

## Informed Consent: Federal Regulations, Institutional Policy & Good Practice

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## Belmont Report

“...respect for persons demands that subjects enter into the research voluntarily and with adequate information.”

- Nuremberg Code; Declaration of Helsinki
- HHS: 45 CFR 46.116 (a) 1-8 & (b) 1-6
- FDA: 21 CFR 50.25 (a) 1-8 & (b) 1-6

## Consent

- A process of information exchange that takes place between the prospective subject and the investigator, before, during and sometimes after the study
  - Written materials (consent form, letters, brochure)
  - Verbal instructions/explanations
  - Q & A
  - Periodic reaffirmation/re-consent

## Elements of Informed Consent

### Required

- Introduction\*
- Purpose
- Description of Study Procedures
- Risks/Discomforts
- Benefits
- Alternatives to Participation
- Confidentiality of Records\*
- Contact Persons\*
- Voluntary Participation Statement\*
- Statement that subjects will receive a signed copy\*

### Additional\*\*

- Payments
- Costs
- Number of Subjects
- Probability of Random Assignment
- Circumstances for Withdrawal (by the investigator)
- Funding
- Conflict of Interest

\* See RSRB Consent Document Templates for standard language  
\*\* Additional elements may apply depending on the nature & risk level of the study

## Consent Issues In Research Involving Minors

- Combination of assent (agreement) of child and permission of the parent or legal guardian
- If either refuses, the child cannot be enrolled

## Consent Issues In Research Involving Minors – Federal Regulations

- IRB shall determine that adequate provisions are made for soliciting the:
  - Assent of the child
    - Age, maturity and psychological state
  - Permission of each child's parent/legal guardian
    - IRB may find that permission of one parent is sufficient based on risk level assigned to study
    - Usually...if determined to be minimal risk, permission from only one parent is required
    - If both parents required..."both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility..." (45 CFR 46.08[b])

## Consent Issues In Research Involving Minors – Federal Regs & /UR Guidelines

- Regulations: IRB shall determine how assent must be documented...
  - UR Guidelines for Documentation
    - 7 and under
      - Parent Permission; No assent required
    - 8-12 year olds
      - Parent Permission & Verbal Assent
    - 13-17 year olds
      - Parent Permission & Written Assent
- \*\* Assent permits subjects to opt out if parent(s) opt in

## Alterations of the Consent Process

- Waiver of Documentation of Consent
  - May permit if:
    - Minimal risk & does not involve procedures for which written consent is normally required
  - OR -
  - Only record linking the subject and the research is the consent document
- RSRB may require investigator to provide subjects with a written description of the study
  - Verbal Consent; Information Sheets

## Alterations of the Consent Process

- Waiver of Consent for Deception Research

Deception = Intentionally misleading subjects or withholding information about the nature or purpose of the experiment

- Must be scientifically & ethically justified
- Minimal risk only

→ Because subjects are not provided all information they can't truly consent ...use Consent to Procedures prior to the start of study participation & Consent to Data Use after debriefing

\*\* See RSRB Investigator Guidance & APA Guidelines

## Alterations of the Consent Process

- Waiver of Consent for Deception Research
  - Consent to Procedures
    - Reveal as much as possible without threatening ability to test the hypothesis
    - Include what subjects will be asked to do, risks associate with study activities, payments (or other rewards), opportunity to withdraw, opportunity to ask questions, contact information
    - Missing info should not increase risk
    - Do not include untruthful information

## Alterations of the Consent Process

- Waiver of Consent for Deception Research
  - Consent to Data Use
    - Debrief as soon as possible
    - Include full description of ways in which deception was used, opportunity to withdraw without penalty & a permission statement to use data... *if no, data provided by subject must be destroyed*
    - \*\*Principal Investigator is responsible for ensuring that the subject leaves the research setting with an accurate understanding of the deception

## Recruitment



Cartoonist: Don Mayne ([www.researchcartoons.com](http://www.researchcartoons.com))

## Recruitment

- Direct advertising considered part of the informed consent process
- Includes: websites, newspaper ads, radio ads, TV ads, flyers, brochures, telephone scripts, recruitment letters
- Must be reviewed by the RSRB
  - Coercive?
  - Imply favorable outcome?
  - Consistent with protocol & consent?
  - Benefits beyond what is outlined in the consent & protocol?
- Psychology Research Pool

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## Writing Consent Documents

- Must be understandable to the subject population
  - If you anticipate enrolling even one subject who does not speak English, RSRB requires that a translated document be submitted for review
- Use lay terms
- Information must be consistent with the study protocol and RSRB application
- Write as if you were talking to the subject
  - “You will be asked to...”
- Check to make sure items are in a logical order (start at the beginning; end at the end)
- Use consistent terminology

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## Writing Consent Documents

- Use subheadings, white space, bullets to improve readability
- Use pictures, graphics, tables, lists or charts to help clarify procedures/schedules
- Use at least a 12 point font
- Aim for nothing higher than an 8<sup>th</sup> grade reading level
- Keep words to 3 syllables or less
- HINT: Work off of a previously approved consent for a similar study

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## The Consent Process



Cartoonist: Don Mayne ([www.researchcartoons.com](http://www.researchcartoons.com))

**\*\* THE PAPER IS NOT THE PROCESS\*\***

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## The Consent Process

→ Recruitment, Presentation & Provision of Additional Info

- Minimize undue influence
  - Seek consent in a private setting
  - Consider method → delegate consent to appropriate study team member; use drop box for anonymous surveys
  - Consider alternatives to participation
- Follow your protocol
  - Who, What, Where, When & How?
- Don't rush the process
- Consider vulnerable populations
- Use additional aides – videotapes, brochures, etc.
- Answer questions & ask open-ended questions
- Ongoing process → before, during & after

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## RSRB Expectations

- University's expectations regarding the consent process are outlined in the RSRB approval letters
  - Comply with the protocol approved by the RSRB
  - Only consents bearing the RSRB watermark may be used
  - Only the most recently approved version of the consent (or recruitment document) may be used
  - Consent forms/recruitment letters must include department letterhead
  - PIs are responsible for maintaining signed consent forms for 3 years after the research is completed (or longer if required by FDA, sponsor, etc.)
- Expectations the same regardless of risk involved in the study

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## Documentation of Consent

- Make sure you're using the correct document
  - Consent or Permission; Written Assent or Verbal Assent
  - Control/Experimental Consent
- Signature/Date required from the subject and the person obtaining consent
  - Generally speaking the dates should be the same. If they aren't, document why
- Anyone obtaining consent needs to be listed on the application as personnel
  - Sections 1.5-1.7 or 85.1

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## Documentation of Consent

- Make sure any checkboxes are completed
- DON'T sign or date the consent for the subject
- DON'T white out, cross out or otherwise change any part of the approved consent form → Any revisions must be submitted to the RSRB as an amendment and approved prior to implementation
- Make sure to provide the subject with a signed copy of the entire consent
- Keep the original of the entire consent, not just the signature page

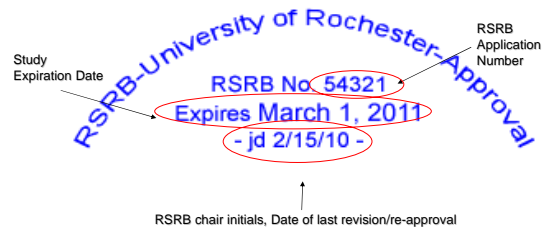
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## Using the Current, RSRB Watermarked Consent

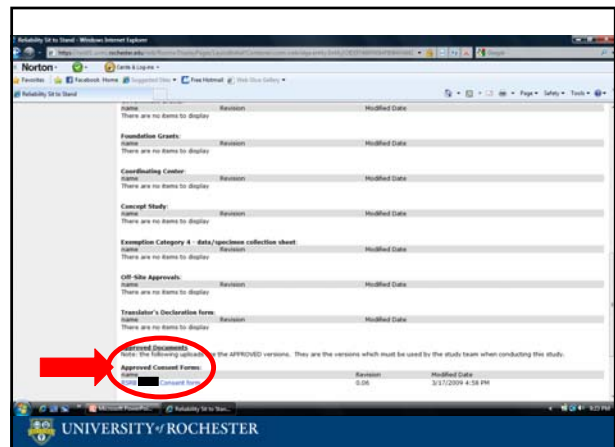
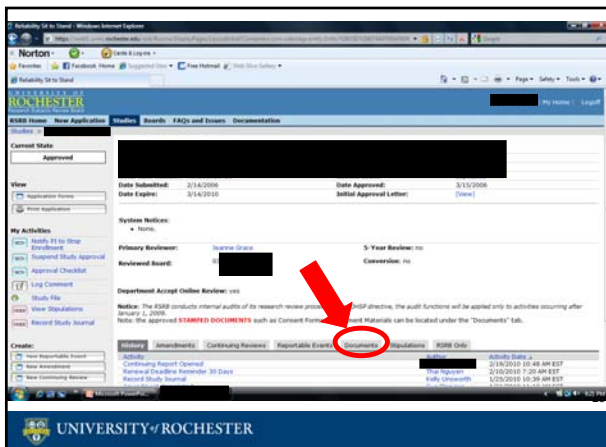
- Only consent the University recognizes as valid
- Each page is watermarked
- Each time the consent is amended, a new watermark is applied
- Each time the study is re-approved, a new watermark is applied

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## The Watermark



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## Mistakes Happen...



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## ...How Can You Prevent Them?

- Incorporate electronic letterhead on consent forms submitted to RSRB
- Name only PI on consent heading
- Leave out subject initials slots
- Have a process for:
  - Maintaining the current approved consent
  - Destroying outdated copies
  - Ensuring the signature page is completed
  - Providing subjects with a signed copy

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## Questions?

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## Additional Resources

- RSRB Website: [www.rochester.edu/rsrb](http://www.rochester.edu/rsrb)
  - Investigator Guidance (Available under “Guidance Documents”)
  - Consent Templates (Available under “Document Templates”)
- OHRP Informed Consent Guidance: <http://www.hhs.gov/ohrp/policy/consent/index.html>
- OHRP Video – General IC Requirements: <http://www.youtube.com/watch?v=URo4x4pv68A&p=5965CB14C2506914>
- APA Code of Conduct: <http://www.apa.org/ethics/code/index.aspx>