Models of Consent
~~Deferred Consent~~ and Opt-out Consent

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Deferred Consent or Delayed Consent and Interventional Research

Context

Our office was approached to clarify how a deferred or delayed consent model would be applied when interventional research was being conducted in the adult and paediatric settings.

Queensland Health has not yet released a final communique so any of following material is not Queensland Health official policy.

Opt-out Consent

For the sake of completeness….

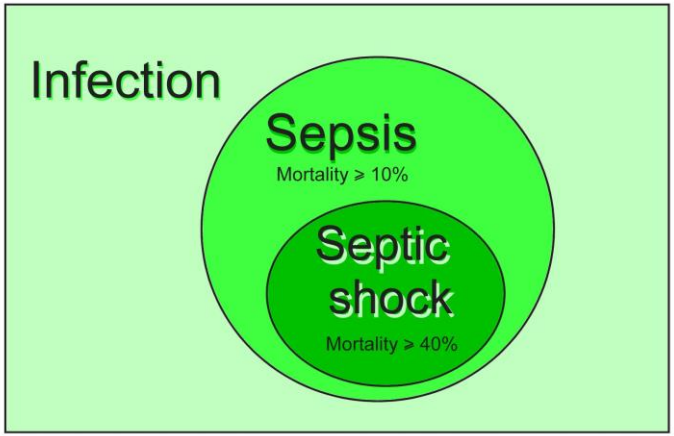
I will also discuss the use of an Opt - out consent model.

Note they hang off the same post.

Deferred Consent or Delayed Consent and Interventional Research

Scene Setting

You are a Research Governance Officer and you receive and application for site authorisation for a study that proposes to use “delayed” consent.



Delayed consent: term not supported

The terms deferred or delayed consent are confusing. They do not exist in the National Statement and do not constitute any form of consent. This is because it is not possible to obtain a person's consent to something after that thing has already happened.

Treating health practitioners must…

always discharge their legal duties to the patient, which include:

to provide treatment only when a patient (or a substitute decision-maker) consents to that treatment, or where consent is not required (such as in an emergency situation);

to warn patients of the material risks attaching to the treatment; and

to exercise reasonable skill and care in the provision of services, including examination, diagnosis and treatment.

Clinical Equipoise

Ethical research

If the study involves researching, for example, the effectiveness of specific, randomly assigned clinical interventions, the study must involve a state of ‘clinical equipoise’. Clinical equipoise is where there is no intervention being studied that is reasonably considered by health practitioners to be ‘better’ than the others in the study.

Site Authorisation

Considering our DRAFT policy

The study involves a state of ‘clinical equipoise’

The study will be authorised

Opt-out Consent

Section 2.3.5 of the National Statement there is advice on when to use an Opt Out consent process

2.3.6 Before approving the use of an opt-out approach for research, an HREC or, where appropriate, another review body must be satisfied that:

involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

Opt-out Consent

the public interest in the proposed activity substantially outweighs the public interest in the protection of privacy

the research activity is likely to be compromised if the participation rate is not near complete, and the requirement for explicit consent would compromise the necessary level of participation

Opt-out Consent

reasonable attempts are made to provide all prospective participants with appropriate plain language information explaining the nature of the information to be collected, the purpose of collecting it, and the procedure to decline participation or withdraw from the research

a reasonable time period is allowed between the provision of information to prospective participants and the use of their data so that an opportunity for them to decline to participate is provided before the research begins

Opt-out Consent

a mechanism is provided for prospective participants to obtain further information and decline to participate

the data collected will be managed and maintained in accordance with relevant security standards

there is a governance process in place that delineates specific responsibility for the project and for the appropriate management of the data

Opt-out Consent

the opt-out approach is not prohibited by State, federal, or international law

If you are relying on consent as a legal permission to do something– Opt Out consent is not appropriate

Note they hang off the same post.

Questions?
Further information

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