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How to..... Consent Forms





Where do these rules come from anyway?

- mostly the federal - office for human research protection
- some HPH nuance



What is the Real Purpose of Consent?



To give the person a 'real' choice





Checklist: MUST haves!

A statement that this IS research and why its being done.

How much of the participants time it will take up.

What exactly the participant will do or will happen to them.

What will happen to any thing they give, sample, opinion and how much control they have over it.

If records are kept how will privacy and confidentiality be manitained.

If there will be any compensation, even if none.

What the risks (or discomforts) are, even if they are very minimal.

The benefits, even if none to participant state so.

When they can decide to withdraw from the study.

Any alternative treatments open to the participants.

The PI contact details and another person to contact about thier rights as a research subject.

A CLEAR statement this is voluntary and their are no penalties for deciding not to participate, and benefits will not be removed.



Do I have any special circumstances to consider?



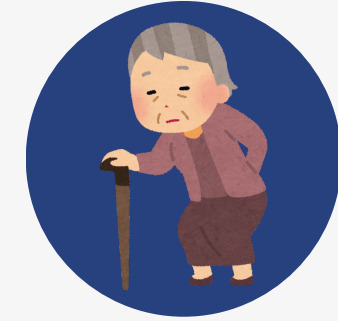
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Assent vs Consent



Translator

Several Languages



May need Assent

Vulnerable populations



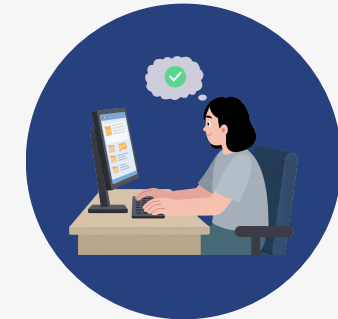
At risk

Timing of Consent



Position of Power

Need for third party
Consent



Online survey

Inplied consent and
waiver of consent

Additional elements to add if needed

pregnant or
reproductive age risks

consent termination
by PI

number of subjects

consequences of
withdrawl during study

consequential findings
during study

costs to participant

findings approved by participant before dissemination

What about incentives?



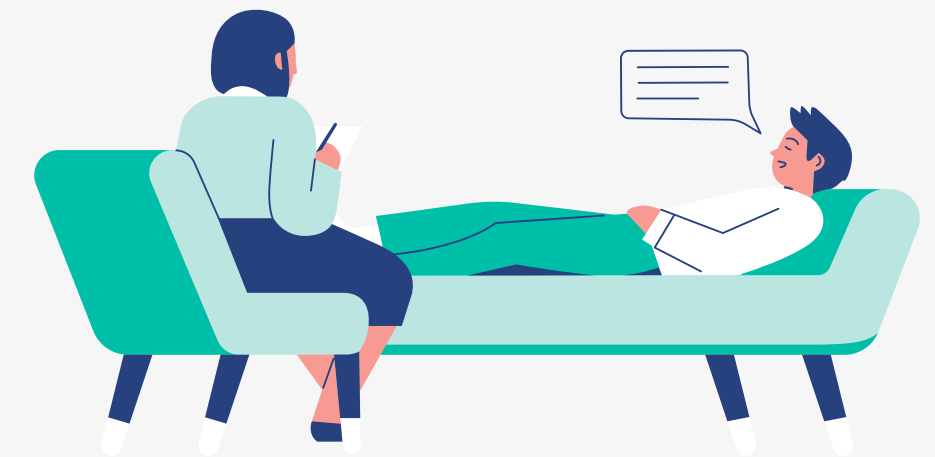
When are they good vs coercive?

Or actually add confounders to your data?

HPH Template



Lets look at it in
detail.



Very last thoughts

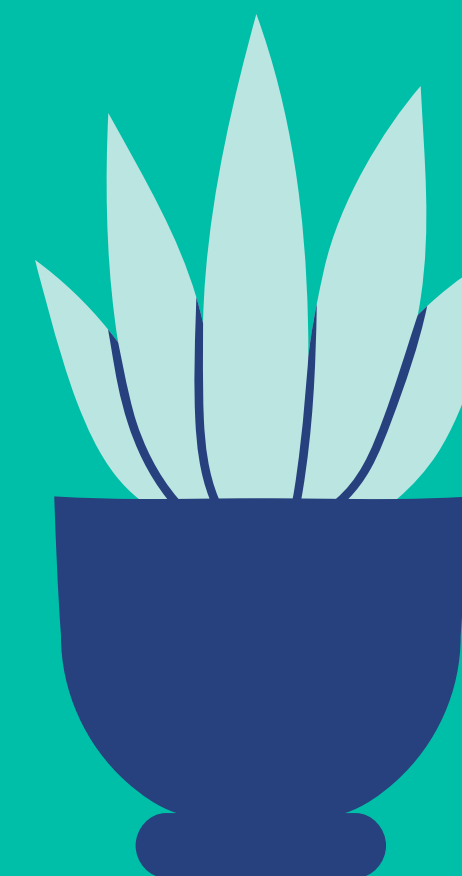


Consent at more than one site....

Recruitment only at HPH as a new site

'Blanket' consent

Changes to my consent after the study has started



Thank you for participating!

in this How to.....

