



Is consent required for MSI & IHC testing?

Clara Gaff, Ian Frayling, Angus Clarke, Mark Rogers
All Wales Medical Genetic Service
The Institute of Medical Genetics

Context

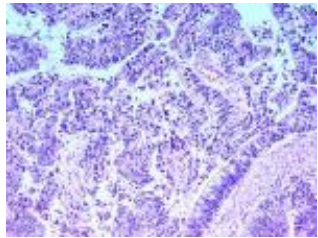


- Clinical
- Genetic risk assessment ('screening')
- Tissue collected from a living person

Clinical Settings



Genetic Service



Anatomical Pathology



Surgeon

Comparison



	Genetics Clinic	Pathologist	Surgeon
Sample	Stored Tissue	New	New
Other tests performed?	No	Yes	Yes
Specific written consent for MSI/IHC	Yes	No	No?
Genetic counselling	Yes	No	No/limited
Duty of care	To individual & family	To perform a full & proper examination	To individual (& family?)



Same test

Same implications

Different information

Different consent procedures



Practical considerations

- Standard approach to consent
- Different duty of care
- Differences in consent for genetic testing occur in other areas of genetics

Legal Considerations - UK 2005



- Uncertain area of law

- Living person

Data Protection Act

Laws of negligence

consent

- Person who 'has died'

no consent

Legal Considerations – UK 2006



- Human Tissue Act (2004) comes into force & is prospective
- HTA applies if...

... *medical information obtained about a person is relevant to another person*

Condition 4, Schedule 1

- Tissue samples and DNA samples are considered separately



Consent required?

DNA

- Living person (probably) **consent**
- A person who 'has died' **consent**

Tissue

- Living person **consent**
- A person who 'has died' **consent**



Giving consent

The Human Tissue Act does not specify what information needs to be given

The Human Tissue Authority will give guidance on this.



Final thoughts

- Legally, sometimes need consent, sometimes not
- A provider can choose to do more than the minimum legal requirement
- Education approach (screening)

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