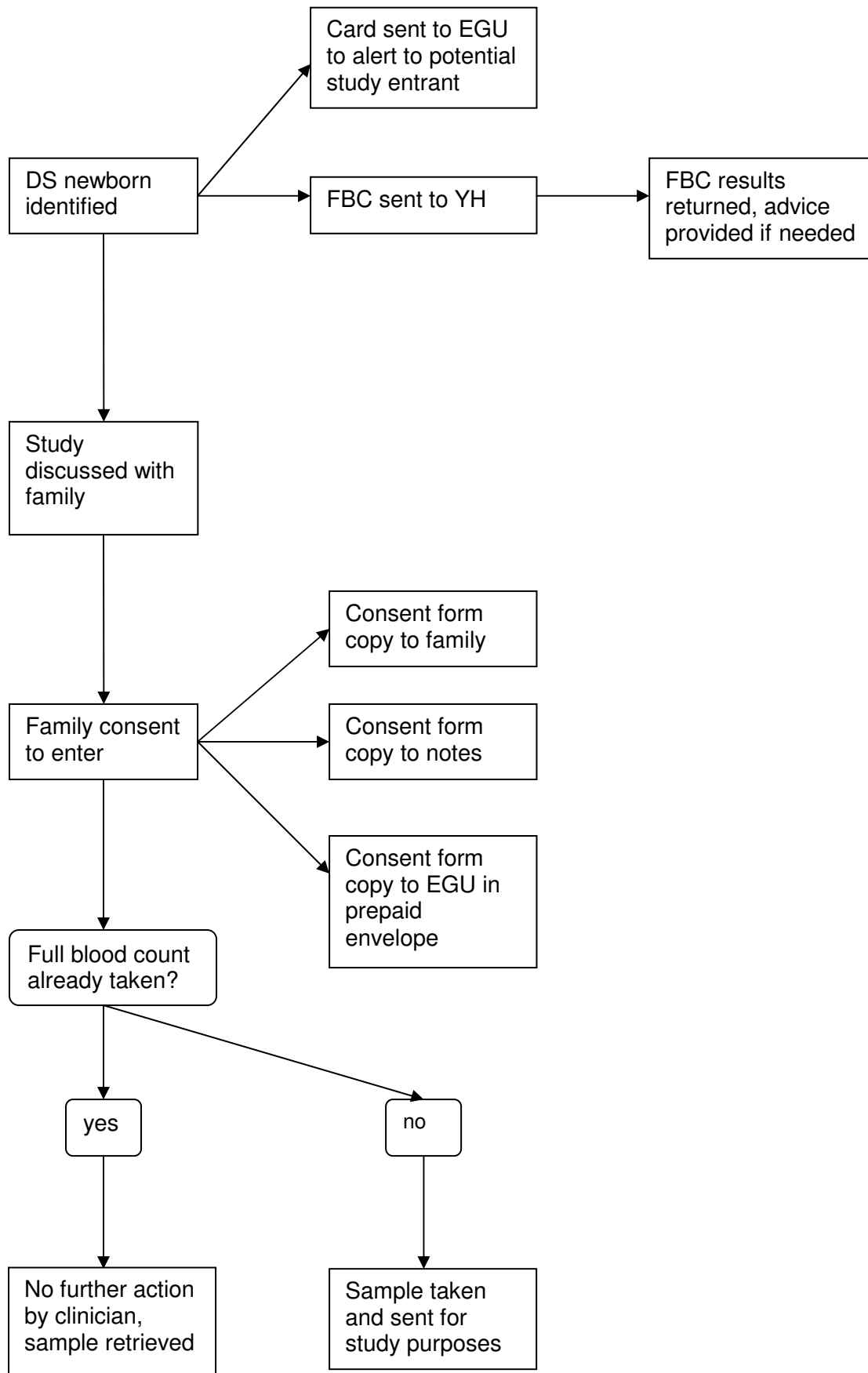
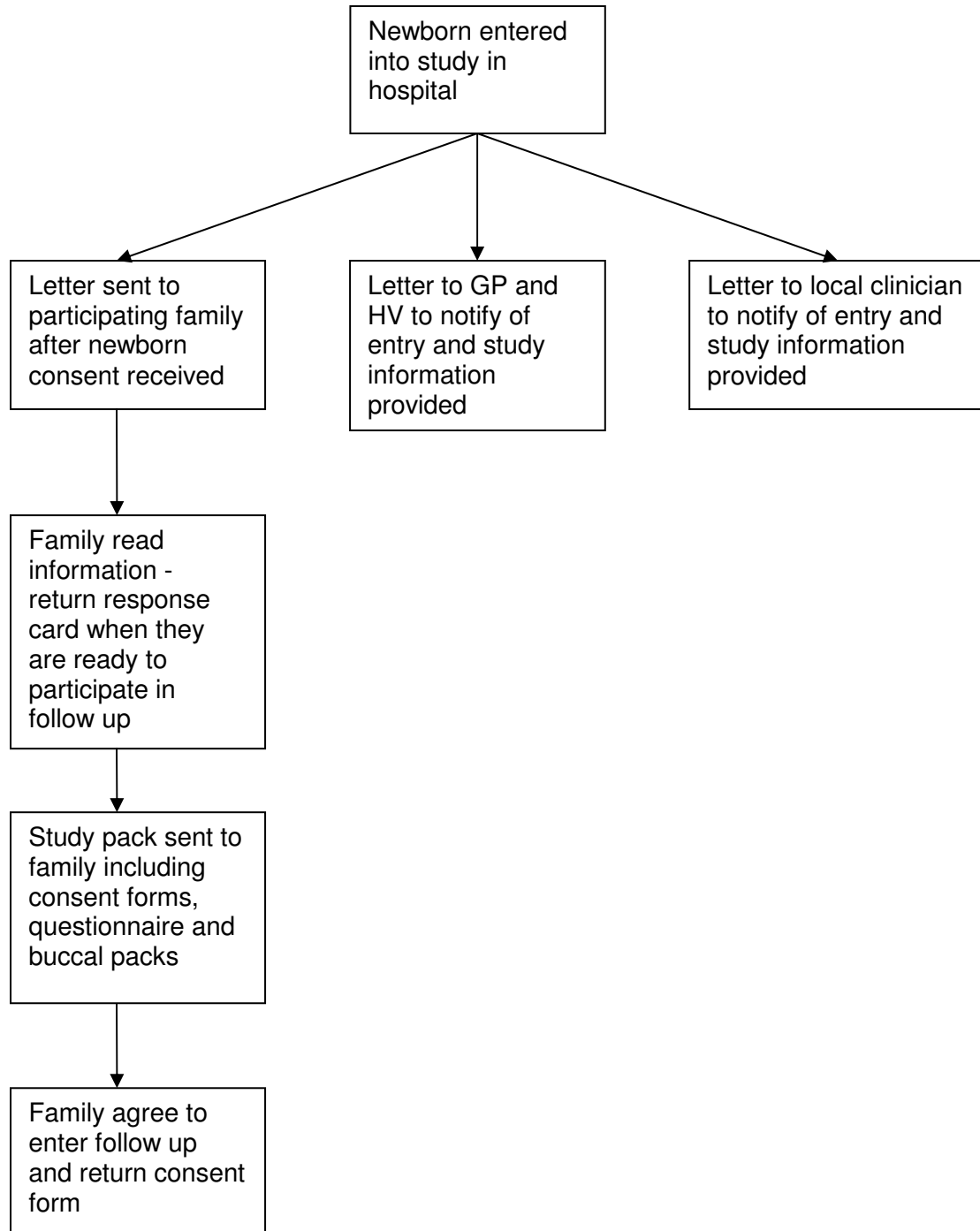


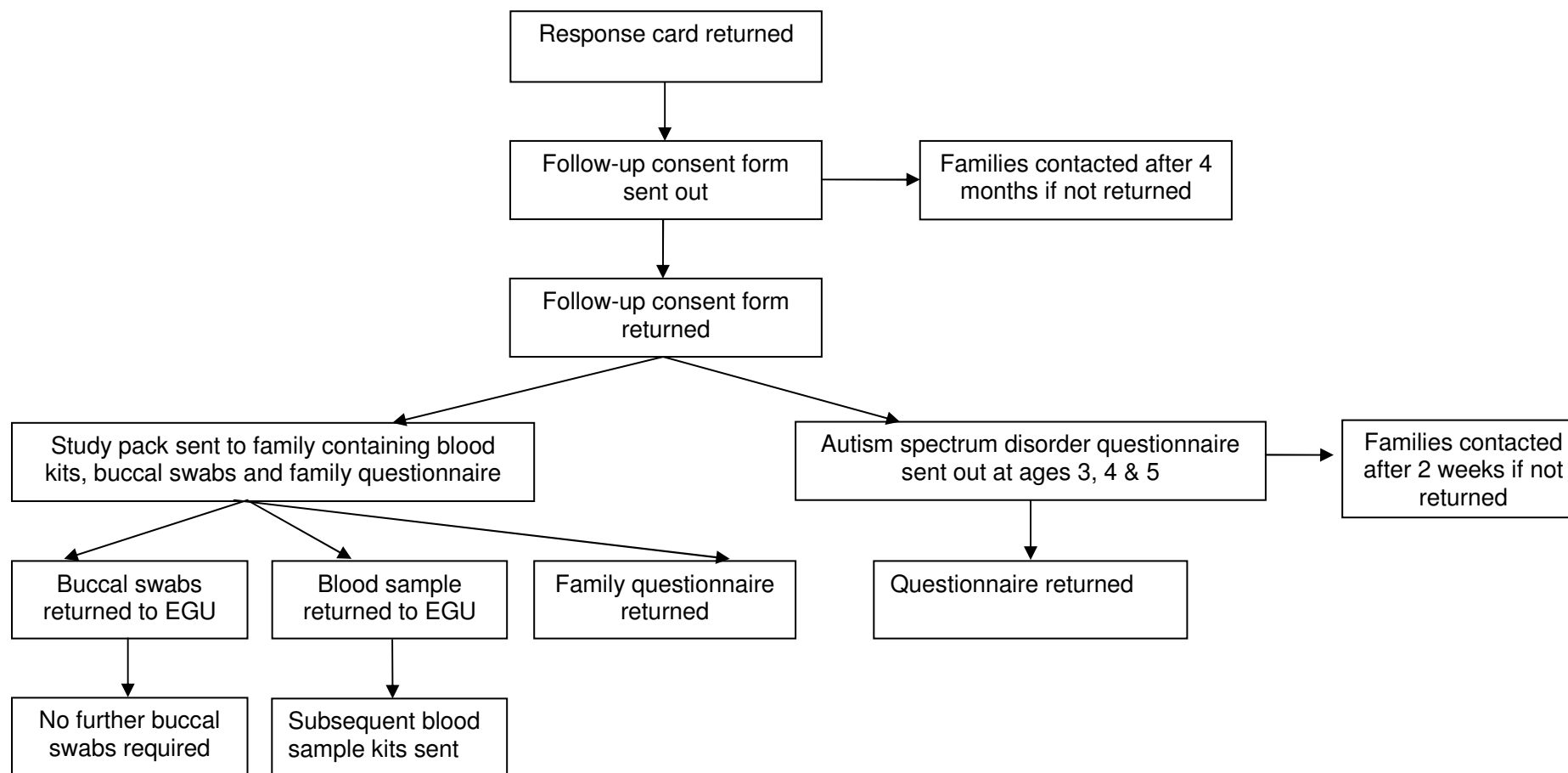
## Appendix 1: Flow chart to describe process of entry into the study



**Appendix 2: Flow chart to describe process of contact with families after hospital**



### Appendix 3: Flow chart to describe follow-up



#### **Appendix 4: membership of the steering committee**

Pat Ansell	University of York
Rachel Davies	Downs Syndrome Association
Pat Doyle	London School of Hygiene & Tropical Medicine
Beki James	University of York
Sally Kinsey	Leeds Teaching Hospitals NHS Trust
Tracy Lightfoot	University of York
Liz Marder	DSMIG
Lawrence Miall	Leeds Teaching Hospitals NHS Trust
Sheila Puri	Community Paediatrician Leeds
Eve Roman	University of York

## Appendix 5: Adjacent Regional Neonatal Networks

### Greater Manchester Neonatal Network:

14 hospitals  
Total births per annum 34 000

### Northern Regional Neonatal Network:

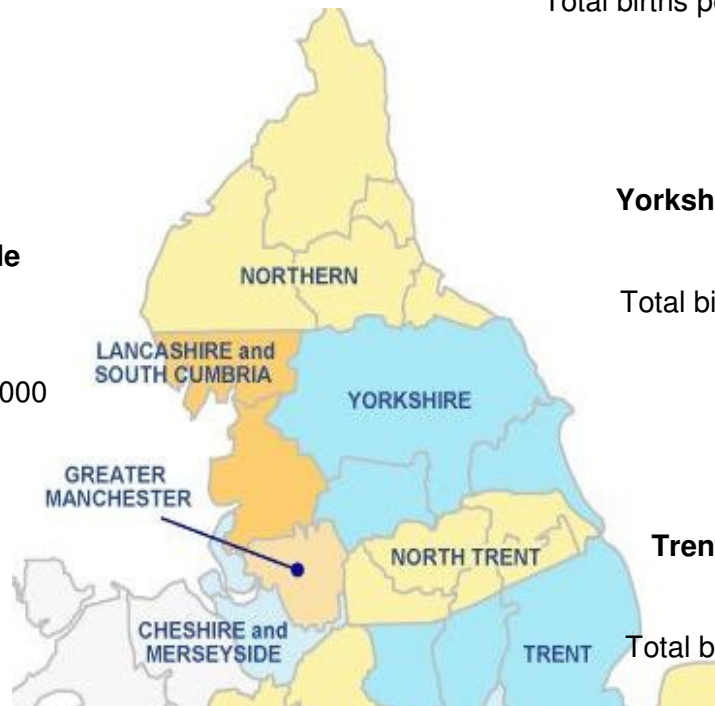
17 hospitals  
Total births per annum 31 000

### Yorkshire Neonatal Network:

12 hospitals  
Total births per annum 37 000

### Cheshire and Merseyside Neonatal Network:

8 hospitals  
Total births per annum 25 1000



### Trent Neonatal Network:

6 hospitals  
Total births per annum 23 000

### North Trent Neonatal Network:

8 hospitals  
Total births per annum 27 000

## Appendix 6: Details of the adjacent Regional Neonatal Networks

### Yorkshire Neonatal Network

St James' University Hospital, Leeds  
Leeds General Infirmary  
Bradford Royal Infirmary  
Calderdale Royal Infirmary  
York District General Hospital  
Scarborough Hospital  
Airedale General Hospital  
Huddersfield Royal Infirmary  
Pontefract General Infirmary  
Dewsbury and District General Hospital  
Harrogate District Hospital  
Hull Royal Infirmary

Number of births per annum: 37 000

### North Trent

Barnsley District General  
Bassetlaw District General Hospital , Worksop  
Chesterfield & North Derbyshire Royal Hospital  
Diana Princess of Wales Hospital , Grimsby  
Doncaster Royal Infirmary  
Jessop Wing of Sheffield Teaching Hospitals  
Rotherham District General Hospital  
Scunthorpe General Hospital  
Sheffield Children's Hospital Neonatal Surgical Unit

Number of births per annum: 27 000

### Trent

Lincoln County Hospital  
Derbyshire Children's Hospital  
King's Mill Hospital  
Nottingham City Hospital  
Pilgrim Hospital  
Queen's Medical Centre University Hospital

Number of births per annum 23 000

### Greater Manchester Neonatal Network

Billinge Hospital , Wigan  
Fairfield General Hospital , Bury  
Hope Hospital  
Macclesfield District General Hospital  
North Manchester General Hospital  
Royal Oldham Hospital  
Rochdale Infirmary  
St Mary's Hospital

Stepping Hill Hospital , Stockport  
Tameside General Hospital  
The Royal Bolton Hospital  
Trafford General Hospital  
Wythenshawe Hospital

Number of births per annum: 34 000

Northern Region Neonatal Network

Bishop Auckland General Hospital  
Cumberland Infirmary, Carlisle  
Darlington Memorial Hospital  
Friarage Hospital, Northallerton  
University Hospital of Hartlepool  
Hexham General Hospital  
James Cook University Hospital, Middlesbrough  
University Hospital of North Tees  
North Tyneside General Hospital  
Queen Elizabeth Hospital, Gateshead  
Royal Victoria Infirmary (Newcastle)  
South Tyneside District General Hospital  
Sunderland Royal Hospital  
University of Durham Hospital  
Wansbeck General, Ashington  
West Cumberland, Whitehaven

Number of births per annum: 31 000

Cheshire and Merseyside Neonatal Network

Arrowe Park Hospital, Wirral  
Countess of Chester  
Leighton Hospital, Crewe  
Liverpool Women's  
Macclesfield Hospital  
**Ormskirk Hospital**  
Warrington Hospital  
Whiston Hospital  
Alder Hey Hospital

Number of births per annum: 25 100

**Appendix 7: Proforma for review of neonatal blood films**

Copy of FBC attached?      Yes  No

DIFFERENTIAL %

Blasts	<input type="text"/>
Myeloid precursors	<input type="text"/>
Neutrophils	<input type="text"/>
Monocytes	<input type="text"/>
Eosinophils	<input type="text"/>
Basophils	<input type="text"/>
Lymphocytes	<input type="text"/>

DYSPLASIA

None = 0, Mild = 1, Mod. = 2, Severe = 3

NEUTROPHILS

Hypogranular	<input type="text"/>
Agranular fragments	<input type="text"/>
Hypersegmentation	<input type="text"/>
Pelger forms	<input type="text"/>

RED CELLS

Macrocytes	<input type="text"/>
Basophilic stippling	<input type="text"/>
Poikilocytes	<input type="text"/>
Normoblasts	<input type="text"/>

PLATELETS

Giant forms	<input type="text"/>
Megakaryoplast	<input type="text"/>

MONOCYTES

Elongated lobes	<input type="text"/>
Azurophilic granules	<input type="text"/>

Slide reviewed by \_\_\_\_\_

Date \_\_\_\_\_



Appendix 8: List of abnormalities of the full blood count which will trigger discussion with a Paediatric Haematologist at the Regional Centre for Paediatric Haematology

If any of the full blood count parameters are *outside* the limits below then the results must be discussed with a Paediatric Haematologist at the Regional Centre for Paediatric Haematology at the soonest possible opportunity:

	0-3m	3-6m	6-12m	2y	3y	4y	5y
Hb g/dl	<7 >16	<7 >17	<7 >17	<7 >17	<7 >17	<7 >17	<7 >17
PCV L/L	<0.25 >0.6	<0.25 >0.5	<0.25 >0.5	<0.25 >0.5	<0.25 >0.5	<0.25 >0.5	<0.25 >0.5
MCV fL	<70 >110	<70 >110	<65 >100	<65 >100	<65 >100	<65 >100	<65 >100
WBC x 10 <sup>-9</sup> /L	<4 >20	<4 >20	<4 >20	<4 >20	<3 >18	<3 >18	<3 >18
Neutrophils x 10 <sup>-9</sup> /L	<0.5 >10	<0.5 >10	<0.5 >10	<1 >10	<1 >10	<1 >10	<1 >10
Lymphocytes x 10 <sup>-9</sup> /L	<2 >12	<2 >12	<2 >12	<1 >10	<1 >10	<1 >10	<1 >8
Basophils x 10 <sup>-9</sup> /L	>0.2	>0.2	>0.2	>0.2	>0.2	>0.2	>0.2
Eosinophils x 10 <sup>-9</sup> /L	>1.5	>1.5	>1.5	>2	>2	>2	>2
Platelets x 10 <sup>9</sup> /L	<100 >500	<100 >500	<100 >500	<100 >500	<100 >500	<100 >500	<100 >500

If the Paediatric Haematologist believes that further clinical management is required then the study co-ordinator will be informed and the identity of the person from whom the sample was taken will be retrieved. The concerns will then be discussed with the clinician managing that person so that they can take appropriate action. The concerns or results will not be discussed directly between the study team and an individual person.

## The Children with Down's Syndrome Study



### Progress report December 2006

Thank you all for supporting the Children with Down's Syndrome Study. We have been really pleased with its progress, and have also had positive feedback from families. Below is a brief study update.

### Recruitment into the study

More children have taken part in the study than we anticipated which has been very encouraging. The recruitment rates, determined by date of consent, are shown below:

Month	Number recruited	Cumulative total
June 2006	6	6
July 2006	1	7
August 2006	3	10
September 2006	6	16
October 2006	5	21
November 2006	6	27

It is also encouraging to note that the process of recruitment into the study has had positive feedback from both clinicians and families, who report that the instructions are clear and the literature family-friendly.

### Geographical coverage

The geographical coverage is also proceeding well, with the study running in almost two thirds of the target hospitals. The current situation is shown below:

Stage	Number of hospitals
Study is up and running	41
Research and Development approval pending	6
Talk given, Local Lead to be decided	2
Talk pending	8
Talk date yet to be set, but contact made	7
Total	64

### Problems

There have been problems with a few of the neonatal blood samples:

- clotting – as the samples are likely to have a relatively high haematocrit they are prone to clotting. This should be avoided if the tube is gently agitated after the sample has been taken.
- missing label – one sample was unlabelled. In the newer packs I have stapled a label to the form to help avoid this.
- insufficient sample – ideally about 0.75-1.0ml is needed for analysis.
- age of sample – where possible we are happy to have existing samples to avoid unnecessary interventions, however we can only use samples that have already been taken if they are less than 3 days old. Slides of any age can give us helpful information.

### Website

The website has been updated and the family forum is now open. This is a secure part of the website for families where they can post messages and photos, and which we hope will be a real support to many of them especially in the first few months.

**Funding**

We had another successful grant application for the study which will allow two more people to join the study team.

**Publications**

Although the study is clearly still at an early stage the neonatal samples are already being reviewed by a panel of Senior Paediatric Haematologists: Professor Irene Roberts, Hammersmith Hospital; Dr Sally Kinsey, Regional Centre for Paediatric Haematology in Leeds; Dr Georgina Hall, The Radcliffe Hospital, Oxford. We are planning to publish the preliminary findings of morphological review once slides from the first 100 entrants have been reviewed.

**Approaches for collaboration**

We have had various new approaches from groups in this country and overseas wishing to discuss possible collaborations. We are keen for the data gathered to be used to the full to help us learn about children with Down's syndrome and so to plan their care more effectively. Any such collaboration would need to pass through all the relevant ethics committees. We will let you know when we have more information about collaborations.

**Conclusion**

We are extremely pleased with the current progress. The next meeting of the Stakeholder Committee is 3<sup>rd</sup> January when we will discuss future directions. Both the Down's Syndrome Association and the Down's Syndrome Medical Interest Group will be represented as we look at how to maximise the study's potential. It is a mark of the study's success so far that we are planning to drop the word 'Northern' from the title, as it is spreading out beyond this confine. In future, we will refer to the study as 'The Children with Down's Syndrome Study'.

Thank you all again for your help.

Beki James  
Study Coordinator  
11.12.06



# CDSS Children with Down's Syndrome Study

## Progress report: May 2007

Thank you for your continued support for this important study. The Children with Down's Syndrome Study (CDSS) has now been running for one year and your assistance is vital for its ongoing success. The study is going very well and we have had positive feedback from the families involved.

### Recruitment

To date, out of 66 children born with Down's Syndrome in the participating hospitals, 57 families have consented to take part in the newborn stage of the study and we are awaiting consent from a further 3. In addition, 28 families have now agreed to enter the follow up stage of the study.

### Geographical coverage

The study is up and running in 52 hospitals across the six regions included in the study (Trent, North Trent, Greater Manchester, Cheshire and Merseyside, Yorkshire and Northern).

### Website

The study has a new website address ([www.cdss.org.uk](http://www.cdss.org.uk)) which is hopefully easier to remember. The old address will still take you to the site for the time being.

The family forum section of the website has now been open for a few months and families are starting to use the site to contact other parents and share experiences. Five families have joined the forum so far and we hope this will grow as the study progresses.

### Stakeholder Committee Meeting

The first meeting of the steering group since the study began recruiting participants was held on the 3<sup>rd</sup> January 2007. All committee members are pleased with the progress of the study and ways of taking the study forward were discussed. The next meeting is scheduled to take place in October 2007.

### Study poster

We have enclosed a poster containing details of the study with this newsletter. This can be displayed in staff areas to help remind colleagues about the study and how to recruit a new family. If you would like further copies, please contact Sarah Woodhall, R&D coordinator on [sarah.woodhall@egu.york.ac.uk](mailto:sarah.woodhall@egu.york.ac.uk) or tel: 01904 321896.

Thank you all again for your help.

### Contact details

For any general enquiries, please contact us on:

Free phone: 0800 3280655

Email: [cdss@egu.york.ac.uk](mailto:cdss@egu.york.ac.uk)



# CDSS Children with Down's Syndrome Study

## Progress report: March 2008

The Children with Down's Syndrome Study (CDSS) has now been running for almost 2 years and it is going really well:



**121 families have joined so far**, and we have had positive feedback from families who have found it helpful to be part of the study as they adjust to the diagnosis.



**At least 2/3 of eligible babies are joining the study** - we have been able to compare our numbers against the National Register which records births by hospital. In 2006 67% of all eligible cases joined the study - with some hospitals managing to recruit all cases. We are waiting for the 2007 figures, which may well be even higher.



**53 hospitals are now taking part in the study**, and we are waiting for R&D approval for another 8 hospitals. Discussions are underway with a view to expanding into Scotland and Ireland.



**The new entry packs are working well.** If you still have the old packs then please discard them: we had a set of old consent forms arrive recently...



**We are having a few problems blood samples arriving late.** Most samples arrive the next day, but some seem to take a few days to arrive, which can make the results quite hard to interpret. It would really help if you could mark the padded envelope as urgent. If it is possible to get the sample in the post within an hour of it being taken then that makes a big difference.



**We are talking at the Spring Meeting of the Royal College of Paediatrics and Child Health.** We have been invited to present the study as the first talk in the Childhood Disability session on Tuesday 15<sup>th</sup> April. Please do come and join us there.

When we set out it was our hope that the CDSS would make an important contribution to improving the healthcare of children with Down's syndrome. We are delighted to see it working so well. Thank you all again for your help in achieving this.

### Contact details

These have changed! We are always happy to be contacted, but please make sure you have updated our contact details to:

Free phone: 0800 3280655

Email: [cdss@egu.york.ac.uk](mailto:cdss@egu.york.ac.uk)



# CDSS Children with Down's Syndrome Study

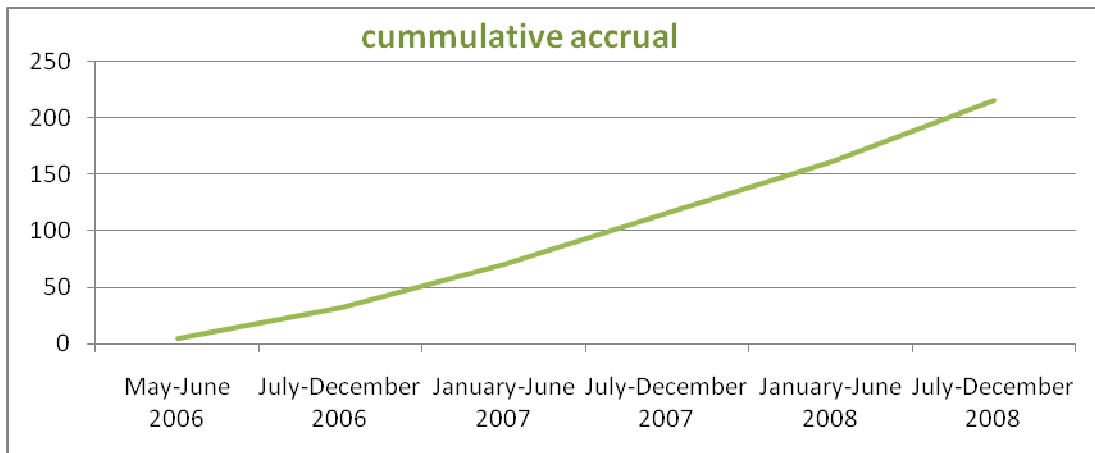
Progress report: May 2009

Many thanks for your continued support of The Children with Down's Syndrome Study (CDSS) which has now entered its third year of recruitment.



**245 families have consented to be part of CDSS and we are recruiting in 61 hospitals.**

We are currently comparing our data against the National Register which records births by hospital and we will then feedback consent rates to each individual hospital.



**CDSS has been included on the National Institute for Health Research Clinical Research Portfolio (UKCRN).** This has led to approaches by other hospitals to be involved in the study and plans are underway to extend to the West Midlands South research network.



Our aim is that CDSS will make an important contribution to improving the healthcare of children with Down's syndrome. We have recently established collaborations to investigate autism in Down syndrome as well as speech and language development.



We have started to abstract data from obstetric records across several of the neonatal networks and hope to expand to other area in the forthcoming year.



We still receive old paperwork occasionally, if you find that you have run out of entry packs the relevant documentation is available on the CDSS website ([www.cdss.org.uk](http://www.cdss.org.uk))

**We are delighted to see CDSS working so well and thank you all again for your help in achieving this. We are always happy to be contacted if you have any questions or suggestions about the study.**

Free phone: 0800 3280655 or email: [cdss@egu.york.ac.uk](mailto:cdss@egu.york.ac.uk)