The Consent Process: Best Practices

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The views and opinions expressed in this presentation are my own, and do not necessarily reflect the opinions or determinations of the HRPO, HRRC, UNM Health Sciences or any other entity.
About me

• HRRC Manager, UNM HS HRPO
• Certified IRB Professional (CIP®) (2016)
• PhD, Anthropology, U of Michigan (2012)
  • Additional research experience: Linguistics, Education, Psychology
Overview

• Ethical background of consent process
• Autonomy as central to the Consent process
• Special populations/research situations
• Practical aspects of the consent process, with recommendations for improvement
The Consent Process: Best Practices

- Consent: Process, not just form
- Regulatory requirements vs. implementation
- “Best Practice” vs. better practice
Ethical background

• 3 principles of human subjects research regulation:
  • Respect for persons
  • Beneficence
  • Justice
Ethical background

• Respect for persons: Autonomy
Ethical background

• Respect for persons: Autonomy
• Autonomy central to consent process
• Autonomy in consent process:
  • Capacity
  • Comprehension
  • Voluntariness
Autonomy: Capacity

- Capacity to provide consent
Autonomy: Capacity

• Capacity to provide consent
  • Understanding:
    • Purpose of study
    • Appreciation of risks and benefits
  • Reasoning ability: Weighing risks/benefits
  • Ability to communicate choices

(Weissinger and Ulrich 2019)

Weissinger, G.M. and C.M. Ulrich. Informed Consent and ethical reporting of research in clinical trials recruiting participants with psychotic disorders. *Contemporary Clinical Trials.*
https://doi.org/10.1016/j.cct.2019.06.009
Autonomy: Capacity

- Capacity to provide consent
  - Limitations:
    - Legal: age, incompetence
    - Medical: Conditions that interfere with cognition (temporary or permanent)

(Weissinger and Ulrich 2019)

Weissinger, G.M. and C.M. Ulrich. Informed Consent and ethical reporting of research in clinical trials recruiting participants with psychotic disorders. *Contemporary Clinical Trials.*
https://doi.org/10.1016/j.cct.2019.06.009
Autonomy: Capacity

- Capacity to provide consent
  - Even in research with populations at high risk of temporary or permanently cognitive impairment, capacity to consent to research participation is not assessed reliably
    - High-risk research involving individuals with psychotic disorders: 5.3% reported assessment of capacity, only half of these used standardized assessments (Weissinger and Ulrich 2019)

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Autonomy: Capacity

• Assessing capacity: Practice recommendations
  • Establish assessment process (who, how, when/where)
    • Ongoing assessment if participants may have temporary impairment
  • Use standardized assessments, especially in high-risk populations (Sturman 2005)
  • Obtain assent to the degree that impairment allows

Autonomy: Comprehension

• Comprehension
Autonomy: Comprehension

• Comprehension
  • Health/scientific ‘literacy’
  • Literacy
Autonomy: Comprehension

- Health/scientific ‘literacy’
  - Therapeutic misconception
    - Limited comprehension of aims of treatment vs. aims of research
  - Therapeutic misestimation
    - Over-estimate benefits, under-estimate risks
    - Unrealistic optimism
      (Miller and Joffe 2013)

Autonomy: Comprehension

• Health/scientific ‘literacy’
  • ‘Cutting edge’ research
    • Genomic/biobank research
      • Results have implications beyond the individual tested
        • Conflict between individual and communal benefits/risks
      • Scientific progress may change the information that can be obtained from samples in the future
      • Participants have particularly poor understanding of this type of research (D’Abramo et al 2015)

Autonomy: Comprehension

- Health/general ‘literacy’: Practice recommendations
  - Role separation: Care provider vs. investigator (Atz et al 2014)
  - Clearly separate discussions of SOC treatment from discussion of research intervention (in consent process and in consent documents)
  - Assessment tools for voluntariness/therapeutic misconception (Joffe et al 2001; Miller et al 2009)


Autonomy: Comprehension

• Health/general ‘literacy’: Practice recommendations
  • Use formal assessments to check for participants’ comprehension of the research

• Biobank/genomic research:
  • Provide options for future use of biological specimens (D’Abramo et al 2015)
  • Community engagement (May et al 2014)


Autonomy: Comprehension

- Literacy (ability to read and understand written language)
Autonomy: Comprehension

- Literacy (ability to read and understand written language)
  - Consent documents
  - “The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.” (45CFR46.116)
  - Reading comprehension level: 8th grade reading level
Autonomy: Comprehension

- Literacy: Consent documents
  - Regulatory requirement
    “The consent form, and the consent process, should provide subjects with the information needed to make an informed decision about whether to participate.” (2018 Common Rule)

Autonomy: Comprehension

• Literacy: Consent documents
  • Real-world:
    • Length of consent documents has been increasing, not decreasing
    • Longer consent documents can have negative effect on understanding

(Corneli et al. 2017)

Autonomy: Comprehension

- Literacy: Consent documents
  - New regulatory requirement (2018):
    Key information about the study must be provided at the beginning of the consent document.

Autonomy: Comprehension

- Literacy: Consent documents
  - Key information
    - Science behind the study
    - Trade-offs for participant
    - What will happen
    - Side effects: How bad, how likely/often
  (Schwartz and Woloshin 2018)
Autonomy: Comprehension

- Consent documents: Practice recommendations
  - Reading level:
    - Use online resources (dictionaries of medical terminology and lay language, ‘calculators’ of reading level of documents)
  - Shorten consent documents
    - Remove redundancy (elements of consent in key information section, group procedures by frequency, group side effects by commonality)
    - Organize the document (key information, appendices)
  - Consult with target population/community members

(Corneli et al 2017)

Autonomy: Voluntariness

- Autonomy to provide consent: Voluntariness
Autonomy: Voluntariness

• Voluntariness
  • Coercion
  • Undue influence
  • Dynamics of interaction
**Autonomy: Voluntariness**

- Voluntariness: Dynamics of interaction
  - Vulnerability (“naked and afraid”)
    - (hospitalized) patients are sick
    - Don’t understand what’s happening
    - “will do whatever the people in white coats ask of them to get well”

(Annas 2018)
Autonomy: Voluntariness

- Voluntariness: Dynamics of interaction
  - Variations in individual and community values regarding communication with authority figures, especially medical personnel
    - “White Coat syndrome”
Autonomy: Voluntariness

- Voluntariness: Dynamics of interaction
  - “Nudging”
    - In clinical care: Provider knows what’s best for the patient
    - In clinical research: Conflict between researcher’s and participant’s best interest
Autonomy: Voluntariness

- Voluntariness: Practice recommendations
  - Consent process: timing, location, person obtaining consent
  - Use decision aids (Fagerlin 2018)
    - Provide accurate, balanced information
    - Clarify patients’ values
    - Improve shared decision-making (Fagerlin 2018)
  - Confirm ongoing consent as research continues
  - Consult with community
    - May have its own authority figures

Fagerlin, A. The Role of Decision Aids in Assessing Understanding and Integration of Information. Meeting New Challenges in Informed Consent in Clinical Research. September 7, 2018
Consent Process: Special populations

- Conducting the consent process with special populations
Consent Process: Special populations

• Conducting the consent process with special populations
  • Children
  • Cognitively impaired
  • Non-English speakers
Consent Process: Special populations

• Conducting the consent process: Non-English Speakers
  • Comprehension: Translation
Consent Process: Special populations

• Conducting the consent process: Non-English Speakers
  • Comprehension: Translation
    • Use of translators in consent process
      • Professional interpreters
      • Family members
Consent Process: Special populations

- Conducting the consent process: Non-English Speakers
  - Comprehension: Translation of consent documents
    - Speaking a language ≠ literacy
Consent Process: Special populations

- Conducting the consent process: Non-English Speakers
  - Comprehension: Translation of consent documents
    - Regulatory requirement:
      “The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.” (45CFR46.116)
    - Regulatory options:
      - Fully translated consent form
      - Short form of consent “stating that the elements of informed consent required by 46.116 have been presented orally to the subject or the subject’s LAR, and that the key information required by 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. (45CFR46.117)”
Consent Process: Special populations

• Conducting the consent process: Non-English Speakers
  • Comprehension: Translation of consent documents
    • Regulatory requirements
    • Regulatory options: Full translation vs short form of consent
      • FDA guidance: Short form is appropriate only for unexpected enrollment of non-English speakers
      • Respect for persons, beneficence and justice

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent#nonenglish
Consent Process: Special populations

• Non-English Speakers: Practice recommendations
  • Adequate resources:
    • Consent document
    • Consent process
  • Justification for excluding non-English speakers
The Consent Process: Best Practices

• Concluding remarks
  • Clinical research differs from clinical care, so the consent process for each also differs
  • Consent is a process: Consent document as the starting point, not the end
  • Both researcher and participant bring their own ideas, values and goals to the table to engage in a complex dynamic in the consent process
  • Regulations are the basis for approvability of a particular consent process, but do not capture the complexities of the consent process that may need to be considered for different types of research
The Consent Process: Best Practices

- Questions?
- Comments?
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