MERIDIAN Study – Form D
NIHR HTA 09-06-01
Initial Fetal Medicine Consultation
Referral for in utero MR

Patient name
Patient DOB
Study ID (if known)

Background information

Date of Clinic
Referring Clinician
Clinic phone no:
NHS number
Patient phone no:
Gestational age ☐☐ weeks ☐☐ days
☐ Singleton pregnancy
☐ Multiple pregnancy

Structural diagnoses

List multiple abnormalities where necessary (brain only); please use "ViewPoint" diagnostic classification wherever possible. Please provide other relevant details, e.g. Location / side of abnormality). For multifetal pregnancies please specify fetus number.
Please attach or fax a copy of the most recent fetal medicine clinic letter or summary sheet.

Please complete for each diagnosis identified	Fetus #	Other details if relevant	Confidence of diagnosis: very unsure (10%)	unsure (30%)	equivocal (50%)	confident (70%)	highly confident (90%)
Ventriculomegaly*			☐	☐	☐	☐	☐
Agenesis of the corpus callosum			☐	☐	☐	☐	☐
Other (please specify):							
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐

*Ventriculomegaly cases

Normal situs? ☐ Yes ☐ No
If no, please give details:

	Trigone size (mm)	Please tick (√) near field measurement
Left side	☐☐.☐	☐
Right side	☐☐.☐	☐

MERIDIAN Study – Form D (continued)
NIHR HTA 09-06-01
Initial Fetal Medicine Consultation
Referral for in utero MR

Patient name

Patient DOB

Study ID (if known)

Prognosis

What are the chances of normal neuro-developmental outcome?

☐ Not Known ☐ Intermediate (50-90%) ☐ Normal

☐ Poor (<50%) ☐ Favourable (>90%)

Management

Was TOP discussed? ☐ Yes ☐ No i.e. Was there any discussion at all about termination of pregnancy, whether raised by you or the woman herself?

Was TOP offered? ☐ Yes* ☐ No i.e. Did you discuss TOP as a potential management choice which would be available to the woman if she wishes?

*If yes, was this based on a substantial risk of handicap? ☐ Yes ☐ No i.e. Do you consider that the CNS abnormality alone is of sufficient severity to justify termination under clause E (significant risk of serious mental or physical handicap)?

Other comments:

Technical factors

Were there any technical factors that contributed to a low confidence structural diagnosis? ☐ Yes ☐ No

If yes: (please indicate all that apply)

☐ High body mass index ☐ Fetal position ☐ Oligohydramnios

☐ Other, please specify

Which ultrasound technique was used to make the diagnosis (one or both)? ☐ 2D ☐ 3D*
*Please save 3D US volume for retrospective analysis where possible

Date of Referral:

MERIDIAN Study – Form E
NIHR HTA 09-06-01
Attendance for MRI scan
In utero MR diagnostic feedback

Patient name

Patient DOB

Study ID (if known)

Background information

Date of MR

Referring Clinician

Patient hospital no:

Gestational age weeks days

☐ Singleton pregnancy
☐ Multiple pregnancy

Reporting radiologist

Contact no:

Adverse events / problems

Were any adverse events or problems encountered relating to the MRI examination? ☐ Yes ☐ No
(e.g. Patient injury, claustrophobia, incomplete or suboptimal examination, radiographer or patient-reported MR phenomena)

If yes: (please indicate all that apply)

- ☐ Loose metallic object/projectile
- ☐ Medical implant / prosthesis
- ☐ Anxiety/claustrophobia – Was the examination completed? ☐ Yes ☐ No
  If no: Was any useful diagnostic information provided? ☐ Yes ☐ No
- ☐ Skin heating/other sensory effects
- ☐ Persistent fetal movement causing incomplete / suboptimal examination
- ☐ MR equipment or software failure causing incomplete / suboptimal examination
- ☐ Other, please specify

Other relevant details / comments including incident reference number:

MERIDIAN Study – Form E (continued)
NIHR HTA 09-06-01
Attendance for MRI scan
In utero MR diagnostic feedback

Patient name
Patient DOB
Study ID (if known)

Structural diagnoses

List multiple abnormalities where necessary (brain only); please use "ViewPoint" diagnostic classification wherever possible.
Please also comment on each diagnosis identified at referral.
For multifetal pregnancies please specify fetus number.

Please complete for each diagnosis identified	Fetus #	Other details if relevant (e.g. Location / side of abnormality)	very unsure (10%)	unsure (30%)	equivocal (50%)	confident (70%)	highly confident (90%)	Diagnosis excluded
Ventriculomegaly*	☐		☐	☐	☐	☐	☐	☐
Agenesis of the corpus callosum	☐		☐	☐	☐	☐	☐	☐
Other (please specify):								
	☐		☐	☐	☐	☐	☐	☐
	☐		☐	☐	☐	☐	☐	☐
	☐		☐	☐	☐	☐	☐	☐

*Ventriculomegaly cases

	Trigone size (mm)
On the same side as the heart / stomach	☐☐.☐
Opposite side to the heart / stomach	☐☐.☐

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Effective date: 25 May 2011

MERIDIAN Study – Form G
NIHR HTA 09-06-01
Subsequent Fetal Medicine Consultation
Clinical feedback following in utero MR

Patient name
Patient DOB
Study ID (if known)

Please attach or fax a copy of the most recent fetal medicine clinic letter or summary sheet.

Background information

Date of Clinic

Consultant

Clinic phone no:

Patient hospital no:

Gestational age weeks days

☐ Singleton pregnancy
☐ Multiple pregnancy

Diagnosis

Did the MRI provide additional information in this case? ☐ Yes ☐ No

If yes, was this information also visible on your follow up US? ☐ Yes ☐ No

Prognosis

What are the chances of normal neuro-developmental outcome?

☐ Not Known ☐ Intermediate (50-90%) ☐ Normal

☐ Poor (<50%) ☐ Favourable (>90%)

Did the MRI change your prognosis in this case? ☐ Yes ☐ No

Management

Was TOP discussed? ☐ Yes ☐ No i.e. Was there any discussion at all about termination of pregnancy, whether raised by you or the woman herself?

Was TOP offered? ☐ Yes* ☐ No i.e. Did you discuss TOP as a potential management choice which would be available to the woman if she wishes?

*If yes, was this based on a substantial risk of handicap? ☐ Yes ☐ No i.e. Do you consider that the CNS abnormality alone is of sufficient severity to justify termination under clause E (significant risk of serious mental or physical handicap)?

Did MRI change your counselling in this case?

☐ Not at all ☐ Minor influence (reassurance or confirmation only)

☐ Major change (changed discussion of management options)

MERIDIAN Study – Form G (continued)
NIHR HTA 09-06-01
Subsequent Fetal Medicine Consultation
Clinical feedback following in utero MR

Patient name
Patient DOB
Study ID (if known)

Please attach or fax a copy of the most recent fetal medicine clinic letter or summary sheet.

Management

Chosen management plan:

- ☐ Continued pregnancy – discharged from fetal medicine clinic
- ☐ Continued pregnancy – with fetal medicine follow-up
  - ☐ Further imaging planned to monitor progress? ☐ Yes ☐ No
  - **If yes**: ☐ US ☐ MRI
- ☐ Termination of pregnancy With feticide: ☐ Yes ☐ No

How do you rate the contribution of MRI to the final choice of management?

☐ None ☐ Minor ☐ Significant ☐ Major ☐ Decisive

Other investigations

Were other investigations performed? ☐ Yes ☐ No

If yes: (indicate all those performed and whether they were contributory)

		Changed the prognosis and counselling?	Major factor in choice of management?
☐ Karyotype	☐ Normal ☐ Abnormal	☐ Yes ☐ No	☐ Yes ☐ No
☐ Echo	☐ Normal ☐ Abnormal	☐ Yes ☐ No	☐ Yes ☐ No
☐ Infection screen	☐ Normal ☐ Abnormal	☐ Yes ☐ No	☐ Yes ☐ No
☐ 3D US*		☐ Yes ☐ No	☐ Yes ☐ No
☐ Other, please specify		☐ Yes ☐ No	☐ Yes ☐ No

*Was 3D imaging performed at initial fetal medicine assessment – prior to MRI ? ☐ Yes ☐ No
*Did 3D US modify your initial diagnosis prior to MRI? ☐ Yes ☐ No
*Was the volume saved and interpreted off-line by an expert? ☐ Yes ☐ No
*Did 3D US provide the same diagnostic information as MRI? ☐ Yes ☐ No
*Did 3D US modify your confidence in the 2D US diagnosis? ☐ No change ☐ Increased ☐ Decreased

***Please save the 3D volume for subsequent analysis wherever possible.**

Other comments, including results of karyotyping or virology

MERIDIAN Study – Form H
NIHR HTA 09-06-01
Pregnancy Outcome Data Collection
Outcome Data Collection Form (First child)

Patient name
Patient DOB
Study ID (if known)

Background information

Date of clinical/note review

Reviewed by:

Contact no:

Hospital:

Patient hospital no:

Consultant:

Details of clinic visits following entry into the study

Do you have access to hand held notes and full patient records? ☐ Yes ☐ No (If no: Please go to next page)

Fetal medicine clinic visits
(consultant appointment with detailed ultrasound examination, e.g. Initial consultation; follow-up visits for counselling with consultant)

No. of visits

Details (e.g. Fetal medicine, fetal medicine and neonatology (if joint) and dates (if known))

Other fetal medicine clinic visits
(consultation with therapy or special investigation, e.g. Amniocentesis; feticide)

No. of visits

Details
(e.g. Clinic visits and dates (if known))

Other hospital antenatal clinic visits
(other obstetric consultant appointments, or appointments for counselling, advice or monitoring with midwife)

No. of visits

Details
(e.g. Clinic visits and dates (if known))

Other clinic visits
(e.g. Paediatric neurology, surgery, neonatology etc)

No. of visits

Details (e.g. Neurology, surgery and neonatology (if joint) and dates (if known))

MERIDIAN Study – Form H
NIHR HTA 09-06-01
Pregnancy Outcome Data Collection
Outcome Data Collection Form (First child)

Patient name
Patient DOB
Study ID (if known)

Outcome (First child)

Pregnancy outcome ☐ Livebirth (Complete Section A) ☐ Non-livebirth (Complete Section B)

Section A - Livebirths

If livebirth

Child name

Child date of birth

Gestational age* weeks days

*if < 37 weeks please also complete section C (page 5)

Hospital or NHS/CHI number (if known)

Mode of delivery ☐ Caesarean section ☐ Instrumental / Assisted ☐ Normal delivery

Place of delivery ☐ Hospital / labour ward ☐ Home / other

Surviving infant? ☐ Yes ☐ No** (Please go to next page)

If Yes, please complete postnatal diagnosis

Postnatal Diagnosis

Please select one of the following diagnostic sources:
(**listed in the order of preference**)

☐ Postnatal MR
☐ Postnatal CT
☐ Transcranial ultrasound
☐ Third trimester ultrasound - date
☐ Clinical diagnosis recorded in paediatric case notes

Diagnosis

Please complete the continuation sheets for multiple pregnancies

MERIDIAN Study – Form H
NIHR HTA 09-06-01
Pregnancy Outcome Data Collection
Outcome Data Collection Form (First child)

Patient name
Patient DOB
Study ID (if known)

Section A - Livebirths (perinatal, neonatal and infant deaths)

****If Not Surviving infant** (perinatal, neonatal and infant deaths)

Date of death:

Post Mortem Diagnosis

Please select one of the following diagnostic sources:
(**listed in the order of preference**)

- ☐ Post mortem autopsy
- ☐ Post mortem MR
- ☐ Third trimester ultrasound - date
- ☐ Clinical diagnosis recorded in paediatric case notes

Diagnosis

Cause of death as recorded on death certificate or paediatric case notes

Please complete the continuation sheets for multiple pregnancies

MERIDIAN Study – Form H
NIHR HTA 09-06-01
Pregnancy Outcome Data Collection
Outcome Data Collection Form (First child)

Patient name
Patient DOB
Study ID (if known)

Section B (Non-livebirth)

Tick one box only ☐ Stillbirth or miscarriage/intrauterine fetal demise

Detected by ultrasound prior to delivery? ☐ Yes* ☐ No

*If yes, gestation recorded ☐☐ weeks ☐☐ days

☐ Termination of pregnancy - Feticide: ☐ Yes ☐ No

Date of delivery ☐☐☐☐☐☐☐☐

Gestation** ☐☐ weeks ☐☐ days

**if < 37 weeks and not TOP please also complete section C (page 5)

Post Mortem Diagnosis

Please select one of the following diagnostic sources:
(**listed in the order of preference**)

☐ Post mortem autopsy

☐ Post mortem MR

☐ Third trimester ultrasound - date ☐☐☐☐☐☐☐☐

☐ Clinical diagnosis recorded in paediatric case notes

Diagnosis

Cause of death (where recorded on certificate of death/stillbirth or paediatric case notes)

Please complete the continuation sheets for multiple pregnancies

MERIDIAN Study – Form H
NIHR HTA 09-06-01
Pregnancy Outcome Data Collection
Outcome Data Collection Form (First child)

Patient name
Patient DOB
Study ID (if known)

Section C – Preterm deliveries (not TOP)

Did the mother present in preterm labour? ☐ Yes ☐ No

If No, was labour induced? ☐ Yes ☐ No

Reason for preterm labour:

- ☐ Spontaneous preterm labour
- ☐ Spontaneous preterm rupture of the membranes
- ☐ Medically indicated induction of preterm delivery (maternal disease)
- ☐ Medically indicated induction of preterm delivery (fetal anomaly)
- ☐ Medically indicated induction of preterm delivery (fetal compromise)
- ☐ Other

Please give further details

Was delivery by caesarean section? ☐ Yes ☐ No

If yes, was this an elective procedure? ☐ Yes* ☐ No**If emergency procedure please give details on page 6

*Reason for elective caesarean:

- ☐ Breech presentation
- ☐ Multiple pregnancy
- ☐ Prior caesarean section
- ☐ Fetal anomaly
- ☐ Fetal compromise
- ☐ Other

Please give further details

Please complete the continuation sheets for multiple pregnancies

Section C – Preterm deliveries – emergency caesarean section

**Reason for emergency caesarean :

- ☐ Failure to progress in labour
- ☐ Suspected fetal compromise (fetal distress)
- ☐ Other

Please give further details

Please complete the continuation sheets for multiple pregnancies