Remote Consent – Ethical considerations

Dr Simon Kolstoe

Reader in Bioethics

UNIVERSITY OF PORTSMOUTH

Ministry of Defence

European Commission

NHS Health Research Authority

UK Health Security Agency

Public Health England

Consent (disambiguation)

From Wikipedia, the free encyclopedia

Consent is defined as when one person voluntarily agrees to the proposal or desires of another.

Consent may also refer to:

- Sexual consent, voluntary agreement to engage in sexual acts
- Informed consent, obtaining subject approval for medical procedures
- Consent (BDSM), consent as it relates to BDSM
- Consent (criminal law), a defense against criminal liability
- Consent (roleplaying), how much control a player has over their character in a role-playing game
- *Consent* (play), a 2017 play by Nina Raine

WMA DECLARATION OF HELSINKI – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.

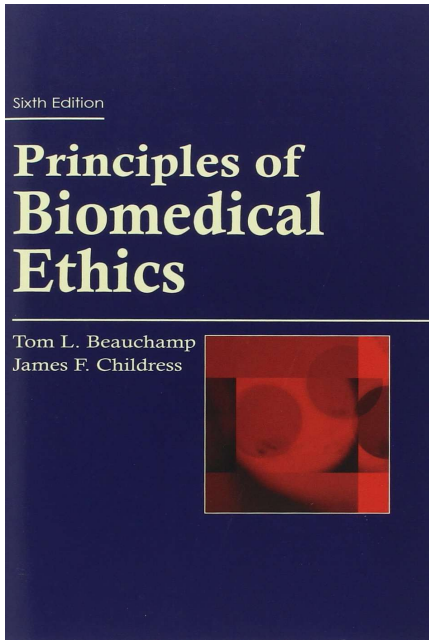
29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorised representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative.

31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.

32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee.

“Fully Informed Consent”



“Principlism”

1. **Autonomy**
2. Beneficence
3. Non-maleficence
4. Justice

How much does someone need to know in order to be “fully informed”?

“Appropriately Informed” or **“Sufficiently Informed”**

(from an ethics perspective)

“Appropriately Informed” or “Sufficiently Informed”

Informed Consent

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

Data Protection Act 2018 /GDPR/ UK GDPR

Article 6:

(a) Consent: the individual has given clear consent for you to process their personal data for a specific purpose.

(b) Contract: the processing is necessary for a contract you have with the individual, or because they have asked you to take specific steps before entering into a contract.

(c) Legal obligation: the processing is necessary for you to comply with the law (not including contractual obligations).

(d) Vital interests: the processing is necessary to protect someone's life.

(e) Public task: the processing is n
interest or for your official functions,
law.

(f) Legitimate interests: the proce
or the legitimate interests of a third
the individual's personal data which
cannot apply if you are a public auth
tasks.)

What are the conditions for processing special category data?

Article 9 lists the conditions for processing special category data:

(a) Explicit consent
(b) Employment, social security and social protection (if authorised by law)
(c) Vital interests
(d) Not-for-profit bodies
(e) Made public by the data subject
(f) Legal claims or judicial acts
(g) Reasons of substantial public interest (with a basis in law)
(h) Health or social care (with a basis in law)
(i) Public health (with a basis in law)
(j) Archiving, research and statistics (with a basis in law)

For the purposes of the GDPR, the legal basis for processing data for health and social care research should NOT be consent. This means that requirements in the GDPR relating to consent do NOT apply to health and care research.

- For universities, NHS organisations, Research Council institutes or other public authority the processing of personal data for research should be a 'task in the public interest'.
- For commercial companies and charitable research organisations the processing of personal data for research should be undertaken within 'legitimate interests'.

Research and statistics

This exemption can apply if you process personal data for:

- scientific or historical research purposes; or
- statistical purposes.

It is unlikely to apply to the processing of personal data for commercial research purposes such as market research or customer satisfaction surveys, unless you can demonstrate that this research uses rigorous scientific methods and furthers a general public interest.

It exempts you from the GDPR's provisions on:

- the right of access;
- the right to rectification;
- the right to restrict processing; and
- the right to object.

The GDPR also provides exceptions from its provisions on the right to be informed (for indirectly collected data) and the right to erasure.

	Right to erasure	Right to portability	Right to object
Consent			✘ but right to withdraw consent
Contract			✘
Legal obligation	✘	✘	✘
Vital interests		✘	✘
Public task	✘	✘	
Legitimate interests		✘	

Data Protection Act
2018

General Data Protection Regulation (GDPR)

Regardless of the lawful basis under GDPR – consent is probably still needed for research activities because…

Offences under the Human Tissue Act 2004

1. Removing, storing or using human tissue for Scheduled Purposes without appropriate consent.
2. Storing or using human tissue donated for a Scheduled Purpose for another purpose.
3. Trafficking in human tissue for transplantation purposes.
4. Carrying out licensable activities without holding a licence from the HTA (with lower penalties for related lesser offences such as failing to produce records or obstructing the HTA in carrying out its power or responsibilities).
5. Having human tissue, including hair, nail, and gametes, with the intention of its DNA being analysed without the consent of the person from whom the tissue came or of those close to them if they have died.

MEDICINES

The Medicines for Human Use (Clinical Trials) Regulations 2004

3.—(1) For the purposes of this Schedule, a person gives informed consent to take part, or that a subject is to take part, in a clinical trial only if his decision

(a) is given freely after that person is informed of the nature, significance, implications and risks of the trial; and

(b) either—

(i) is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or

(ii) if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing.

(2) For the purposes of this Schedule, references to informed consent—

(a) shall be construed in accordance with paragraph (1); and

(b) include references to informed consent given or refused by an adult unable by virtue of physical or mental incapacity to give informed consent, prior to the onset of that incapacity.

Overview

Consent to treatment

- **Overview**
- Assessing capacity
- Children and young people

Consent to treatment means a person must give permission before they receive any type of medical treatment, test or examination.

This must be done on the basis of an explanation by a clinician.

Consent from a patient is needed regardless of the procedure, whether it's a physical examination, organ donation or something else.

The principle of consent is an important part of medical ethics and international human rights law.

Mental Capacity Act 2005

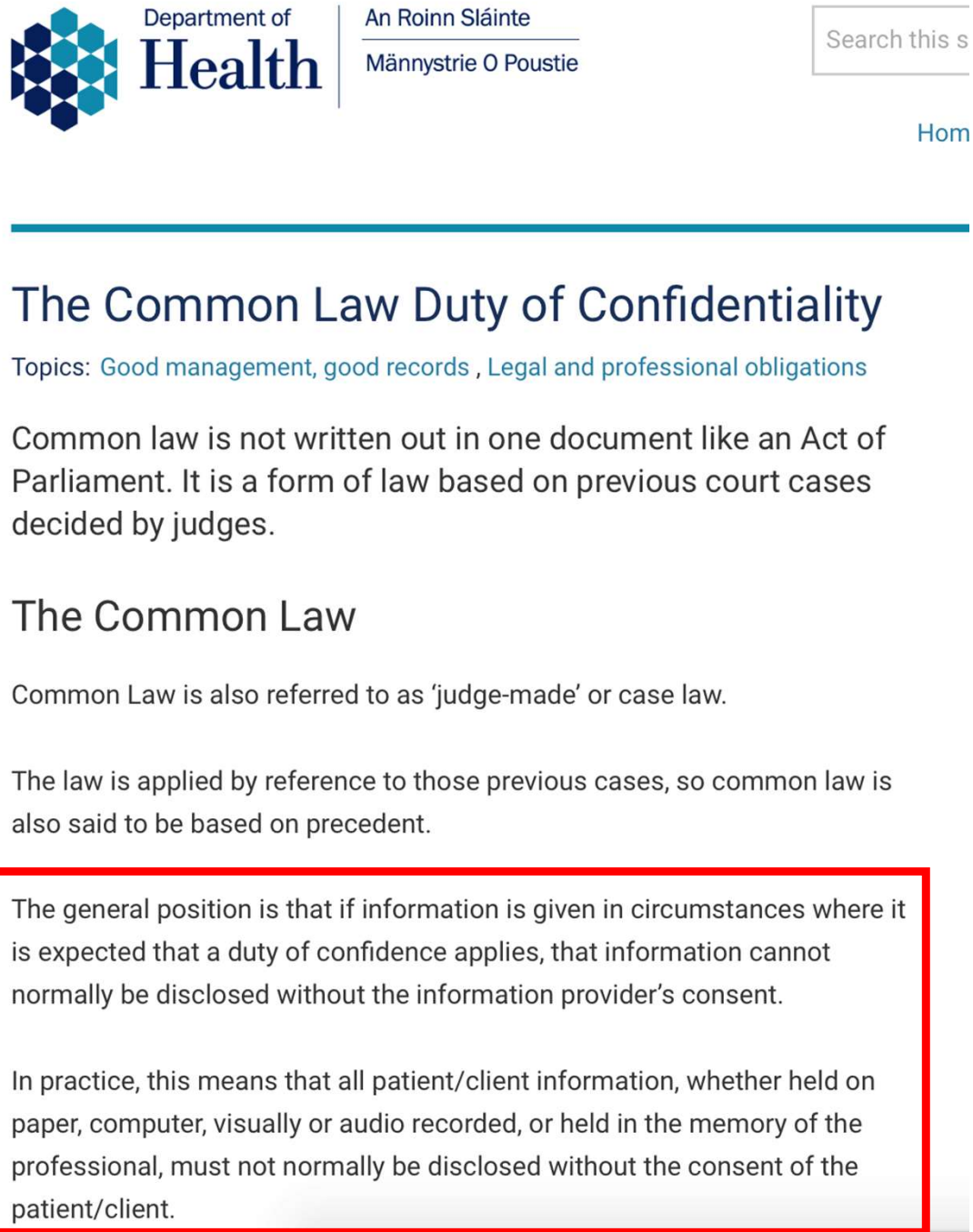
DH Department of Health

Treatment without consent/Assault

Reference guide to consent for examination or treatment
Second edition

Common Law Duty of Confidentiality

"No Surprises"



Department of Health | An Roinn Sláinte | Männystrie O Poustie

Search this s

Hom

The Common Law Duty of Confidentiality

Topics: Good management, good records , Legal and professional obligations

Common law is not written out in one document like an Act of Parliament. It is a form of law based on previous court cases decided by judges.

The Common Law

Common Law is also referred to as 'judge-made' or case law.

The law is applied by reference to those previous cases, so common law is also said to be based on precedent.

The general position is that if information is given in circumstances where it is expected that a duty of confidence applies, that information cannot normally be disclosed without the information provider's consent.

In practice, this means that all patient/client information, whether held on paper, computer, visually or audio recorded, or held in the memory of the professional, must not normally be disclosed without the consent of the patient/client.

Home › Approvals and amendments › What approvals and decisions do I need? ›

Confidentiality Advisory Group

Last updated on 12 Oct 2021

If you intend to access confidential patient information without consent in England and Wales you should apply to the Confidentiality Advisory Group (CAG). You will need to apply whether your project is managed as research or non-research.

THE CONVERSATION

Academic rigour, journalistic flair

Search analysis, research, academics...

COVID-19 Arts + Culture Business + Economy Education Environment + Energy Health + Medicine Politics + Society Science + Technology COP26

Coronavirus: researchers no longer need consent to access your medical records

May 31, 2020 9.17pm BST

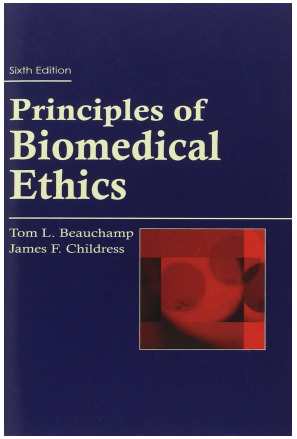
Author

Simon Kolstoe
Senior Lecturer in Evidence Based Healthcare and University Ethics Advisor, University of Portsmouth

Regardless of your lawful basis under GDPR… you probably still need to get consent from participants in EXACTLY the same way as you would have done prior to GDPR!

…albeit you need to re-write your privacy statement….

NOT "data will be handled in accordance with Data Protection Legislation"



“Appropriately Informed” or **“Sufficiently Informed”**

”US interpretation”

Participant Information Sheet is a contract

You must tell the person everything and make them sign (in ink and ideally witnessed) on the dotted line

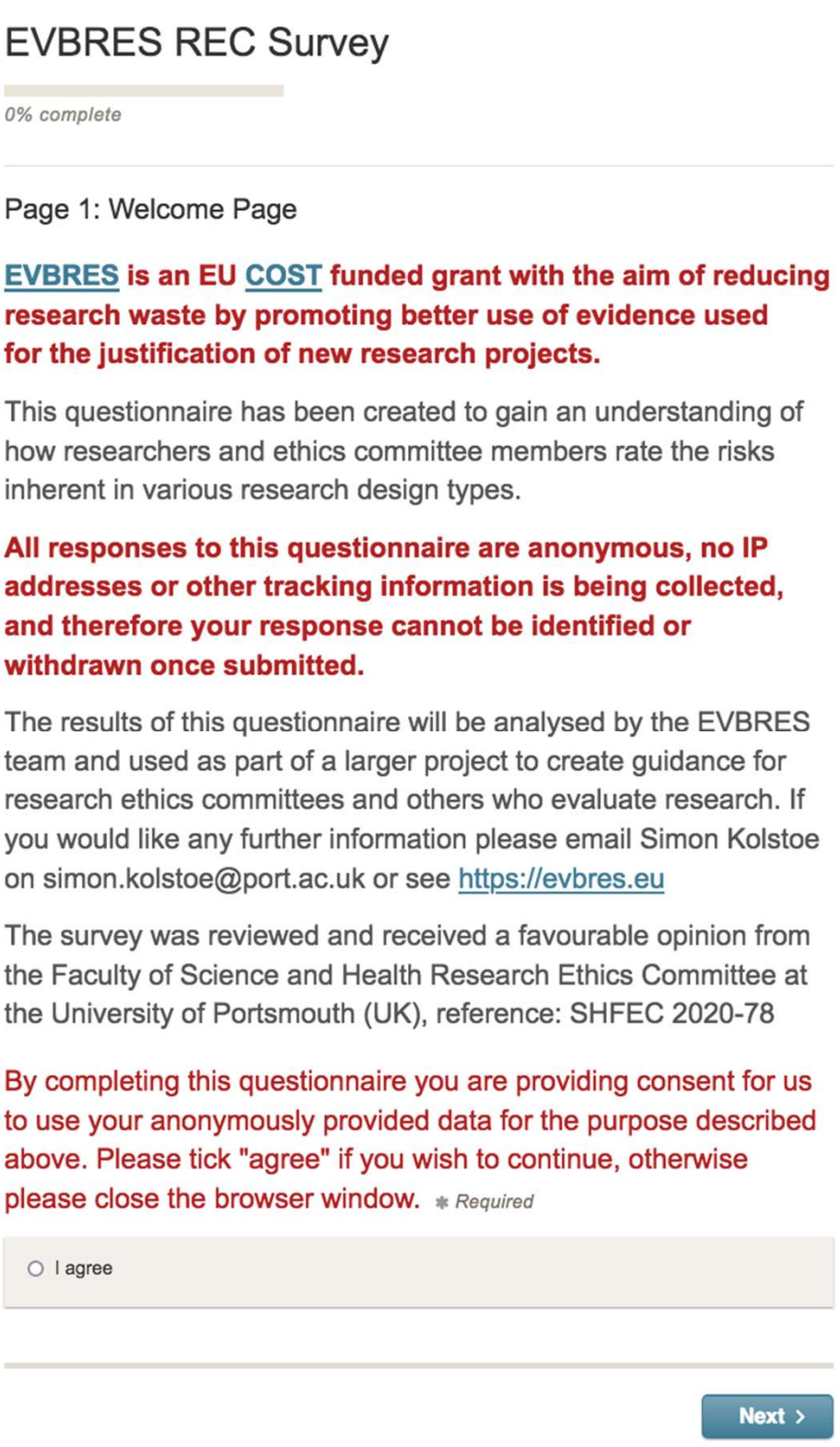
Example 1: Online Anonymous Questionnaire/Survey

What and who

Anonymity

Results & further information

“Opt in” consent



Example 2: Online Questionnaire/survey collecting Personal or Personal Sensitive Data

- Invitation/Summary of research
- Why have I been invited & do I have to take part?
- What will I be asked to do?
- What are the benefits/disadvantages of taking part?
- How will my data be collected/used?
- Source for further information/support
- Contact/complaint details
- Specific opt in clause

May need to send information in advance as part of invitation

* discuss with ethics committee *

“Appropriately Informed” or **“Sufficiently Informed”**

Example 3 – Online Interview/Focus Group

Must send information in advance as part of invitation

- Invitation/Summary of research
- Why have I been invited & do I have to take part?
- What will I be asked to do?
- What are the benefits/disadvantages of taking part?
- How will my data be collected/used?
- Source for further information/support
- Contact/complaint details

Record of consent: email completed form in advance, recorded, WhatsApp…

“Appropriately Informed” or **“Sufficiently Informed”**

Example 4 – Intervention Study * Most involve attending clinic/lab etc *

Must send information in advance as part of invitation

COVID: discuss study in advance & remotely?

Example 5 – Highly Invasive Study (Human Challenge/Full Genome Sequencing)

“Appropriately Informed” or **“Sufficiently Informed”**

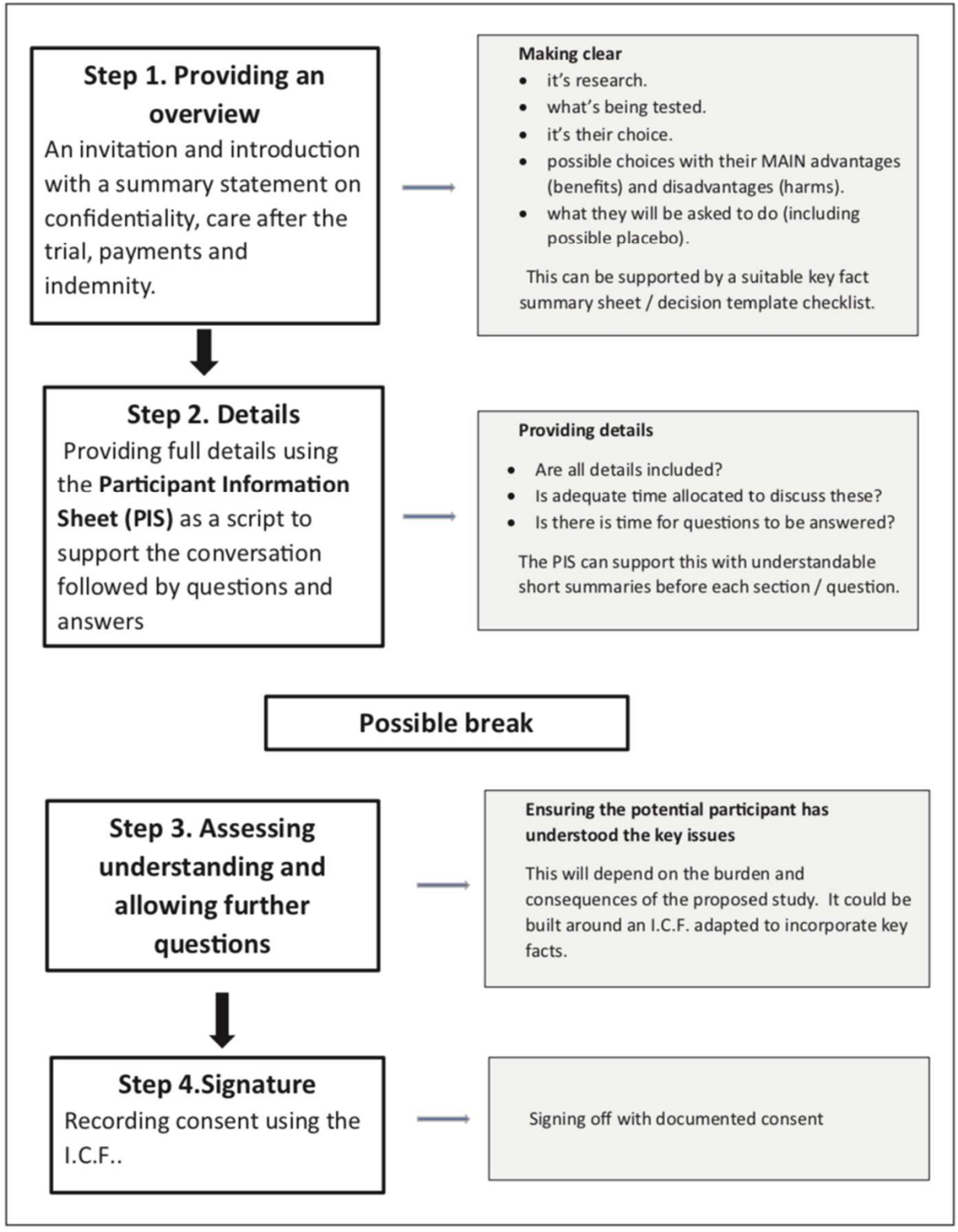
- Might include information/briefing sessions
- Might include some kind of understanding test
- Might include frequent reminder sessions

Reshaping the review of consent so we might improve participant choice

Hugh Davies on behalf of the Oxford "A" Research Ethics Committee
Chair Oxford "A" REC

Research Ethics
1–10

DOI: 10.1177/17470161211043703
journals.sagepub.com/home/rea
SAGE



evbres
Evidence-Based Research

The project is supported by

cost
EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

Funded by the Horizon 2020 Framework Programme of the European Union

Assessing Risk in Research Studies

Jennifer D
FAAN; Silv
Simon Kol

27 Septem

12 On a scale of 1 (not at all risky) to 10 (extremely risky) what level of risk do you think is generally characteristic of the following types of research design?

	1 - Not at all risky	2	3	4	5	6	7	8	9	10 - Extremely risky
Non-intrusive questionnaire study	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Sample Demographics (N = 283)

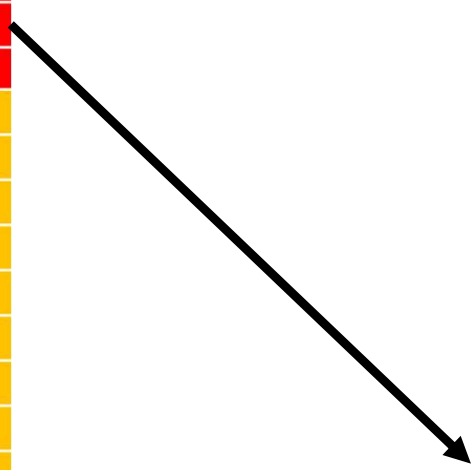
evbres
Evidence-Based Research

51% UK; **29%** AU/NZ; **14%** EU

45% REC Member + Researcher; **34%** REC Member; **17%** Researcher

80% Hold a Higher Research Degree (MA, MSc, PhD, MD, etc.)

Study Design	Mean Risk Score
Phase I Clinical Trial	8.4
Phase II Clinical Trial	7.59
Clinical Psychology/Psychiatry Intervention Study	7.38
Phase III Clinical Trial	6.85
Genetic Testing with Clinical Significance	6.65
Whole Genome Sequencing	6.54
Intrusive Focus Group (face-to-face)	6.41
Intrusive Focus group (remote via video conferencing)	6.34
Intrusive interview (online with video and audio)	6.32
Intrusive interview (face-to-face)	6.18
Intrusive Questionnaire Study	5.99
Physiological Intervention Study	5.94
Validated Clinical Questionnaire Study	5.92
Major Psychological or Behavioural Intervention Study (overt)	5.91
Intrusive Interview Telephone (audio only)	5.85
Identifiable Secondary Analysis of Healthcare Data	5.57
Phase IV Clinical Trial	5.25
Randomised Non-Drug Clinical Study	5.23
Identifiable Secondary Data Analysis	4.9
Genetic Testing with no Clinical Significance	4.71
Observational Study in Private Spaces	4.58
Non-intrusive Interview Online (video and audio)	3.79
Minor Psychological or Behavioural Intervention Study (subtle)	3.76
Non-intrusive Focus Group (face-to-face)	3.72
Non-intrusive Focus Group (remote video conferencing)	3.65
Non-intrusive Interview (face-to-face)	3.53
Observational Study in Public Spaces	3.16
Non-intrusive Interview Telephone (audio only)	3.04
Anonymous Secondary Analysis of Healthcare Data	2.7
Non-intrusive Questionnaire Study	2.48
Anonymous Secondary Data Analysis	2.04



- Phase I Clinical Trial
- Phase II Clinical Trial
- Clinical Psychology/ Psychiatry Intervention Study

“Appropriately Informed” or **“Sufficiently Informed”**

Study Design	Mean Risk Score
Phase I Clinical Trial	8.4
Phase II Clinical Trial	7.59
Clinical Psychology/Psychiatry Intervention Study	7.38
Phase III Clinical Trial	6.85
Genetic Testing with Clinical Significance	6.65
Whole Genome Sequencing	6.54
Intrusive Focus Group (face-to-face)	6.41
Intrusive Focus group (remote via video conferencing)	6.34
Intrusive interview (online with video and audio)	6.32
Intrusive interview (face-to-face)	6.18
Intrusive Questionnaire Study	5.99
Physiological Intervention Study	5.94
Validated Clinical Questionnaire Study	5.92
Major Psychological or Behavioural Intervention Study (overt)	5.91
Intrusive Interview Telephone (audio only)	5.85
Identifiable Secondary Analysis of Healthcare Data	5.57
Phase IV Clinical Trial	5.25
Randomised Non-Drug Clinical Study	5.23
Identifiable Secondary Data Analysis	4.9
Genetic Testing with no Clinical Significance	4.71
Observational Study in Private Spaces	4.58
Non-intrusive Interview Online (video and audio)	3.79
Minor Psychological or Behavioural Intervention Study (subtle)	3.76
Non-intrusive Focus Group (face-to-face)	3.72
Non-intrusive Focus Group (remote video conferencing)	3.65
Non-intrusive Interview (face-to-face)	3.53
Observational Study in Public Spaces	3.16
Non-intrusive Interview Telephone (audio only)	3.04
Anonymous Secondary Analysis of Healthcare Data	2.7
Non-intrusive Questionnaire Study	2.48
Anonymous Secondary Data Analysis	2.04

- Phase III Clinical Trial
- Genetic Testing with Clinical Significance
- Whole Genome Sequencing
- Intrusive Focus Group (face-to-face)
- Intrusive Focus group (remote via video conferencing)
- Intrusive interview (online with video and audio)
- Intrusive interview (face-to-face)
- Intrusive Questionnaire Study
- Physiological Intervention Study
- Validated Clinical Questionnaire Study
- Major Psychological or Behavioural Intervention Study (overt)
- Intrusive Interview Telephone (audio only)
- Identifiable Secondary Analysis of Healthcare Data
- Phase IV Clinical Trial
- Randomised Non-Drug Clinical Study

“Appropriately Informed” or **“Sufficiently Informed”**

Study Design	Mean Risk Score
Phase I Clinical Trial	8.4
Phase II Clinical Trial	7.59
Clinical Psychology/Psychiatry Intervention Study	7.38
Phase III Clinical Trial	6.85
Genetic Testing with Clinical Significance	6.65
Whole Genome Sequencing	6.54
Intrusive Focus Group (face-to-face)	6.41
Intrusive Focus group (remote via video conferencing)	6.34
Intrusive interview (online with video and audio)	6.32
Intrusive interview (face-to-face)	6.18
Intrusive Questionnaire Study	5.99
Physiological Intervention Study	5.94
Validated Clinical Questionnaire Study	5.92
Major Psychological or Behavioural Intervention Study (overt)	5.91
Intrusive Interview Telephone (audio only)	5.85
Identifiable Secondary Analysis of Healthcare Data	5.57
Phase IV Clinical Trial	5.25
Randomised Non-Drug Clinical Study	5.23
Identifiable Secondary Data Analysis	4.9
Genetic Testing with no Clinical Significance	4.71
Observational Study in Private Spaces	4.58
Non-intrusive Interview Online (video and audio)	3.79
Minor Psychological or Behavioural Intervention Study (subtle)	3.76
Non-intrusive Focus Group (face-to-face)	3.72
Non-intrusive Focus Group (remote video conferencing)	3.65
Non-intrusive Interview (face-to-face)	3.53
Observational Study in Public Spaces	3.16
Non-intrusive Interview Telephone (audio only)	3.04
Anonymous Secondary Analysis of Healthcare Data	2.7
Non-intrusive Questionnaire Study	2.48
Anonymous Secondary Data Analysis	2.04

- Identifiable Secondary Data Analysis
- Genetic Testing with no Clinical Significance
- Observational Study in Private Spaces
- Non-intrusive Interview Online (video and audio)
- Minor Psychological or Behavioural Intervention Study (subtle)
- Non-intrusive Focus Group (face-to-face)
- Non-intrusive Focus Group (remote video conferencing)
- Non-intrusive Interview (face-to-face)
- Observational Study in Public Spaces
- Non-intrusive Interview Telephone (audio only)

“Appropriately Informed” or **“Sufficiently Informed”**

Study Design	Mean Risk Score
Phase I Clinical Trial	8.4
Phase II Clinical Trial	7.59
Clinical Psychology/Psychiatry Intervention Study	7.38
Phase III Clinical Trial	6.85
Genetic Testing with Clinical Significance	6.65
Whole Genome Sequencing	6.54
Intrusive Focus Group (face-to-face)	6.41
Intrusive Focus group (remote via video conferencing)	6.34
Intrusive interview (online with video and audio)	6.32
Intrusive interview (face-to-face)	6.18
Intrusive Questionnaire Study	5.99
Physiological Intervention Study	5.94
Validated Clinical Questionnaire Study	5.92
Major Psychological or Behavioural Intervention Study (overt)	5.91
Intrusive Interview Telephone (audio only)	5.85
Identifiable Secondary Analysis of Healthcare Data	5.57
Phase IV Clinical Trial	5.25
Randomised Non-Drug Clinical Study	5.23
Identifiable Secondary Data Analysis	4.9
Genetic Testing with no Clinical Significance	4.71
Observational Study in Private Spaces	4.58
Non-intrusive Interview Online (video and audio)	3.79
Minor Psychological or Behavioural Intervention Study (subtle)	3.76
Non-intrusive Focus Group (face-to-face)	3.72
Non-intrusive Focus Group (remote video conferencing)	3.65
Non-intrusive Interview (face-to-face)	3.53
Observational Study in Public Spaces	3.16
Non-intrusive Interview Telephone (audio only)	3.04
Anonymous Secondary Analysis of Healthcare Data	2.7
Non-intrusive Questionnaire Study	2.48
Anonymous Secondary Data Analysis	2.04

- Anonymous Secondary Analysis of Healthcare Data
- Non-intrusive Questionnaire Study
- Anonymous Secondary Data Analysis

“Appropriately Informed” or **“Sufficiently Informed”**

Further thoughts/issues:

- Opt in vs Opt out
- Myth of the 24 hours
- Legal Requirements (consider using appendices)
- PPI
- Piloting with participant groups
- Summaries/diagrams
- eConsent – doesn't make much difference!

Consent forms

54 Consent forms can be a helpful prompt to share key information, as well as a standard way to record a decision that can make regular review easier. They can also be used to review decisions made at an earlier stage, and the relevant information they were based on.

55 But, filling in a consent form isn't a substitute for a meaningful dialogue tailored to the individual patient's needs.