

# Video information to support the process of obtaining informed consent: using foetal tissue for brain tumour research

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/01/2009	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr DA Walker

### Contact details

Academic Division of Child Health  
School of Human Development  
E Floor East Block  
University Hospital  
Nottingham  
United Kingdom  
NG7 2UH  
+44 (0)115 924 9924 ext 43324/41727  
david.walker@nottingham.ac.uk

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0192107555

# Study information

## Scientific Title

A randomised controlled trial of the use of video information to support the process of obtaining informed consent: to use foetal tissue for brain tumour research

## Study objectives

To assess whether the use of recorded media (video tape) within the informed consent process is as acceptable, feasible and informative as the conventional face-to-face informed consent processes used in current clinical practice.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

## Health condition(s) or problem(s) studied

Informed consent processes

## Interventions

Randomised controlled trial to assess whether the use of recorded media (video tape) within the informed consent process is as acceptable, feasible and informative as the conventional face-to-face informed consent processes used in current clinical practice.

## Intervention Type

Other

## Phase

Not Applicable

**Primary outcome measure**

1. Patient assessment of acceptability
2. Patient anxiety levels
3. Patient level of relevant knowledge
4. Patient degree of satisfaction
5. Clinical feasibility and acceptability of the different methods of obtaining informed consent

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

30/01/2002

**Completion date**

31/12/2006

**Eligibility****Key inclusion criteria**

1. Age range of subjects 18 - 40 years
2. Female

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Female

**Target number of participants**

Patients = 20 terminations of pregnancy

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

30/01/2002

**Date of final enrolment**

31/12/2006

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**  
**Academic Division of Child Health**  
Nottingham  
United Kingdom  
NG7 2UH

## **Sponsor information**

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Queen's Medical Centre University Hospital NHS Trust (UK)

## **Results and Publications**

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Interim results article</a>	interim results	01/12/2003		Yes	No