NHS
Health Research Authority

Fair consent processes in early phase research involving patients

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How does the (early phase) patient see it all?

Nolite timere – be not afraid: they're on our side and can be powerful allies

But they may see things differently (the research as a "T.O.P.P.").

Time pressure – the theme of this meeting

It may take time NOW, but involving patients from the start will save time later!

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AND it’s the right (ethical) thing to do – research and drug development is a partnership.

Consent

Explaining what we are asking of them

1. Putting an invitation up front in straightforward words
2. Laying out the decisions and the choices to be made
3. Describing how they will be helped to make these

Presenting in a way they find easiest

1. It’s the conversation that matters.
2. Complex proposals need a summary to start .
3. A study is often best portrayed in summary picture.
4. Laying out the consequences (benefits and harms) of all alternatives side by side with space for the patient's own concerns.
5. Providing “PIS” in a way they don’t drown in detail and ignorance.

What REALLY matters – the benefits and harms of a study

1. **All potential benefits** should be listed.
2. **All potential harms** should be listed.
3. The fact that not all potential harms are known (uncertainty) needs to be explicit.
4. These should not be presented apart.
5. Potential benefits and harms of a trial should be **compared with what would happen** outside the trial
6. The harms should be separated into **serious and less serious**
7. **Suitable visual representations** might be appropriate

Modified from Svobodova et al 2023
https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-022-06780-1l

An IDeA to help us

A 4 sided **maximum** “Information and Decision Aid” to **guide the conversation** (that fits into current practice)

SIDE 1

An introduction and invitation to join a research study testing …….

This study is to [description of study purpose]. The results will help us improve treatment for future patients.

It's your decision but we'll help you all we can, involving any others you'd like to talk to. In this summary we highlight key points and your possible choices.

IF YOU HAVE QUESTIONS, PLEASE ASK THEM AT ANY TIME

KEY FACTS
1
2
3
4
5
6

Your first thoughts.

SIDE 2

TRIAL SCHEMA – processes from the patient's/child's perspective

Other points

- Reasonable travel costs will be covered, and any required accommodation costs will also be considered – both for you and a carer.
- There are special rules in place to keep your personal information safe and we will follow all relevant laws.
- [Further key points e.g., treatment allocation / placebo]

On the next page we've drawn up a table called "WEIGHING UP YOUR CHOICES" to help you decide. It starts with ideas from other patients and their doctors but more importantly, we've then put in rows for your own concerns that we will discuss together.

We can photo or / scan this summary and give you a copy.

SIDE 3

WEIGHING UP YOUR CHOICES	
We've done our best to provide accurate information but as this is very new there are continuing uncertainties, which we can only estimate. We'll let you know if these change.	
If I choose not to join the study – STANDARD CARE	**If I choose to join this study**
Description of likely treatment	*Description of treatment*
Treatment benefits	
Treatment side effects	
Required appointments and tests	

SIDE 4

WEIGHING UP YOUR CHOICES	
If I choose not to join the study – STANDARD CARE	**If I choose to join this study -**
Your own considerations	

If you're still interested once we've been through this introduction and answered your questions, we'll give you more detail and take you or your parents through a full Patient Information Sheet (PIS).

Then you can have as much time as you need to decide. If you choose to participate, we'll go through this summary again so you can check you've got all the information you need. before we ask you to sign our Informed Consent Form.

My key points

1. Let’s work with patients and patient groups (PPI).
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2. Sponsors and clinicians need to work more closely (mind the gap).
3. There are many examples / models to help.
4. We must see consent as a conversation and process, recognising the individuality of each patient (and their decision making).

Fair consent

Our duties around consent 1

1. Taking it seriously
2. Explaining what we are asking of participants
3. Presenting the proposal in a way participants find easiest
4. Recognising participants as individuals
5. Helping participants make a decision / choice (they can be happy with)

Our duties around consent 2

1. Ensuring consent processes meet their stated purposes - helping participants represent their own interests and exercise their autonomy
2. It’s NOT an exercise in exculpation
3. Finding out what matters to our patients…