Returning Results To Participants

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Background

Conditions & Assumptions

- Half million to a million people in cohort
- Distributed through several different environments
- Will measure environmental exposures of many sorts, along with genes/alleles, gene expression, proteomics, epigenetics, etc.
- The project **will generate much clinically and personally relevant info** (some genetic and some not)

Resource vs Studies

- Build a resource = collect…
  - Specimens
  - Data, data, data
- Follow-on studies use the resource
  - Will generate more information about participants

- Resource development vs follow-on research differ in respects that may matter for the ethical and pragmatic analysis re. returning results:
  - Proximity of researchers to participants (temporal and spacial)
  - Type of information obtained and generated
  - Regulatory regime and how it applies

Returning Results – No Ethics Consensus

The Spectrum

- Don’t return any individual results
- Return a very limited set of clinically-relevant results
- Return much/any clinically relevant info
  - Where does reproductive info fit?

Why not return individual results?

- **Clinical validity has not been established**
  - Balance of harm-benefit more likely to tilt in favor of not returning individual results, costs of sharing non-validated or ambiguous information are high (e.g., time, difficulty of interpreting results) therefore the information cost is high
- Want to increase confidentiality/privacy protections
- Relationship of research and researcher to participant is distant in time and/or(?) space—
  - E.g., Temporal distance may decrease the utility of the information, may increase the emotional costs to participants of receiving info, may increase $$ cost of returning information, may be impracticable.
  - Value of reciprocity between those who have a relationship
- Helps maintain cognitive & legal distinction between research and medicine

Return some individual results

- Which results?
- To Whom?
- How?
- When

Which results?

- Wide agreement that researchers should not return results unless they have **analytic and clinical validity**

- Reasons in favor of returning results are stronger when the results in question:
  - Have serious medical implications for the participant
  - Would change medical management
  - Are unlikely to be discovered through routine medical care
  - More robust relationship btwn ppt-researcher means → value of reciprocity has greater weight
  - Respect for participants???

Which Results Continued…

- Does the nature of the research provide reasons for returning results or create obligations to return results?
  - Does it matter whether the findings were—
    - expected and were the focus of the research?
    - incidental but foreseeable?
    - incidental and unforeseeable?
  - Do researchers ever have a duty to look for clinically relevant info that is not relevant to or the subject of their particular study, but which is likely in their data set?
- Is there a right not to know?
  - Existing recommendations say “yes” and most ethicists probably say “yes,” but some clinical researchers say “no.”

Propose Three Categories

- Category I: obliged to report back
  - No matter what the focus of the research
  - No matter who the researcher
    - No agreement on obligation to search for this info
- Category II: permissible to report back
- Category III: impermissible to report back

How—General Principles

- Method depends on category
- The process of reporting back should be planned out as part of protocol
  - Approved by IRB
  - Included in consent process and forms
  - **Person with relevant expertise** must be involved in the reporting back
- For genetics: validation in CLIA-approved lab is necessary (when???)

How?

- Category I:
  - Initial contact re. individual results invites participant into a discussion
    - Must be followed up with vigor
  - Every effort must be made to have face-to-face delivery of information
  - No obligation to provide follow-up medical services, but researchers should provide information on how to follow up and provide referrals when possible

How?

- Category II:
  - Have a plan up front
  - Need a DSMB or similar entity to help researchers decide which unanticipated results are significant (enough) and well-validated (enough) to be reported back
- In cat I or II: for unexpected findings that should be reported, if researcher has to obtain linking info or cross an info firewall then she/he should make these decisions in conjunction with the IRB

When

- Duration of any obligation to report individual results? Duration of permissible reporting?
  - Data may exist for many years without being analyzed, new implications are discovered for old or existing data
  - Report in a timely manner from time data are obtained

  – Obligation for Cat. I exists for as long as study is active? (active = samples being collected and data analyzed)
    - Does “active” mean so long as the data set and linking info exists?
    - Who has the obligation?
    - Does the obligation diminish over time?

Who has the responsibility?

- Person who made the discovery?
  - When follow-on research is done under an agreement that no linking info will be transmitted to researchers from the resource, who should report to participant and how?
- Resource?
- Institution that houses resource or investigator?

To Whom

- Give participants options
  - Participant
  - Doc
  - Nobody (the right not to know)
- Families… NO, not by researchers/project
  - If the info has relevance for genetically related individuals the participant should be told
- Should researchers make efforts to identify a participant so that they can report back Category I results?

Final Thoughts

- Much reporting back is mostly about permissibility and not obligation
  - Opportunity for participant/community input
  - Opportunity for ethics experimentation
- Reporting back intersects with questions about who is included…
  - If participants are not insured can reporting back ever provide a benefit?
- Reporting back adds lots of $$ so there will be trade-offs between reporting back and data collection, numbers of participants, etc.