

# Returning Results to Participants in Genetic Research Studies: Ethical Considerations

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# Return of Results

- Little guidance available in applicable laws, regulations, or ethical guidelines
- Lack of agreement regarding approaches among researchers, funding agencies, and IRBs/ethics committees
- Issue of growing importance as the pace of genetic research accelerates

# Three Approaches

- Disclose (almost) nothing
- Disclose (almost) everything
- Balancing/contextual approach (or other alternative approach)

# The Disclose (Almost) Nothing Approach

- “Research-Focused Approach”
- The traditional approach in genetics research
- Exceptions:
  - Very rare circumstances where failure to disclose would pose a certain and near-immediate threat to health or life
  - Aggregate study findings (via newsletters, websites, etc.)

# Rationale for the Research-Focused Approach

- Distinction between goals of research and goals of clinical care
- Ethical principle of Justice
- Risk of actual harm to (some) participants
  - Anxiety or distress from learning information they cannot handle
  - Lack of resources for follow-up interventions or counseling
  - Therapeutic/diagnostic misconception
- Practical issues
  - Resources/capabilities of researcher
  - Logistics of providing referrals, maintaining contact for long-term (potentially open-ended) follow-up, etc.
  - Potential legal liability

# Problems with the Research-Focused Approach

- May violate the ethical principles of—
  - Beneficence
  - Respect for Persons
  - Reciprocity
- Arguably paternalistic; may reinforce notions of “genetic exceptionalism”

# The Disclose (Almost) Everything Approach

- “Autonomy-Focused Approach”
- The growing trend in genetics research
- Exception: The right not to know

# Rationale for the Autonomy-Focused Approach

- Consistent with ethical principles of Beneficence, Respect for Persons, and Reciprocity
- Treats genetic research more like non-genetic research (where there is also a growing trend toward increased disclosure)

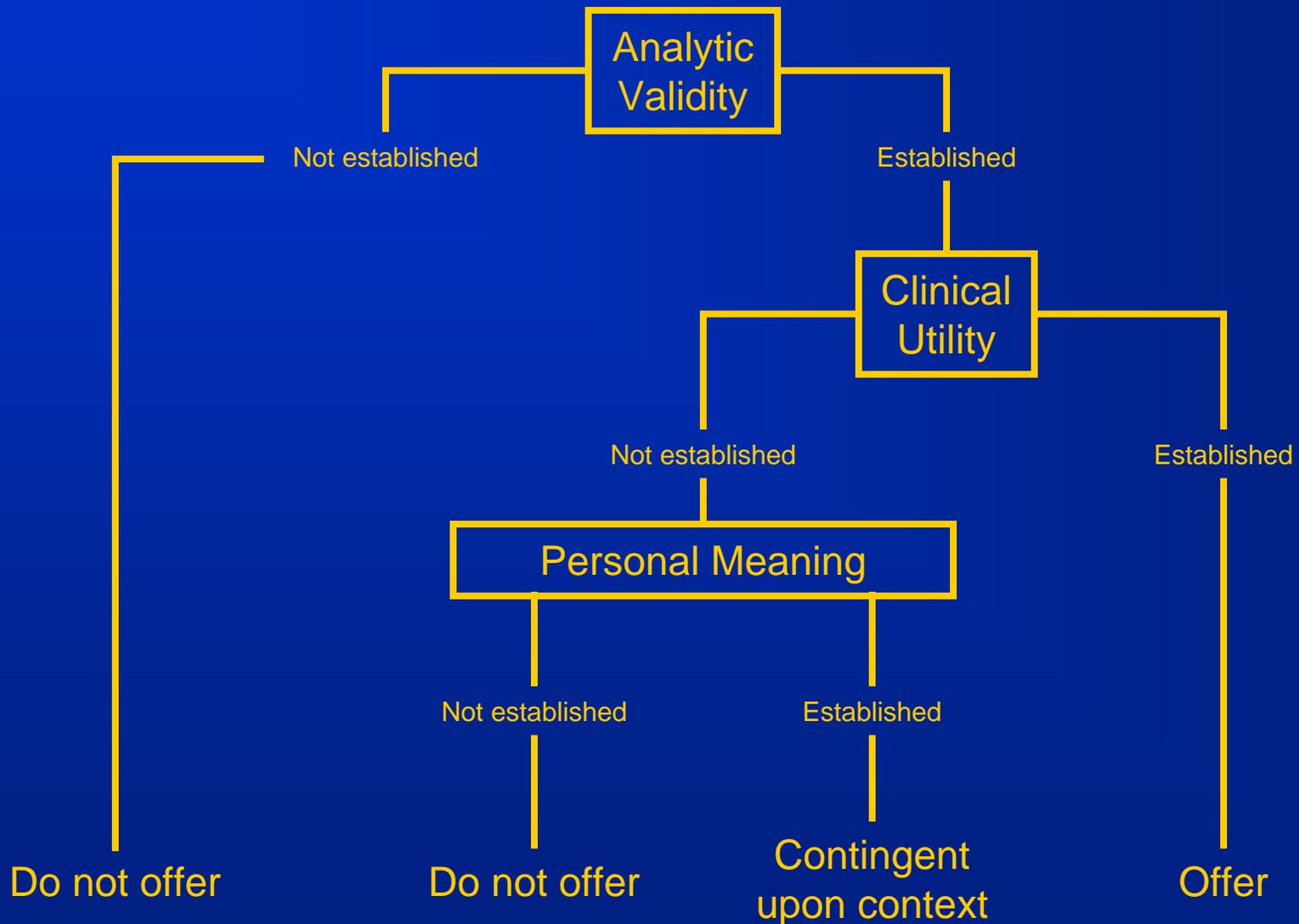
# Problems with the Autonomy-Focused Approach

- Blurs the line between research and clinical care
- May in some cases raise challenges to the ethical principle of Justice
- Risk of actual harm to (some participants)
- Practical issues

# The Balancing/Contextual Approach

- “Results Evaluation Approach”
- Effort to incorporate the most favorable aspects of the other two more extreme approaches
- Requires an examination of:
  - the nature of the information generated in the study
  - the context in which the study is conducted

# Nature of the Information



# Contextual Considerations

- The researcher's capabilities
- The participants' alternative access
- The relationship between the investigator and the participant

# An Alternate Approach: Determining Each Participant's Preferences

- Participants select the general circumstances for disclosure before the research is conducted, using a tiered process
  - Results with reproductive significance, diagnostic significance, treatment significance
  - Nature/severity of condition
  - Preferred method(s) of disclosure
  - Length of time for which disclosure is desired
  - Notification of family members in event of death
- Objective criteria developed by the researcher are applied after the research to determine whether the research finding satisfies the subject's expressed preferences

# Problems with the “Preferences” Approach

- Difficult for participants to understand the implications of various types of disclosure
- Preferences can change over time
- Significance of the information can change over time
- Increased potential for mistakes, miscommunications
- Increased potential for legal liability

# A Few Points of General Agreement

- Issue of return of results should be carefully considered from the outset of the research and communicated to the relevant IRB or ethics committee, so that the appropriateness of the plans can be assessed
- Plans for handling return of results should be clearly communicated to participants as part of the informed consent process
- A clear need for more social science/behavioral research in this area