Guidance on Participant Information Sheets (PtIS) and Consent

Health Research Authority

Select what you want to look at:-

Complete version (for download or printing).

(This excludes "What's changed recently", "The process of our revision", "Examples of practice", "templates" and "annexes")

What's changed recently?

Principles of our revision

The process of our revision

What makes a good Participant Information Sheet?

Writing style and layout

Content of a PtIS

PtIS for adults

Consent forms for adults

PtIS for children and young people

Consent and assent forms for children and young people

PtIS for Adults who lack capacity

Consent forms for adults who lack capacity

10 Key documents

Examples of practice

Templates

Annexes for more detailed information on particular topics

Common REC "findings" and comments

Date

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Annexes

We've tried to collect more information on the topics below

Capacity to provide consent

Children's annexes

Confidentiality

Consent - when should we seek it?

Consent – when might we waive it?

Consent processes - questions and dialogue

Consequences of research – benefit and harm

Deception – what are the acceptable conditions for this?

Emergency research

Exclusion and inclusion

Genetic research - consent

Genetic – feeding back results

ICHGCP items of informed consent

Informed consent – how can we improve it?

Incidental findings – how should we manage these?

Information – what do people understand?

Information sources

Insurance and indemnity

(Internet) – e-research

Patients and public – consulting them in research design

Paying research subjects

Post trial access to therapies

Pregnancy and contraception in research

Public perception of research

Radiation and research

Randomisation

Samples, tissue and consent

Science and ethics

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Children's Annexes

We've tried to collect more information on the topics below

Need for children's research

Principles of children 's research

Children and young people's views of research

Consent, assent and dissent

Pregnancy in research involving young people

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What's changed recently?

The following changes have been made to our guidance :-

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Principles of our revision (I)

We hope our work will give you a head start to develop processes and information that will allow the potential participant to make a decision that best fits his or her interests.

Our guidance is not proscriptive as research comes in many shapes and sizes; any document or process will need to fit the study. However it will ease review if you start with the framework we provide; it can then be adapted.

We also don't wish to hinder development and improvement.

Once we've produced our guidance we will embark on "user testing" to review its value and a training programme for RECs and researchers to make them aware of this revision. We will obviously incorporate ideas for improvement. One new section, to help this, is "Recent Changes" where we will post any changes we make.

Principles of our revision (II)

Evidence indicates that, with occasional exceptions, we would want to be involved in choosing whether to join a research study. To do this we need guidance, help and information on which we can base our decision.

Researchers therefore need to give potential participants appropriate details and consequences of the study, and allow time for questions. What we deem as appropriate (in content and layout) is contended. Together this is the responsibility of the researcher and REC to make judgements on this.

We've used current guidance as a framework, there is much sense in the current guidance. We've striven to avoid making it much longer and worked with the Health Research Authorities Public and Patient Initiatives (PPI forum). Where there are legal stipulations we 'e followed them. We've observed the competent authorities' "Risk adaptive approach" and fitted in with this. We've been asked in the past what is "compulsory" and what is "optional". To help with this, where there **is** a legal requirement or a strong policy or professional mandate we highlight text as **BOLD.** Possible wording or "templates" are in italics.

We try to base our work on evidence (and its strength) and consensus wherever possible.

The length of past guidance has been criticized. Key points were difficult to find so we've therefore provided our principles that we feel underpin fair consent below. We also hope the map at the front will help you find what you need.

And finally all the rules or whatever we put in the guidance for researchers should be seen to apply to us!!! (e.g we've tried to write in simple English).

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What makes a good information sheet (1/8)?

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Recognise the purpose of a PtIS – it's to help people make their choice, decisions that they will feel happy with. But accommodate the idea that they may want help. Influence is fair, coercion isn't.

Recognise the context and broader processes of informing and deciding. See that it is only one part in a larger process- it supports and frames the discussion and is one foundation on which informed consent is built.

"One size will not fit all". Obviously processes will differ according to the nature of the research; RECs must recognise this. Variation will be needed but be prepared to explain this.

What makes a good information sheet (2/8)?

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We advocate a proportionate approach, recognizing information and consent arrangements must match the study's burden and risk/benefit profile. Simple studies can have simple information sheets – e.g. a questionnaire can have a simple front page and completion can be taken as consent.

Match your information to your target group. It's good practice to test your processes and material with relevant people.

There will be occasions when you will need to provide information incrementally (e.g. Emergency research).

What makes a good information sheet (3/8)?

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In particularly long studies ask yourself whether you need to re-assess consent.

The competence of those seeking consent is central and hence training of those seeking consent is key and should be explained to the REC.

What makes a good information sheet (4/8)?

Lay your PtIS out in a simple, comprehensible style. (“Assume ignorance but intelligence”?).

Avoid medical jargon where you can.

Think of it as a (respectful) invitation.

Use the active not passive tense – (“We’d like to invite.... NOT You are invited...”).

What makes a good information sheet (5/8)?

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Try to provide a coherent flow. We suggest a “question and answer format “ which we recognise can interrupt this. If this is problem, consider a short summary at the beginning.

Ask yourself what's the best way to put this information over – tables, diagrams, charts, pictures.

Use all available modern media – (CDs, video, web-based resources).

What makes a good information sheet (6/8)?

Never underestimate the importance of your title; first impressions matter. It should be a concise summary "describing what's in the tin". Consider the acronym - I.P.O.C. - Intervention, Population, Outcome, (Comparator).

Consider a summary box at the front – Answering the questions "Who? Where? What? Why? How? and When?".

Write your PtIS with the question "What does participation mean for me (the research participant)?" uppermost in your mind .

Get to the point, for the patient, quickly!

For more introductory detail go to the files "Writing style and layout" or "Content of a PtIS"

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What makes a good information sheet (7/8)?

Clearly reflect what will happen to the research participant .

State clearly what the risks and benefits are. This is central to fair decision making. These need to include benefits and risks for themselves and others.

For more introductory detail go to the files "Writing style and layout" or "Content of a PtIS"

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What makes a good information sheet (8/8)?

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Where appropriate, the information sheet could be divided into two or three parts:

PART 1: Study summary: “Do I want to read further or is this study “not for me”

PART 2: More details, the condition or treatment under study, the voluntary nature of involvement, what will happen during and after the study, what treatment may be withheld, the participant’s responsibilities; the potential risks, inconvenience or restrictions balanced against any possible benefits and the alternative(s). This should allow the participant to decide whether the study is of interest and whether they wish to read and discuss it further. It is an aid to shared decision making.

PART 3: “Supporting information”: the fine details that should then be discussed. This could be more “template driven”.

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