Navigating the Research Ethics Application Process

continued...

Focus on:
Recruitment, Consent, Power Over and Conflict of Interest

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Recruitment

- Participant eligibility
- Permission to contact
- Who is doing the contact?
- How? - Method

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Consent Process

www.youtube.com/watch?v=8ypYeK8L-DQ

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Informed Consent

- Is a Process…
- Is Dynamic…

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Informed Consent – General Issues

- Must be obtained prior to involvement in research.
- Participant (or representative) must have sufficient time to consider and ask questions
- The possibility of coercion or undue influence must be avoided
- Language should be readable, non-technical and easily understandable
- Should not contain exculpatory language (i.e. wavering subject's legal rights)

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Special Considerations

- Vulnerability
- Competency
  - Full
  - Variable
  - Diminishing
- Language
  - Translation & privacy

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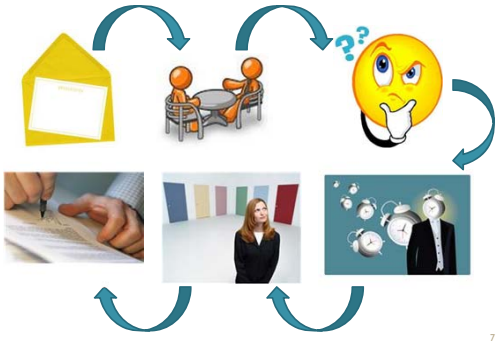
Consent Process



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Ethical Considerations

- Safety – Risk/Benefit
  - Degree of risk
  - Likelihood of risk
- Burden
  - How invasive are the procedures
  - Time involvement
- Compensation
- Use of data
- Dissemination of findings
- Identity protection

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Who Consents?

From the Research perspective:
- Principle Investigator
- Research Coordinator

From the Participant's perspective:
- Participant
- Surrogate
- Proxy

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"Paradox of the Investigator-Participant Dependency"

Clinical/investigative equipoise

"…constant tension between the needs of the researcher and the rights and humanity of the subject". Wolpe. R (2010), The Monitor, Vol 24, 2

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Informed Consent – Required Elements

1. Purpose & Objectives
2. Importance of the research
3. Participant selection
4. What is involved
5. Participant's responsibilities
6. Inconvenience
7. Risks & Reasonably expected benefits (or not)
8. Voluntary Participation

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Informed Consent – Required Elements continued

9. Compensation
10. Researcher's relationship to the participant
11. On-going consent
12. Anonymity/confidentiality
13. Dissemination of results
14. Commercial use of results
15. Disposal of data
16. Contacts

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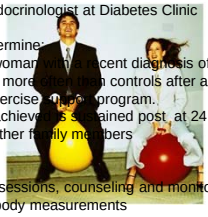
Group Exercise

Study: Intervention for family-centred diabetes prevention following gestational diabetes

PI: Dr Sweet, endocrinologist at Diabetes Clinic



Purpose: To determine:
1. If overweight woman with a recent diagnosis of GDM can achieve a 7% weight loss more often than controls after a 12 month targeted education and exercise program.
2. If any benefit achieved is maintained post at 24 months and transferrable to other family members

Study Methods:
4 visits (learning sessions, counseling and monitoring)
Blood work and body measurements
Recording in food diaries and questionnaires
Participation in a weekly ½ hr Mom & Babe Walking group
24 month follow-up T/C

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Key Considerations

- Nature of the relationship
- Rational for doing research
- Built in safeguards
- Informing the participant

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Conflict of Interest

Definition (TCPS2):
A conflict of interest may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. (Chapter 7, pg 89)

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Forms of Conflict of Interest

- Institutional
  - Strategic Incentive
  - REB Member
- Researcher
  - Dual Role
  - Financial
  - Prestige/recognition

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Ways to Mitigate

- Removal from the conflict
- Full disclosure
- Objective oversight

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Dr Nancy Olivieri

Medical whistleblower Nancy Olivieri awarded honorary degree at Dalhousie University- May 30, 2012

http://www.youtube.com/watch?v=dKL4UJW0Qeo&feature=results_main&playnext=1&list=PL39C5DDA85DB8387F

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Any Questions?

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