

Generic and enduring consent – the essential elements

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Consent

Latin origin 'consentire'

'con' meaning 'with' or 'together with'

'sentire' meaning 'to think and feel'

'To think and feel together'

To agree in opinion or sentiment; to be of the same mind; to accord; to concur.

Capable, deliberate, and voluntary assent or agreement to, or concurrence in, some act or purpose proposed by another, implying physical and mental power and free action.

➤ **Informed consent**

Consent given after being completely advised of the nature, benefits, costs, and risks of a suggested course of action.

Scale of consent

- **Specific consent**
 - Consent gained for a defined, strictly specified and time limited piece of work
- **Generic or ‘broad’ consent**
 - Type or purpose of research defined in general terms
- **Blanket consent**
 - No restrictions on type or purpose of research

Which can truly be informed consent?

Enduring consent

- No time limit placed on consent to use samples
- Don't have to re-contact patients in the future
- Enables research in the future using as yet unspecified or conceptualised hypotheses or techniques
- Does it make it administratively difficult if consent is withdrawn?

Existing collections

- Collections consented for specific purposes
 - Can these be used again for different purpose?
 - Should you go back to re-consent?
 - How do you go back to re-consent?

‘Qui tacet consentire videtur.’ (Legal)

He who is silent (about a thing) appears to give consent (to that thing).

‘I shall assume that your silence gives consent.’

[Plato](#)

Do tissue banks fit?

- Are we trying to fit into consent definitions and parameters designed for others?
- Consent historically used where an intervention is being suggested
 - Surgery
 - Clinical trial
- Tissue banks have changed the possibilities for sample research

Standardisation

- Should there be an international norm for consent level for research tissue banks?
 - Opt out countries
 - IRB review
 - Does the material and purpose of collection affect the level of consent?
- When working across national borders have to respect law or practice in those countries where samples collected

Consent forms

DESIGN

- Choices to opt in or out of by tick boxes
 - Administrative issues
- All or nothing
- Specific v generic
- Single project v open ended
- Single page

CONSENT FORM FOR PATIENT

White/VICR, Green/Cancers notes, Blue/Pathology, Key
Yellow/Patient, Pink/Patient Notes

Wales Cancer Bank
NHS GIG

Patient Identification Number for this study:
Title of Project: Wales Cancer Bank
Name of Principal Researcher: Professor Malcolm Mason
Contact telephone number: 029 2031 6964

To confirm agreement with each of the statements below, please initial in the box

1. I confirm that I have read, understood and have had time to consider the information sheet dated (version number 3) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and will not affect my medical treatment or legal rights in any way.
3. I understand that sections of my medical notes may be looked at by responsible individuals from the Wales Cancer Bank where it is relevant to this study. I give permission for these individuals to have access to my records.
4. I understand and agree that some of my medical information may be passed to other organisations involved in the research on the understanding that my personal patient confidentiality will be maintained.
5. I understand, and agree to, data relating to my donated samples being stored electronically.
6. I agree that I will ask my partner/friend if they would be willing to participate in this study as a control.
7. I confirm agreement to take part in the above study.

Name of patient: Date: Signature:

Name of person taking consent: Date: Signature:

OR

Researcher: Date: Signature:

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Version 3 - 03/09/08

Can it work?

YES – it does for the Wales Cancer Bank

- Consenting for 4 years using generic and enduring consent
 - 99.1% patients (2650) agree to consent
- No patients have (yet) withdrawn consent
- Patient information sheets need to be clear
- Consent recorded on clinical database

Why ask?

- Commonly voiced opinion
 - Should excess tissue automatically be used for research?
 - Patients often assume this happens
 - ‘Pay off’ for free NHS treatment?
- Human Tissue Act
 - ‘Gold standard’
- Does it need to be written? Implied consent

Who should take consent?

- Nurses?
- Ward staff?
- BMS?
- Research fellow?
- Clinician/surgeon?

- What is the appropriate training?
 - Is GCP enough?
- Should there be a recognised tissue bank training course to address the issues specific to tissue banking including consenting?

Conclusion

- Generic (broad) and enduring consent for future research is valid ethically and useful for tissue banks, but
 - personal information related to research must be handled safely;
 - donors of biological samples must be granted the right to withdraw consent;
 - changes to the legal or ethical authority or status of a tissue bank are approved by an NRES ethics committee.

Remember

‘No one can make you feel inferior
without your consent.’

Eleanor Roosevelt