Why and when should control groups consent? Do ethical considerations relating to harm, burden, rights and reasonable expectations help us to answer this question?

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Why consent? 1

”Informed consent” is a particular procedure designed to protect underlying ethical value(s)

There is no independent value in obtaining informed consent

Our standard understanding of informed consent and its elements was developed in relation to clinical interventions and clinical research

There may be other ways of protecting the underlying ethical values

Important to remember the additional protection offered by the right/opportunity to withdraw from research

Ethical values

No imposition of harm
No imposition of burden

Rights

- Self-determination
- Bodily integrity
- Privacy / Confidentiality / Control of personal information

Reasonable expectations from the ordinary understanding of the patient-HCP relationship

I am involved in health care decisions that have a major impact on me

I am told when things happen that are not usual in a patient-HCP relationship, e.g. randomisation of treatment

I am told if I am exposed to extra risks or burdens that are not a necessary part of my treatment or care

Why consent? 2

Value	Informed consent to research	Alternative protection
No imposition of harm	Consent to risk of harm **of** research (≈ risk of **additional** harm)	Design with no risk of harm **of** research
No imposition of burden	Consent to extra burden related to research	Design with no extra burden related to research
Rights • Self-determination • Bodily integrity • Privacy	Consent to what would otherwise be rights violations	Design with no additional interventions impinging on bodily integrity or privacy Prior general consent Prior general consent + information*
Reasonable expectation	Consent to elements that are incompatible with ordinary understanding of patient-HCP relationship, e.g. randomisation	Prior general consent Prior general consent + information*

* To create transparent opportunity to withdraw

Nested case-control study of intervention

Cohort assembled and consented for use of data to research questions related to a specific condition or set of conditions

At t_0 a random sample is drawn from the cohort and consented for a trial of a new intervention

At t_1 the trial stops and cases are matched with controls from the cohort

Consent is not sought from the matched controls since they have already consented to use of data

Ethically OK?

Nested RCT

If you thought that the case-control design was OK, you should also think that the following design is OK

Cohort assembled and consented for use of data to research questions related to a specific condition or set of conditions

At t_0 a random sample is drawn from the cohort and consented for a trial of a new intervention, a random control sample is drawn at the same time

At t_1 the trial stops and data are analysed

Consent is not sought from the control group since they have already consented to use of data

When should control groups consent – tentative answers

If there is no prior general consent to data use in the relevant context

If a trial imposes extra risk or burden on the control group

If a trial involves arms with treatments that are so different that a reasonable person could prefer one over the other, even in a situation of clinical equipoise concerning effectiveness

Important to note that the question of consent is a different question than whether control groups should be informed of their participation in a trial