Lunenfeld-Tanenbaum Research Institute
MOUNT SINAI HOSPITAL
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Research Centre for Women's and Infants' Health BioBank
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Research Centre for Women's and Infants' Health (RCWIH) BioBank
Overview of clinical data collection for research

(updated October 2014)

The following document details the clinical information collected for patients who have provided informed consent for the donation of perinatal specimens (placental tissue, umbilical cord and umbilical cord blood, maternal/paternal samples, *etc.*) to support research projects associated with the Research Centre for Women's and Infants' Health (Mount Sinai Hospital Research Ethics Board approval #10-0128-E). All clinical information is obtained by members of the RCWIH BioBank staff who have received approval of the MSH REB and to protect patient confidentiality only de-identified information (*i.e.* lacking specific patient identifiers such as the patient's name or hospital ID) is provided to study-affiliated investigators. Every effort is made to prepare a complete and accurate clinical profile for each participant in the study, however an incomplete profile may result when certain parameters are unavailable (*i.e.* if data is not reported in patient records or if specific tests were not clinically indicated or performed while the patient was cared for at MSH).

Categories of clinical data collected

1. Patient demographics

- date of birth
- ethnicity, partner's age & ethnicity
- infection status
- blood type and Rhesus factor
- prepregnancy weight, current weight, height and calculated body mass index

2. Obstetrical history

- gravidity and parity
- number of live births (with distinction of term and preterm deliveries)
- number of multiple births
- number of living children
- number of abortions (with distinction of spontaneous losses and therapeutic terminations)
- number of ectopic pregnancies
- details of previous pregnancies (mode of delivery, outcome, gestational age at delivery, sex, birth weight, complications of the pregnancy or delivery)

3. Medical history

- existing medical conditions
- current medications (with relevant treatment duration and dosing information)
- substance use: smoking status, alcohol consumption and recreational/illicit drug use

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4. Details of the current pregnancy

- date of last menstrual period, estimated date of delivery/confinement, and the method used to validate gestational age dating (LMP, ultrasound examination, date of embryo transfer)
- nature of conception (with distinction of spontaneous and assisted conceptions)
- abnormal antenatal test results (*if applicable*)
- complications of current pregnancy (*if applicable*)

5. Labour details (*when applicable*)

- date/time of admission
- reason for admission
- cervical dilatation on admission (*if applicable*)
- presence or absence of labour (with distinction of spontaneous and induced labour)
- mode of induction, if induced labour (*i.e.* amniotomy, oxytocin, prostin gel, other)
- use of any agents to augment labour
- time/date of labour onset, full dilatation, and pushing onset
- time/duration of labour stages 1 through 3

6. Delivery details

- date/time of delivery
- gestational age at delivery
- mode of delivery (vaginal, ceasarian section with or without labour)
- indication for mode of delivery (induction of labour and/or caesarian section)
- for vaginal deliveries the nature of the delivery (*i.e*. spontaneous, assisted by vacuum or forceps)
- rupture of membranes (with distinction of spontaneous and artificial rupture)
- time/date of membrane rupture and duration before birth
- description of amniotic fluid (*i.e*. clear, blood- or meconium-stained fluid)
- outcome of delivery (*i.e*. singleton, multiple birth, intrauterine fetal demise)
- fetal sex, birth weight and calculated weight percentile (Note: calculations are based on singleton data reported by Kramer et al. 2001 Pediatrics 108(2) p. e35)
- APGAR score (evaluations at the 1 and 5 minute time points)
- fetal measurements at birth (head circumference and length)
- any complications of delivery
- placental weight (wet, untrimmed) and calculated weight percentile
- chorionicity of placenta and membranes (for multiple gestations)

7. Blood work and urinalysis data *(reported for multiple days where possible)*

- date of test and gestational age at testing
- hemoglobin levels
- white blood cell count
- platelet count
- serum levels of aspartate aminotransferase (AST) and alanine aminotransferase (ALT)
- serum levels of uric acid, creatinine and indirect bilirubin
- glucse random plasma
- results of glucose challenge tests (GCT) and 3-hour glucose tolerance tests (GTT)
- First Trimester Screening and Integrated Pregnancy Screening results (serum levels of PAPP-A, free beta-hCG, AFP, hCG, Inhibin A, unconjugated estriol (uE3), and calculated risks for trisomy 21, 18/13 and open spina bifida)
- urinalysis by dipstick (negative, trace, 1+, 2+, 3+, 4+) or following 24-hour urine collection (reported as grams per day)
- other relevant lab results

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8. Ultrasound evaluations *(reported for multiple days where possible)*

- date of test and gestational age at testing
- placental length, width and site (*i.e.* anterior, posterior, lateral, fundal, *etc.*)
- insertion of umbilical cord and description of cord
- assessment of placental morphology (normal or abnormal, with identification of infarcts, echogenic lesions, or abnormalities)
- uterine artery Doppler analysis (left and right uterine artery PI and presence/absence of notching)
- umbilical artery Doppler analysis (PI and cord flow or EDV)
- middle cerebral artery Doppler analysis (PI and PSV)
- ductus venosus waveform
- estimated fetal weight and fetal weight percentile
- biophysical profile
- fetal anatomy measurements (biparietal diameter, head circumnference, abdomen circumference and femur length)
- amniotic fluid index
- identification of fetal anomalies (generalized as involving CNS, skeletal, respiratory, cardiac, genitourinary, or gastrointestinal systems)
- other relevant observations

9. Blood pressure data *(reported for multiple days where possible)*

- date of test and gestational age at testing
- maximum systolic and maximum diastolic pressures on the date of testing
- characterization of blood pressure prior to pregnancy (described as normal or elevated)

10. Relevant parameters for preterm deliveries

- cervical length measured by ultrasound and gestational age at testing
- presence and type of cervical cerclage (*if applicable*)
- infection status for Group B Streptococcus
- presence of vaginal/cervical infections (*with information on type of infection and gestational age at onset*)
- clinical evidence of infections (highest maternal temperature, maximum white blood cell count, tachycardia)
- administration of tocolytics, glucocorticoids or antibiotics (along with the type, gestational age at treatment and relevant dosing information)

11. Gross and microscopic placental features following pathological evaluation

- fixed, trimmed placental weight and overall dimensions
- umbilical cord insertion, coiling, and diameter
- presence of relevant gross or microscopic features including (but not limited to): acute chorioamnionitis (Stage 1 or Stage 2/3), intervillous thrombi, infarction, perivillous fibrin deposition, subchorionic hemorrhage, retroplacental hemorrhage, chronic villitis, acute chorionic vasculitis, acute funisitis, fetal vascular thrombotic lesions, decidual vasculopathy, distal villous hypoplasia, villous dysmaturity/immaturity, advanced villous maturity for gestational age, chronic deciduitis, plasma cell deciduitis, chorioangioma, chorangiosis, *etc.*

12. Digital images

- maternal and fetal surfaces of the placenta are captured at the time of delivery