclusions

• Changes in the research environment and broad specimen and data sharing present challenges to traditional models of informed consent.
• Other models of informed consent may be appropriate depending upon the research context.
• Emerging consensus that broad consent is generally acceptable and appropriate for much specimen and data sharing, however good governance and oversight mechanisms are critical.