

Informed Consent

JONATHAN M. GREEN, MD MBA

DIRECTOR: OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS,
NATIONAL INSTITUTES OF HEALTH

Disclaimer

The presentation today represents my own personal opinion, and is not official policy of the US Government, DHHS or the NIH.

I have no conflicts of interest.

I am not a lawyer.

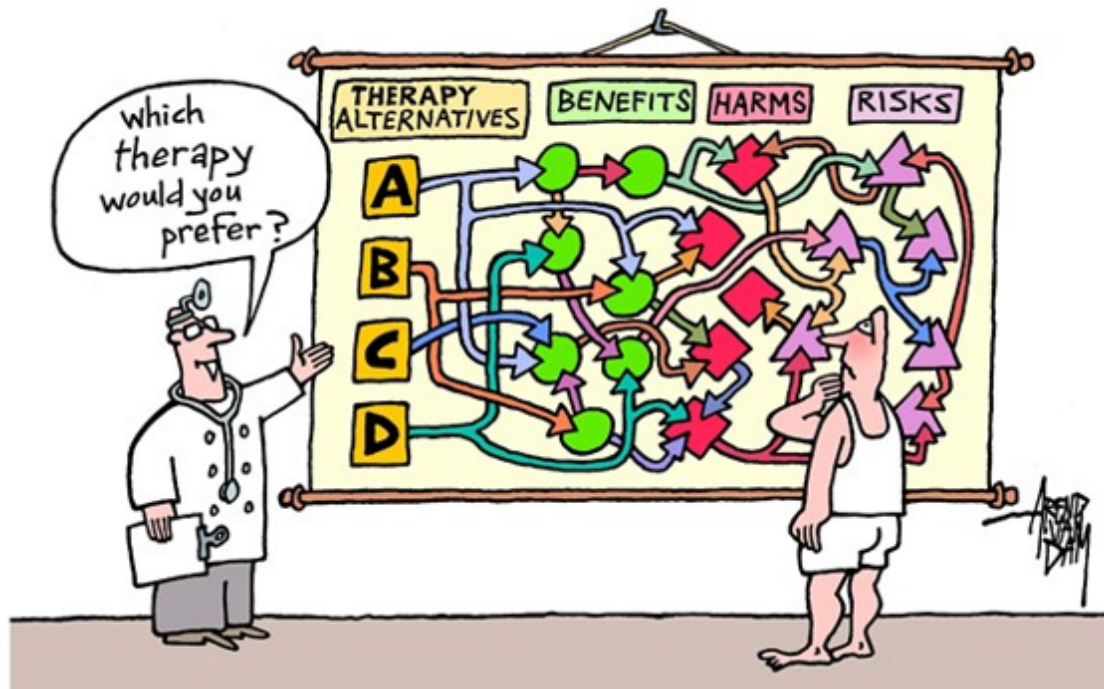
Doctor-Patient Relationship





The transformative power of consent

CONSENT MAKES THE
IMPERMISSIBLE,
PERMISSIBLE



Informed Consent

EXERCISE AUTONOMY



Words Matter

“Getting consent”

VS

Understanding goals &
aiding in a decision

Valid Informed consent



Voluntary



Competence



Disclosure



Understanding



Authorization

When is consent required?

Nature and Consequences of the decision

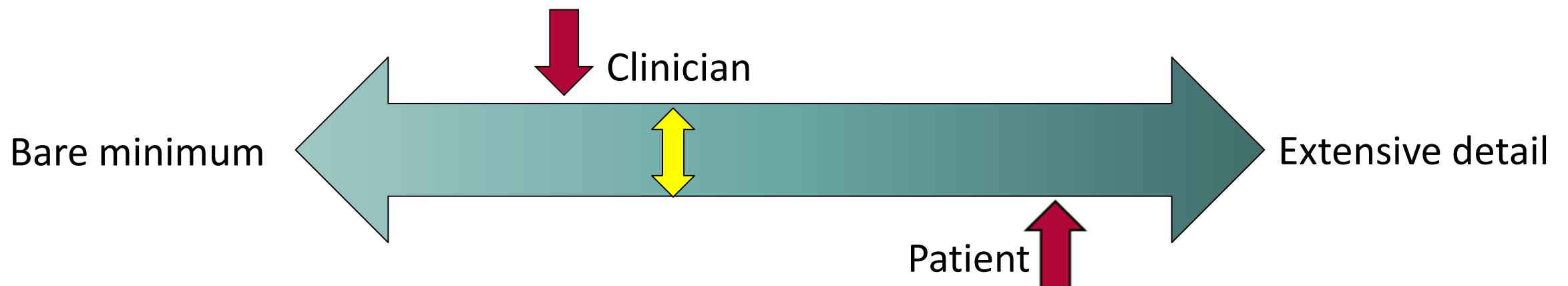


When must a rare risk of harm be disclosed?

- It depends
 - Nature of the potential harm
 - Likelihood disclosure would alter decision

Sliding scale of informational need

- Amount/type
- Minimum Necessary
- Contextualized





LISTEN!
