Informed consent is an ideal---a goal

There are barriers to achieving this goal

Present in the population at large

And: sub-populations who are particularly vulnerable to misunderstanding and not fully voluntary participation
Informed consent is a dynamic process—

Investigators must carefully consider risks and benefits of the proposed research and formulate the information with clarity, concision and level of discourse appropriate to the patient/subject population

Research subjects are asked to process this information and ask questions to aid their decision making process
Informed consent historically and pragmatically does not only serve to promote beneficence and respect for subject autonomy.

The process of informed consent demands that investigators carefully and openly consider foreseeable risks and barriers to voluntary participation thereby providing an extra barrier to unintended mischief.
• Standard of care research is “research”

• The elements of informed consent should not be compromised by assuming that subjects /patients are knowledgeable about the risks and options of “standard care”

• Surveys indicate that about 50-60% of patients are aware of major risks associated with their therapy
There are populations in the US and internationally
For whom Standard of Care is an aspiration
Comparing one drug to another or one intervention to another may not meet the requirements of equipoise in these contexts
Tyranny of the written form

- The written form with the subject’s signature of consent is a proxy for informed consent.
- It is a token for the process of informed consent.
- Too much emphasis has been placed on the written medium for education and information.
- The *Informed Consent Form* should not be conflated with *Informed Consent*.
Informed Consent: How much do patients understand:

- 54% of subjects understood the aim of the study.
- 50% understood the process of randomization.
- 47% understood the nature of volunteering.
- 50% understood the risks of the study.

• Research has shown that the written form is a modestly effective educational instrument.

• The solution is not longer and longer forms
• When the written form is emphasized as the prime medium of information transmission it creates particular populations who are vulnerable to misunderstanding and coercion.
Vulnerable: power differential, cognition, potential for coercion

- Children

- Individuals with cognitive disability,
  Individuals with low literacy non-english speakers

- Hospitalized patients

- Patients who are too ill to understand or consent

- Emergency situations when initiating therapy immediately

- Cultural / Religious /ethnic minorities

- Medically uninsured and/or impoverished

- Prisoners
Parable of the Four children at the Seder:
the wise one who understands when informed
the one who doesn’t want to listen
the one who doesn’t quite understand
the one who doesn’t even know how to ask

We tend to aim for the wise one----we need to attend more intently to the other three
Elements of Understanding

- Comprehending relevant information
- Language complexity / technical terms
- What is their medical condition
- What is randomization
- What is risk with or without enrolling
- Volunteering / non-coercion
- Options when not volunteering
The barriers to understanding consent forms include:

- Understanding information about likelihood of risk
- Understanding randomization
- Mistrust of “research” (status of guineapighood)
- Fear of consequences of not cooperating with providers of needed services
Concepts of probability are not well understood by many adults.

(Las Vegas casinos make a lot of money by taking advantage of this).

Care must be taken to ensure that risk estimates are expressed at the appropriate level of discourse.
• Specific risks and benefits may have a higher or lower valence for specific subpopulations.

• Even a very low risk of loss of fertility or impotence may weigh very heavily of some subjects’ decision making.
• Special areas of concern in standard of care research:
  • Explaining randomization
  (and especially the sub-category of cluster randomization)
Explaining protocol based care and addressing the issue of patients’ assumption that their care is “individualized”
Explaining “voluntary” participation and possibilities of exit from the study
Explaining that non-participation will not jeopardize care.
There is a need for more research on techniques of achieving more fully understood informed consent

---use of multimedia, visual and auditory “story telling”

---multi-part process of consent when feasible

---use of “plain language” ---short sentence non-technical vocabulary. Use of concrete not abstract language.