MEMO FROM GENETIC LABORATORY

TO: Health Care Provider
FROM: Department of Medical Genetics at Shodair Children’s Hospital
RE: Fetal Pathology Specimens

Enclosed please find forms regarding shipment of the fetal loss specimen or products of conception to our laboratory for genetic studies and/or external fetal exam.

Take into consideration that if at the time of specimen collection the patient is “admitted” at your site, Shodair will bill the referring facility.

- Please be aware that we need to have the form “Authorization for Fetal Studies and Dispatch” reviewed and signed by the patient. We would like this enclosed with the specimen, however it may be FAXed to (406)444-1022 if enclosure with specimen is not practical. We will not be able to process the specimen for any studies without this signed form.

- It is especially important to let your patients know that, in many circumstances, the cost of the fetal exam and genetic laboratory studies may not be a covered expense by their insurance provider, including Medicaid. It is recommended that the insurance provider be contacted before submitting the specimen. Patients are responsible for any charge not covered by insurance.

- A genetic counselor is available to speak with your patient about this loss. Someone can be reached at 1-800-447-6614 during normal business hours.

- If you have further questions please contact us at (406)444-7532. Please leave a voice mail with contact information if you are calling after hours.

Please fill the forms in the last three pages (page 6, 7 and 8) in this package and send the forms with the specimen!
An explanation of the different options:

**Limited Fetal Pathology (external exam):** An external exam of the body and placenta to identify any physical abnormalities or birth defects that might explain the cause for the demise.

**Cytogenetics:** A sample of tissue is taken to culture cells for study. This looks at the structure of the fetal chromosomes to identify any obvious structural defects or missing or extra chromosomes as you would see for example in Down syndrome.

**Limited Fetal Pathology (external exam) and cytogenetics:** After the external exam, a geneticist confers with the ordering physician to discuss whether to continue with chromosome studies. *If the family is unsure which options they want, this is the best one to choose as chromosome studies can always be cancelled. There is a setup fee of $150 that is charged if the studies are started and cancelled.*

Please use FedEx overnight shipping services, and check the option of “Saturday delivery” if specimens are ready to send out on Friday. On the weekends we do have lab staff on site. You can either call 406-444-7532 and leave a message which they will return, or call 1-800-447-6614 which will connect you with one of our inpatient units. Ask for the genetics laboratory and they will get a message to them.
Instructions for shipping

Before Dispatch, Please Call Shodair Genetics Lab at 406-444-7532 or 1-800-447-6614 (Ask for The Cytogenetics Laboratory)

Chromosome and DNA Studies

General:
- May be on any tissue, but typically the samples are: Blood, Bone Marrow, or Fetal Tissue Biopsies.
- Method of shipment should be overnight by FedEx. Please check the option “Saturday Delivery” for specimen sent out on Friday.
- Order form/referral sheet should be filled out completely and included for each specimen.
- Call Shodair with any questions before 5pm:
  - 1-800-447-6614, ext 7532.
  - Weekends and after 5pm: 406-444-7532 (voicemail after hours)

Details of packaging and shipping:
- Specimen containers must be marked with the patient name and a second unique identifier such as referring lab number or date of birth. Be sure that paperwork is included with the specimens.
- Enclose specimens in biosafety-approved packaging. Packaging should be leak-proof and the paperwork protected from specimen. BIOHAZARD LABELS ON THE INSIDE BOX ONLY.
- Send specimen as soon as possible by preferred carrier (FedEx or other professional couriers). Sample should arrive no later than the day following collection.
- Label with our address and designate:
  - URGENT – KEEP AT ROOM TEMPERATURE

Fetal Pathology Specimens

General:
- Send the whole UNFIXED/UNFROZEN specimen (fetus and placenta). If tissue sampling is done onsite, label with tissue type. Place specimen in sterile container with proper transport media.
- If the specimen (gestation less than 20 weeks or weighing less than 500g) is small, place in a sterile plastic urine jar.
- If specimen is large, place placenta in a sterile sealable plastic container and tape to seal. Double bag fetus and place in Styrofoam or plastic container laying flat. Use bags to pack the fetus securely in the container for transit.
- Insulate with absorbent material and place in appropriately sized cardboard box for shipping with completed paperwork, protected from leakage.
- Mark the outer box with “fragile” and “do not freeze.” Do NOT mark outer box with “biohazard.” Send specimen as soon as possible by preferred carrier (FedEx or other professional couriers).
- Before dispatch, please call Shodair at 1-800-447-6614, ext 7532.
Packaging of POC Laboratory Specimens for Send Out

POC of fetal Demise (must be fresh tissue, non-fixed, non-frozen)

1. Transport tissue biopsies in sterile saline with no preservatives, viral transport media or tissue culture media.
2. Place smaller specimens in tube or submit original container, label tube or container with patient information and biohazard sticker.
3. Place tube in biohazard bag.
4. Place tube in 2nd plastic non-sterile container, line with absorbent materials and label with biohazard sticker.
5. Tape container securely.
6. Enclose completed request form in biohazard bag paperwork slot.
7. Place in Styrofoam box with cold packs if necessary.
8. Place in cardboard box.
9. Make sure that Delivery Service knows that it is a Clinical Laboratory Specimen to ensure proper transportation.
10. Do not place biohazard warning stickers on outside of boxes.
11. Call (406)444-7532 to review shipment of sample and get further instructions if needed.
FETAL PATHOLOGY SERVICES

PROTOCOL FOR SENDING PRODUCTS OF CONCEPTION AND ABORTUSES

I. Discuss appropriateness of genetic referral with the parents.

II. Decide if fetal pathology, chromosome study or both are indicated. Refer to a current price list, if appropriate, for this decision.

III. Send the WHOLE UNFIXED / UNFROZEN specimen including FETUS AND PLACENTA. See Shipping Instructions for details.

For fetal material of less than 20 weeks gestation or less than 500 grams, the following documents must accompany the specimen:

□ 1. Shodair form "Authorization for Fetal Studies and Dispatch" SIGNED BY PARENT(S); COPY GIVEN TO PARENTS. This form is available from the Shodair Genetics Laboratory, or copy the example in this catalog.

□ 2. Shodair Fetal Studies Request Form. This form is available from the Shodair Genetics Laboratory, or copy the example in this catalog.

□ 3. Any relevant OB records, medical summary, ultrasound report, etc.

For fetal material of age 20 weeks gestation or more the following documents in addition to those listed above must accompany the specimen:

□ 4. The MONTANA DEPARTMENT OF HEALTH AND ENVIRONMENTAL SCIENCES, AUTHORIZATION FOR REMOVAL, TRANSPORTATION AND FINAL DISPOSITION OF A DEAD BODY form. It is available through your hospital, and required by Montana law. The upper portion of this form should be filled in and the bottom line signed by physician, physician’s designee, coroner or mortician authorizing body removal from the place of death. (This document is not necessary if sampling is done onsite and only a piece of fetal material is sent to Shodair for cytogenetic studies.)

□ 5. Wrap specimen in absorbent material and place in a strong, leak-proof and insulated container (preferably two such containers, one inside the other). Cold packs may be enclosed with larger specimens, but no ice.

□ 6. Mark Biohazard on inside box only.

Send immediately to the Shodair Genetics Laboratory via FedEx overnight delivery. CALL THE LABORATORY AT SHODAIR HOSPITAL WHEN YOU ARE SENDING THE SPECIMEN OR IF YOU HAVE QUESTIONS: 406-444-7532; 1-800-447-6614.

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FETAL STUDIES REQUEST FORM (Please send this completed form with the specimen)

MOTHER: LAST NAME ___________________ FIRST NAME ___________________ DOB ___________________
FATHER: LAST NAME ___________________ FIRST NAME ___________________ DOB ___________________
Fetus Gender M / F ___________________ DATE & TIME OF DELIVERY: ___________________ Optional: Fetus Name: ___________________
REF. LAB #: ___________________ DATE COLLECTED: ___________________ DATE RECEIVED: ___________________

ETHNIC BACKGROUND: (Circle all that apply) European Caucasian, Hispanic, Native American, African American, Asian, Other

REFERRING PHYSICIAN/HEALTH PROFESSIONAL:
Name: ___________________ Address: ___________________ City, State, Zip: ___________________
Telephone: ___________________ FAX: ___________________

PRIMARY CARE PHYSICIAN:
NAME: ___________________

REFERRED INSTITUTION / CLINIC / LABORATORY:
Name: ___________________

ADDITIONAL REPORTS TO:
Name: ___________________

PHYSICIAN SIGNATURE: ___________________
(required for Medicare / Medicaid billing)
Date: ___________________

BILLING INFORMATION:
☐ REFERRING INSTITUTION

New clients please call laboratory with financial contact information.

☐ INSURANCE
Name of policy holder: ___________________
Policy holder DOB: ___________________
SS # (Guarantor): ___________________
Address: ___________________
Phone #: ___________________
Relationship to patient: ___________________
Insurance Co. / Policy #: ___________________
Insurance Co Contact / Phone #: ___________________

☐ Medicaid #: ___________________
State (MT, ID, WY): ___________________
SS#: ___________________

☐ SELF PAY

☐ Inpatient

CLINICAL INFORMATION
GRAVIDA: _______ PARA: _______ Spontaneous Abortions: _______ Therapeutic Abortions: _______ MOLAR: Yes _______ No _______ Stillbirths: _______

PRESENT PREGNANCY LMP: ____________ Pregnancy weeks by U/S: ____________ Date of U/S: ____________

FAMILY HISTORY
Repeated miscarriages _______ NO _______ SPECIFY _______
Stillbirth _______ NO _______ SPECIFY _______
Malformed _______ NO _______ SPECIFY _______
Mental retardation _______ NO _______ SPECIFY _______
Other _______ NO _______ SPECIFY _______

MATERNAL SERLOGICAL ESTS:
Toxoplasmosis _______ NO _______ SPECIFY _______
Syphilis _______ NO _______ SPECIFY _______
Rubella _______ NO _______ SPECIFY _______
CMV _______ NO _______ SPECIFY _______
Herpes _______ NO _______ SPECIFY _______
Coombs _______ NO _______ SPECIFY _______
Others (Specify) _______ NO _______ SPECIFY _______

PRESENT PREGNANCY
Threatened abortion _______ NO _______ SPECIFY _______
Oligo/polyhydranmosis _______ NO _______ SPECIFY _______
Diabetes _______ NO _______ SPECIFY _______
Pre-eclampsia/eclampsia _______ NO _______ SPECIFY _______
Hypertension _______ NO _______ SPECIFY _______
Alcohol _______ NO _______ SPECIFY _______
Drugs _______ NO _______ SPECIFY _______
Cigarettes _______ NO _______ SPECIFY _______
X-rays _______ NO _______ SPECIFY _______
Other exposures _______ NO _______ SPECIFY _______
Prenatal diagnosis _______ NO _______ SPECIFY _______
Illnesses/operations _______ NO _______ SPECIFY _______
Consanguinity _______ NO _______ SPECIFY _______
At risk serum screen _______ NO _______ SPECIFY _______

Other: ___________________

SPECIMEN TYPE: (Please circle) PLEASE NOTIFY THE LABORATORY WHEN A SPECIMEN IS BEING SENT. 1-800-447-6614, EXT. 7532
☐ Fresh tissue: _______ POC _______ fetal _______ other (specify source): ___________________

TEST REQUESTED: (Please check one or more; test descriptions with CPT codes and prices faxed on request)
☐ Limited Fetal Pathology (external exam) _______ Cytogenetics _______ Other: ___________________

Date Set Up: ____________ Med. Rec. # ____________ Admit # ____________ Shire # ____________

PLEASE CALL LAB @ (406)444-7532 WITH SHIPPING DETAILS.
Authorization for Fetal Studies and Dispatch
(Please send this completed form with the specimen)

To be filled out for all specimens regardless of gestational age.

We ( ), ___________________________, delivery date ________________, hereby permit release to the Department of Medical Genetics at Shodair Children's Hospital, Helena, MT, for limited fetal pathology studies (external exam, no removal of organs) and chromosome studies as indicated below:

Check from the following:

PROCEDURE

☐ Limited Fetal Pathology (external exam) $241

☐ Cytogenetic studies only $887

☐ Limited Fetal Pathology (external exam) and Cytogenetics $1,128

☐ Molecular (DNA) studies if required Please inquire

Further, I authorize: (Check only one box)

☐ The return of the remains to ___________________________ (mortuary) or Hospital Laboratory

☐ Shodair Children's Hospital to dispose of the remains. (applies only to <20 weeks gestation)

☐ Cremation and return of ashes to: (May apply to any gestational age)

☐ Cremation without return of ashes. (Applies only to ≥ 20 weeks gestation)

* Please Note: There is a $75.00 (<20 weeks) or $100.00 (≥ 20 weeks) charge for cremation of fetal material.

* A detailed price list is available.

I understand that I should contact my insurance provider (including Medicaid) for coverage of these services and that I am financially responsible for charges not covered by insurance.

Mother's signature

Father's signature

Witness

Witness

A genetic counselor is available to speak with you about your loss and answer questions about laboratory services. Please contact the Medical Genetics Department at Shodair Children's Hospital by calling toll-free 1-800-447-6614. (This form may be photocopied).

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MONTANA DEPARTMENT OF
PUBLIC HEALTH AND HUMAN SERVICES
Vital Statistics Bureau
PO Box 4210, Helena, MT 59604-4210

AUTHORIZATION
FOR REMOVAL, TRANSPORTATION AND FINAL DISPOSITION OF A DEAD BODY

☐ ORIGINAL TO Local Registrar
☐ ONE COPY TO Coroner
☐ ONE COPY TO MORTUARY/PERSOIN IN CHARGE OF DISPOSITION
☐ ONE COPY TO CEMETERY/CREMATORY OR TO ACCOMPANY REMAINS OUT-OF-STATE

Machine or Facsimile copies of this form shall be valid for all purposes

If fetal death, check this box: ☐ and provide data for mother or fetus as appropriate

NAME: ___________________________ DATE OF BIRTH: __________

SOCIAL SECURITY NUMBER: ___________________________ ☐ Male ☐ Female

DIED (or was found) ON: ___________________________

date and time

AT: ___________________________

name of institution, address, location of death or discovery as best described, including city or town

_________________________ COUNTY.

TO BE COMPLETED BY INDIVIDUAL AUTHORIZING REMOVAL, TRANSPORTATION AND FINAL DISPOSITION:

I HEREBY AUTHORIZE THE REMOVAL, TRANSPORTATION AND FINAL DISPOSITION OF THE REMAINS OF THE ABOVE-NAMED DECEDENT (OR IDENTIFIED FETUS) PURSUANT TO MY AUTHORITY UNDER 50-15-405 M.C.A.

I CERTIFY THAT I AM:

☐ THE CORONER HAVING JURISDICTION ☐ A MORTICIAN LICENSED UNDER 57-19-302, M.C.A.
☐ THE PHYSICIAN IN ATTENDANCE AT DEATH or THE PHYSICIAN'S DESIGNEE

________________________________________ date __________________________

signature Montana license # (if any)

________________________________________

name (typed or printed) name of agency or firm represented (if applicable)

address city state zip

If authorization is by person other than a mortician licensed under 57-19-302, M.C.A.

name and address of mortuary/person in charge of disposition and filling of death certificate under 50-15-402, M.C.A.

________________________________________

name (typed or printed) firm (if applicable)

address city state zip

Cremation Authorization: ____________________________ coroner's signature __________________________

date signed

CEMETERY OR CREMATORY AUTHORITY MAY COMPLETE

date of disposition ____________________________ ☐ buried ☐ cremated

cemetery or crematory name

city of disposition county state sexton or person in charge