ADVANCED CARE OB/GYN

PATIENT REGISTRATION FORM

www.advancedcareobgyn.com

PLEASE COMPLETE ALL INFORMATION. IF NOT APPLICABLE, MARK "N/A"

Patient Name_____SSN_____DOB:_____

(If minor) Parent's Names_____

Address_____City_____State_____Zip_____

Phone: Home _____ Cell _____ Work _____

Appointment reminder **"courtesy" preference: CALL: ____Home/____Cell OR _____TEXT MESSAGE*

E-Mail address_____

Referring Provider: _____ Primary Care Physician: _____

Status: Single Married Divorced Widow Legally Separated

Race: _____ Ethnicity: _____ Language: _____

ALLERGIES:_____**PHARMACY**_____**PHARMACY CITY**_____

Employer_____ Address_____Occupation_____

Spouse's Name_____DOB:_____SSN_____

Spouse's Employer_____Business Address_____

Spouse's Occupation_____Work Phone ( )_____ext:_____

PRIMARY INSURANCE INFORMATION_____

Insured's Name_____DOB:_____SSN_____

ID#_____Group#_____

Relationship to patient _____SELF _____ DEPENDENT Is patient a student?_____

SECONDARY INSURANCE INFORMATION_____

Insured's Name_____DOB:_____SSN_____

ID#_____Group#_____

Relationship to patient_____Is patient a student?_____

Patient Release:

I certify that the information I have provided is correct. I authorize the release of medical information as necessary to process insurance claims to insurance companies or their agencies (including Medicare) for the purpose of filing and payment of medical claims. I authorize payment of medical benefits to the provider. I ACKNOWLEDGE THAT INTEREST OR A FEE, AT THE PROVIDER'S CURRENT RATE, MAY BE CHARGED, on all balances owing to the provider that are past due. I permit a copy of this release to be used in place of the original.

Signature:_____ Date: ____/____/____

(Signature of patient or patient's legal representative)

REV: 02/21/13

ADVANCED CARE OB/GYN

HIPAA PRIVACY NOTICE CONSENT FORM

I understand and have been provided with Advanced Care's Notice of Privacy Practices that provides a more complete description of information uses and disclosures. Advanced Care reserves the right to make changes to their Privacy Notice and revised copies are available. By signing this form I acknowledge that I have been afforded the opportunity to consider Advanced Care's Notice of Privacy Practices prior to signing this consent and making healthcare decisions. I also understand and agree to have **my digital photo** identification taken as part of my electronic health records.

I authorize Advanced Care to release medical and financial information, including any or all reports, records, bill for services rendered or opinions found in my medical chart, with respect to treatment to any alternative healthcare giver.

Advanced Care maintains patient medical records on paper, on microfilm and/or electronic media which may be accessible to any physician or healthcare provider participating in my current or future care. Medical records are disclosed according to applicable NJ State and Federal laws, and the provisions of this consent.

HIPAA AUTHORIZATION TO DISCUSS YOUR MEDICAL INFORMATION:

_____ Patient ONLY **OR**

You may disclose my medical information to:

_____	_____	_____
Please Print Name	Relationship	Phone Number

EMERGENCY CONTACT: MEDICAL INFO IS NOT RELEASED TO THIS PERSON. (HOWEVER, THIS PERSON CAN BE THE SAME AS YOUR HIPAA AUTHORIZED CONTACT.)

_____	_____	_____
Emergency Contact	Relationship	Phone Number

I acknowledge that I have received a copy of Advanced Care's Notice of Privacy Practices, Patients Rights & Responsibilities and Patient Notices.

_____	_____
Signature of patient of legal guardian	Date

09/14/11

Advanced Care
Obstetrics Gynecology Infertility

BILLING POLICY

Welcome to Advanced Care OB/GYN. In order to better serve you with your insurance coverage, we are providing you with our billing policy. I understand that the practice will file all claims for services rendered to my insurance carrier for your primary insurance plan. Copays are due at the time of your appointment and there are no exceptions to this. We accept most insurances; however, it is your responsibility to ensure we participate with your plan. You must present your current active insurance at the time of your visit. We do not back bill. ***It is ultimately the patient's responsibility to understand their health coverage. Your employer should have a copy of your Benefits Guidebook or call your insurance company if you need detailed information about your coverage.***

I acknowledge that I am responsible for any balances that may be due to Advanced Care OB/GYN due to any/all of the following:

- ✓ Co-insurance, co pays and yearly deductibles
- ✓ Non-covered services
- ✓ Out-of-network charges
- ✓ Surgical Assistants not covered by your insurance company
- ✓ Terminated coverage
- ✓ No insurance coverage
- ✓ No referral obtained from primary care physician
- ✓ Failure to respond to insurance carrier correspondence (COB)

I understand that I will receive a statement for any balance due after my carrier has processed the claim. I understand and am agreeable that the balance of my statement will be paid in full to Advanced Care OB/GYN within thirty (30) days. If I am unable to pay the entire amount, I am responsible to *immediately*, upon receipt of the statement, call the billing office at 609-272-0506 to arrange a payment plan.

I understand that Advanced Care OB/GYN charges $10 for any non-Federal or State forms that need to be completed or any letters that need to be dictated on my behalf and must be paid in advance. Please be advised that there is a no-show/late cancellation policy. If you no-show or cancel less than 24 hours from your appointment time, you will be charged $50. If you are scheduled for surgery and cancel or no-show, you will be charged $100.

I understand that if I should pay by check to Advanced Care OB/GYN and the check is returned by the bank for non-sufficient funds, I will be charged the amount of the check plus a $30 processing fee. I also understand that I will no longer be able to pay by check for any monies owed to Advanced Care OB/GYN. I understand that failure to pay my balance and/or arrange payments and follow that payment agreement will result in collection agency action, including payment of a 40-50% collection agency fee, and/or discharge from the practice.

PLEASE NOTE: Each visit is documented in your medical record and a diagnosis is made by the provider. Diagnoses are made based on medical information, not based on coverage by insurance companies. To request a diagnosis change solely for the purpose of securing reimbursement from an insurance carrier is inappropriate and considered insurance fraud.

We are committed to giving the best care to our patients; and, in doing so; we ask your cooperation in meeting your financial responsibility.

_____ _____

Print Patient Name Date

_____

Signature of Patient or Patient Legal Representative

Advanced Care
Obstetrics Gynecology Infertility

MUTUAL AGREEMENT TO MAINTAIN PRIVACY

Dr. Salvatore Carfagno, Jennifer Gallas, PA-C and Mikaela Crowley, PA-C of Advanced Care OB/GYN agree to maintain the privacy of _____ ("Patient") as outlined in the HIPAA form. The Physician takes pride in being able to extend a greater degree of privacy than is required by HIPAA, state confidentiality mandates, and common law.

Federal and State privacy laws are complex. Unfortunately, some medical offices try to find loopholes around these laws. For example, HIPAA forbids physicians from receiving money for selling lists of patients or protected health information (PHI) to companies to market their products or services directly to the patients without their authorization. Some medical practices, though, can lawfully circumvent this limitation by having a third party perform the marketing. While personal data is never technically in possession of the company selling its products or services, the patient can still be targeted with unwanted marketing information. Physician believes this is improper and may not be in his patients' best interest. Accordingly, Physician agrees not to be paid for selling patient lists or PHI to any party for the purpose of marketing directly to his patients. Regardless of legal privacy loopholes, Physician will never attempt to leverage his relationship with Patient by seeking Patient's consent for marketing products for others.

In consideration for treatment and the above noted patient protection, Patient agrees to refrain from directly or indirectly publishing or airing commentary regarding Physician and his practice, expertise and/or treatment. Physician has invested significant financial and/or marketing resources in developing his practice. Published comments on web pages, blogs, and/or mass correspondence could severely damage Physician's practice. Physician has the right to equitable relief to prevent the initiation or continuation of publishing or airing of commentary regarding his practice, expertise and/or treatment.

Physician feels strongly about his patients' privacy as well as his practices' right to control its public image and privacy. Both Physician and Patient will work to prevent the publishing or airing of commentary about the other party from being accessed via web pages, blogs, or other electronic, print, or broadcast media without prior written consent. Finally, this Agreement shall be in force and enforceable for a period of five (5) years from Physician's last date of service to Patient.

Patient has been given the opportunity to ask questions and receive adequate explanations to his/her satisfaction.

So agreed this _____ day of _____, 20_____.

_____ _____

Patient Printed Name Patient/Guardian Signature (required)

Advanced Care OB/GYN Initial Office Visit (IOV)

Patient Name: _____ **Date**: _____

Primary Care Physician: _____ Last annual: _____
What is your highest level of education: _____
Are you allergic to any medications: Y or N If yes, which medications: _____
Please list all **medications you are currently taking**: _____
Any food allergies: _____

MENSTRUAL HISTORY:

First day of last menstrual period: __/__/__ Age 1st period started: _____
Do you have bleeding between periods? YES or NO
How often do you menstruate? Every _____ days. Regular Cycles: Yes or No
Cramps: __None __Moderate __Severe Number of pads or tampons used on heaviest day. _____

GYNECOLOGIC HISTORY: Have you ever had any of the following? (Check if yes).

__Abnormal PAP smear _____date of last PAP _____/_____/_____.
__Recurrent Vaginal Infections
__Gonorrhea
__Herpes
__Chlamydia
__Syphilis
__Condylomata (Genital warts)
__Infection of pelvic organs (PID)
__Cryosurgery or conization of cervix
__Surgery on female organs
__Difficulty holding urine
__Pain with intercourse
__Unusual vaginal bleeding
__Premenstrual syndrome (PMS)
__Endometriosis
__Infertility
__Fibroids
__OTHER: _____
How long have you been with your current sexual partner? _____
Did your mother take DES (a hormone to prevent miscarriage) when pregnant? __Y __N __Don't know.

CONTRACEPTIVE HISTORY: Check the methods you have used.

Past	Present		Past	Present	
___	___	Pills	___	___	Norplant
___	___	IUD	___	___	Natural Family Planning
___	___	Diaphragm	___	___	Tubal Ligation
___	___	DepoProvera	___	___	Vasectomy
___	___	Condoms	___	___	Other
___	___	Foam/Spermicide			

PREVIOUS PREGNANCIES: Please give all information in regard to you previous pregnancies by filling in the spaces below. If information is unknown leave space blank. (Include miscarriages)
Summarize previous pregnancies:
FULL TERM ___ PREMATURE___ABORTION/MISCARR.___NOW LIVE___MULTI BIRTHS___

Advanced Care OB/GYN Initial Office Visit (IOV)

Patient Name: _____ **Date**: _____

FAMILY HISTORY: have your parents, brothers or sisters ever had the following? (Check if yes.)

___Heart problems
___Diabetes
___Stroke or paralysis
___High blood pressure
___Blood Clots
___Genetic conditions, birth defects or multi pregnancies
___Jaundice, Hepatitis or liver problems
___Thyroid Problems
___Cancer
___Asthma or Tuberculosis
___Alcoholism or drug dependency
___Depression/Psychiatric illness

MEDICAL HISTORY: Have you ever had any of the following? (Check if yes.)

___Genetic or Birth defect
___High blood pressure
___Heart disease
___Blood clots
___Recurrent bladder infections
___Stroke or paralysis
___Cancer
___Frequent severe headaches
___Gastrointestinal problems
___Liver problems
___Hepatitis (A, B or C)
___Gall bladder problems
___Psych care/Depression
___Lung problems
___Thyroid problems
___Epilepsy or convulsions
___Anemia
___Bleeding problems
___Blood transfusion
___Alcoholism/Drug
___Kidney infection
___Breast problems
___Diabetes
OTHER: _____

___Positive TB test: ___/___/___ (date) Treated for TB: ___/___/___ (date)

REVIEW of SYSTEMS: Are you currently having problems with:

___Chest pain/irregular heart beat
___Abdominal or pelvic pain
___Heart disease
___Nausea/vomiting
___Ear/nose/sinus
___Weight change
___Dizziness/headache
___Muscle/Joint
___Breathing
___Bowel changes
___Bladder/urine leakage
___Anxiety/Nerves/Depression
___Chronic cough
___Bloody sputum
__ Hot flashes

Other please describe: _____ _____

Please list all times you have been hospitalized (excluding childbirth) – surgery and illnesses only:

Date: ___/___/___ Length of stay_____ Illness or Operation _____
Date: ___/___/___ Length of stay_____ Illness or Operation _____
Date: ___/___/___ Length of stay_____ Illness or Operation _____

Do you consider your diet:___Good ___Fair ___Poor On special diet? Y or N If yes what _____
What type of regular exercise: _____
Do you smoke cigarettes: Yes or No Number per day _____
Do you drink alcohol: Yes of No Number of drinks per day _____
Other recreational drugs: Yes or No What types: _____

Provider Signature: _____ Date: _____

ADVANCED CARE OB/GYN

Tay-Sachs Disease and Test

Patient Name: _____ Date: _____

Tay-Sachs disease is an inherited disorder that causes progressive neurologic disease. The infantile form is most common and symptoms become apparent between three to six months of age. They include loss of motor skills, seizures, blindness, neurodegeneration and death by the age four. There is no treatment available at this time. Tay-Sachs disease is caused by the lack of an enzyme called hexosaminidase A2, The deficiency of this enzyme causes the build-up of a special lipid that causes damage to other organs, the brain and nerves. 2

Tay-Sachs disease is inherited in a recessive manner.2 This means that only when both parents are carriers of Tay-Sachs disease can the disease occur in their children. When both parents are carriers of Tay-Sachs, there is a 25% chance with each pregnancy of having an affected child. 1,2 Tay-Sachs disease can occur in all ethnic groups,2 but it is found most commonly in the Ashkenazi Jewish populations. About 1 in 30 Ashkenazi Jewish individuals is a carrier of Tay-Sachs disease.1 Tay-Sachs is also found more frequently in the French-Canadian and Cajun populations. The carrier rate for other Caucasian ethnic groups is about 1 in 300.1 Carriers of Tay-Sachs disease do not exhibit symptoms that lead one to suspect their carrier status. It is recommended by the American College of Obstetricians and Gynecologists that Tay-Sachs screen be offered to couples who are pregnant or considering a pregnancy when at least one partner is Ashkenazi Jewish, French-Candida or Cajun.1 There are three types of screening tests available.

1. Tay-Sachs enzyme analysis in serum. This test is best for men and for women who are not pregnant and not taking birth control pills. This test is inaccurate in pregnancy women and those who take oral contraceptives.1 All positive results should be confirmed by DNA testing to rule out pseudo-deficiency.2 A pseudo-deficiency is caused by a mutation in the Tay-Sachs gene that results in a false-positive enzyme analysis.2 People with a pseudo-deficiency mutation are not at increased risk to have a child with Tay-Sachs, even if their partner is a carrier.2

2 Tay-Sachs enzyme analysis in leukocytes. This test is recommended for pregnancy women, women taking birth control pills and for those who have inconclusive serum results.1 All positive results should be confirmed by DNA analysis to rule out pseudo-deficiency. A pseudo-deficiency is caused by a mutation in the Tay-Sachs gene that results in a false-positive enzyme analysis.2 People with a pseudo-deficiency mutation are not at increased risk to have a child with Tay-Sachs, even if their partner is a carrier.2

3 Tay-Sachs DNA analysis. This test analyzes the Tay-Sachs gene for mutations commonly found in the Ashkenazi Jewish population. For this group, the carrier detection rate is greater than 95%.2 This analysis does not look for non-Jewish mutations. A negative result reduces the chance that a person is a carrier but cannot detect rare mutations. Tay-Sachs DNA analysis is recommended as a follow-up to inconclusive and positive serum and leukocyte results.1

If a couple is identified to be at risk of having a child with Tay-Sachs disease, prenatal diagnosis is available.1,2

References: 1. American College of Obstetricians and Gynecologists. Screening for Tay-Sachs Disease. Committee Opinion, Washington, DC: ACOG; 1995, Number 162.
2. Kaback, MM., GM2 Ganagliiosidoses (Hexosaminidase A-deficient). www.genetests.org. (March 10, 1999).

I have been explained the Tay-Sachs information and offered testing. I elect to:
_____ Accept _____ Decline

_____ _____
Patient Signature **Provider Signature**

Sequential Screen for Down Syndrome

Down syndrome, also known as Trisomy 21, is caused by an extra chromosome 21 in all the cells of the body. It is seen in 1 per 800 live births and usually occurs in women without a family history of genetic abnormalities. It is the most common genetic cause for mental retardation in this country and can also lead to certain birth defects.

In the past, the only method available for identifying women at higher risk for Down syndrome was "advanced material age", which used to be defined as a mother who was 35 years old or greater. However, by using this cut-off, only 30% of all Down syndrome cases could be detected.

There is now a newer screening option available to you which can increase the detection of Down syndrome to 90%. It is called a sequential screen. This test will **not** tell you if the baby does or does not have Down syndrome, but it **will** give you a more accurate estimation of your risk compared to using your age alone.

The sequential screen is a two-part test. Part one involved an ultrasound examination between 10.9 and 13.9 weeks to measure the thickness in the back of the baby's neck (nuchal translucency), along with a blood test from your finger. If the results from part one indicate an increased risk, you will then be notified and offered additional testing (see below). If results from part one are reassuring, you will be asked to complete part two of the test, which is ideally performed at 16 to 18 weeks and requires a blood sample from your arm. After part two is completed, you will be given a final result, which takes into account your age and the results from parts one and two. The sequential screen has a very high detection of Down syndrome (90%) but it requires that you return for both parts of the screen. It may also not be available by all laboratories that we are directed to use by your insurance company.

The sequential screen will also detect 90% of fetuses with Trisomy 18, another serious chromosomal abnormality, as well as 80% of neural tube defects such as spina bifida.

In 3.5% of normal pregnancies, the sequential screen will come back positive for Down syndrome. This is known as the false positive rate. In the vast majority of cases (~90%), women with a positive screen will **not** have a baby with Down syndrome. If the sequential screen does come back positive (either in the first or second trimester), you will be offered genetic counseling to discuss your specific risks, and you will be offered a more invasive test, chorionic villus sampling (CVS) or amniocentesis. These tests sample either the placenta (afterbirth) or amniotic fluid and will tell you for sure if your baby does or does not have Down syndrome.

The sequential screen is available to **all** pregnancy women, regardless of their age. For women over 35, the detection rate for Down syndrome is higher, but more women will have a false positive test result. As the majority will have a negative screen, we encourage women over 35 to consider having the sequential screen.

It is important to remember that the sequential screen is **optional**. If you would not have a diagnostic test for a positive screen, would not terminate a Down syndrome pregnancy, or simply wish not to be tested, you may decline screening.

As stated by the American College of Obstetricians Gynecologists (ACOG), all women have the option to have invasive testing by CVS or amniocentesis. Unlike the sequential screen, SVC and amniocentesis are diagnostic tests which will give you a definite answer but are associated with a small risk of miscarriage. For any patient considering diagnostic testing, you would need to speak with a genetic counselor first to discuss the risks and benefits of this testing.

By signing below, I acknowledge that I have received and read this form and that I understand my options of having a sequential screen, invasive testing (CVS or amniocentesis) or having no screening or testing performed. I have reviewed this form with my physician or provider and have had the chance to ask any additional questions. At this time, I request (check one):

_____ Sequential screen (first plus second trimester screening)

_____ Genetic counseling to discuss CVS (10 – 13 weeks) or amniocentesis (15.5 – 22 weeks), or to ask more questions about first or second trimester screening.

_____ No screening or testing for Down syndrome

Patient Name: _____ Signature: _____ Date: _____

Witness Name: _____ Signature: _____ Date: _____

Provider Name: _____ Signature: _____ Date: _____

Advanced Care OB/GYN
Genetic Screening Questionnaire

Patient's Name **Date of Birth** **Today's Date**

The following questionnaire will help identify genetic risk factors that may affect you or your children. Your answers may indicate that certain tests would be appropriate. Please circle and answer all questions as completely as possible. All information will be kept confidential.

1. If you are pregnant, will you be 35 or older at your due date:_____

2. Are you or the father-to-be from any of these ethnic backgrounds?
Asian Indian, Southeast Asian, Chinese, Filipino, Middle Eastern, Mediterranean (such as Greek, Italian and Spanish), Pakistani, Sri Lankan or Taiwanese
Yes No Don't know
If yes, have you or the father-to-be been tested to see if you are a carrier of thalassemia or another hemoglobin abnormality?
Yes No Don't know
If yes, who was tested and what were the results? _____

3. Have you, the father-to-be or anyone in your families had a neural tube defect (such as open spine, spina bifida, anencephaly)?
Yes No Don't know
If yes, please write the diagnosis or describe the defect._____
How is the person related to you or the father-to-be?_____

4. Have you, the father-to-be or anyone in your families been born with a heart defect?
Yes No Don't know
If yes, please write the diagnosis or describe the defect._____
How is the person related to you or the father-to-be? _____

5. Have you, the father-to-be or anyone in your families had a pregnancy or a child diagnosed with Down Syndrome?
Yes No Don't know
If yes, how is this person related to you or the father-to-be?_____

6. Are you or the father-to-be of Ashkenazi Jewish(Eastern European), French Canadian or Cajun background?
Yes No Don't know
If yes, who was tested and what were the results?_____

7A. Are you or the father-to-be African-American or of African or Caribbean descent?
Yes OR No
7B. Are you or the father-to-be of Hispanic descent?
If yes to either A or B, have either you or the father-to-be been tested to see if you have sick cell trait(are a carrier of sickle cell anemia)?
Yes No Don't know
If yes, who was tested and what were the results?_____

8. Do you, the father-to-be or anyone in your families have hemophilia or another bleeding disorder?
Yes No Don't know
If yes, please write the diagnosis or describe the disorder._____
How is the person related to you or the father-to-be?_____

9. Do you, the father-to-be or anyone in your families have a neuromuscular disease or muscular dystrophy?

Yes No Don't know

If yes, please write the diagnosis or describe the disease._____

How is the person related to you or the father-to-be?_____

10. Do you, the father-to-be or anyone in your families have cystic fibrosis?

Yes No Don't know

If yes, how is this person related to you or the father-to-be?_____

11. Do you, the father-to-be or anyone in your families have Huntington's disease?

Yes No Don't know

If yes, how is this person related to you or the father-to-be?_____

12. Do you, or the father-to-be or anyone in your families have autism, mental retardation or fragile X syndrome?

Yes No Don't know

If yes, please write the diagnosis or describe the disorder._____

13. Do you, the father-to-be or anyone in your families have a chromosome abnormality not previously mentioned in this questionnaire?

Yes No Don't know

If yes, please write the diagnosis or describe the disorder._____

How is this person related to you or the father-to-be?_____

14. Do you have insulin dependent diabetes, phenylketonuria (PKU), lupus or another chronic condition?

Yes No Don't know

If yes, please write diagnosis._____

15. Do you, the father-to-be or anyone in your families have an inherited disorder or birth defect not previously mentioned in this questionnaire?

Yes No Don't know

If yes, please write the diagnosis or describe the disorder._____

How is this person related to you or the father-to-be?_____

16. Have you or the father-to-be had a stillborn child or two or more pregnancy losses in this or any other relationship?

Yes No Don't know

If yes, please describe._____

17. Have you taken any medications, other than prenatal vitamins, recreational drugs or had any alcoholic drinks since your last menstrual period?

Yes No Don't know

18. Did you, the father-to-be or anyone in your families have any other serious medical condition in infancy or childhood?

Yes No Don't know

If yes, please describe._____

How is the person related to you or the father-to-be?_____

I have answered these questions to the best of my knowledge_____

Patient Signature

Provider Signature: _____

ADVANCED CARE OB GYN

Informed Consent for Cystic Fibrosis

I, _____ (Patient's Name) authorize LabCorp or Quest to conduct genetic testing for Cystic Fibrosis, as ordered by my healthcare provider. The lab company will release the results of the genetic testing only to my healthcare provider who ordered the test.

Healthcare Provider Statement

By their signature below, the healthcare provider indicates that he or she has explained the purpose of the test, the procedures, the benefits and risks that are involved in testing to their patient. His or her patient has been given the opportunity to ask questions about this consent and seek genetic counseling. The healthcare provider acknowledges that is or her patient has voluntarily decided to have the test performed.

_____

Signature of Healthcare Provider Date

_____

Print Name of Healthcare Provider

Patient's Statement

I, the undersigned, have been informed about the test(s) purpose, procedures, possible benefits and risks. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to genetic testing.

_____

Signature of Patient Date

_____

Printed Name of Patient

Advanced Care
Obstetrics Gynecology Infertility

HIV Consent
OB 1st Trimester

Name:_____

In accordance with Chapter 174, P.L. 1995:

I acknowledge that I have been counseled on information concerning:

A. How HIV is transmitted

B The benefits of voluntary testing

C. The benefits of knowing if I have the HIV virus or not

D. The treatments which are available to me an my unborn child should I test positive and

E. That I have a right to refuse the test and I will not be denied treatment.

I have consented to be tested for infection with HIV. [ ]

I have declined to be tested for infection with HIV. [ ]

_____ _____
Date Signature

_____ _____
Date Provider signature

Advanced Care OB/GYN

Consent for Vistara (Non-Invasive Prenatal Screening)

Vistara is a cell-free fetal DNA noninvasive prenatal screen that analyzes fetal disorders in maternal blood. Vistara screens for genetic disorders that can cause skeletal dysplasias, cardiac defects, multiple congenital anomalies and/or intellectual defects due to variants in the genes included (see www.natera.com/vistara/conditions). The test cannot be performed without samples from both biological parents. This test is not appropriate for individuals who had a blood transfusion in the last month or a bone marrow transplant.

Vistara will report only pathogenic and likely pathogenic variants and will not report variants of uncertain significance or benign variants. Vistara detects predominantly de novo variants (a gene variant that is present in the fetus but not the biological parents) which occur with increasing frequency as paternal age advances. However, this testing may possibly indicate that a parent of the fetus has or is predisposed to one of these genetic disorders tested. Vistara does not screen for fetal chromosomes aneuploidies or other copy number abnormalies.

Natera may use the information included herein to contact me on my cell or home phone, by mail, e-mail, or via text messaging for treatment options, health related products or services, information about research studies, and billing/collection matters unless I opt out by checking this box: ☐

Vistara should be ordered by a healthcare provider who should provide appropriate genetic counseling to the patient prior to ordering the test and after receiving results. Positive screening results should always be followed-up with an invasive, diagnostic test before any medical decisions are made. I understand that:

1) If the Vistara results are positive, I should consult my physician or genetic counselor and consider further invasive fetal testing.
2) The Vistara results may inform me of a pathogenic or likely pathogenic variant that is present in only myself or my partner, but may not be present in the fetus. The information is important for me to understand the complete risk for this pregnancy. I understand that a negative Vistara result does not rule out the possibility of the fetus, myself, or my partner of having a genetic disorder.
3) It is possible that additional information may come to light during these studies regarding family relationships. For example, data may suggest that family relationships are not reported, such as misattributed parentage (e.g. maternal/paternal identity is different than indicated on the the requisition). Variant interpretation is based on the family relationship information provided to Baylor Genetics and Natera by ordering healthcare provider.

Provider Name	Provider Signature	Date
Witness Name	Witness Signature	Date
Maternal Patient Name	Maternal Patient Signature	Date
Paternal Patient Name	Paternal Patient Signature	Date
Egg Donor Name (if applicable)	Egg Donor Signature (if applicable)	Date

Informed Consent / Refusal for Genetic Testing

DNA Testing

1. The purpose of my DNA test is to look for mutation(s) known to be associated with the following genetic condition or disease: _____
   _____
   _____.
2. This testing is done on a small sample of blood.
3. Mutations are often different in different populations. I understand that the laboratory needs accurate information about my family history and ethnic background for the most accurate interpretation of the test results.
4. When DNA testing shows a mutation, then the person is a carrier or is affected with that condition or disease. Consulting a doctor or genetic counselor is recommended to learn the full meaning of the results.
5. When the DNA testing does not show a known mutation, the chance that the person is a carrier or is affected is reduced. There is still a chance to be a carrier or to be affected because the current testing cannot find all the possible changes within a gene.
6. In some families DNA testing might discover non-paternity (someone who is not the biological father), or some other previously unknown information about family relationships, such as adoption.
7. The decision to consent to, or to refuse the above testing is entirely mine.
8. No test(s) will be performed and reported on my sample other than the one(s) authorized by my doctor, and any unused portion of my original sample will be destroyed within 2 months of receipt of the sample by the laboratory.
9. Genzyme Genetics will disclose the test results ONLY to the doctor named below, or to his/her agent, unless otherwise authorized by the patient or required by law.
10. My signature below indicates that I have read, or had read to me, the above information and I understand it. I have had the opportunity to discuss it, including the purposes and possible risks, with my doctor or someone my doctor has designated. I know that I may obtain professional genetic counseling if I wish, before signing this consent. I have all the information I want, and all my questions have been answered.

YES: I REQUEST that Dr. _____ perform the genetic testing above. I understand and accept the consequences of this decision.

_____ _____ _____
Patient Signature Date Witnessed by

NO: I DECLINE to have the genetic testing offered to me. I understand and accept the consequences of this decision

_____ _____ _____
Patient Signature Date Witnessed by

California, Georgia, New York and Utah have statutes requiring laboratories to send confidential results of certain genetic tests to state or federal health agencies for monitoring the detection of birth defects.

It is standard of care for physicians to obtain informed consent for genetic testing. This model consent form is provided by Genzyme Genetics as a courtesy to physicians and their patients. Relevant patient and/or physician educational materials are also available through Genzyme Genetics.

Informed Consent/Refusal for Genetic Testing

Maternal Serum/Plasma Screening

1. The purpose of maternal serum/plasma screening is to identify pregnancies that may be at increased risk for open neural tube defects (ONTD), Down syndrome, trisomy 18, or trisomy 13.
2. The screening test I am having is (circle one):
   - informaSeq™ Prenatal Test – detects >99.9% of trisomy 21, 97.4% of trisomy 18, 87.5% of trisomy 13, and X,Y aneuploidy and sex determination; no information about ONTD
   - FirstScreen® – detects 83% of Down syndrome and 80% of trisomy 18; no information about ONTD
   - SequentialScreen™ – detects 80% of ONTD, 90.4% of Down syndrome, and 90% of trisomy 18
   - IntegratedScreen™ – detects 80% of ONTD, 92% of Down syndrome, and 90% of trisomy 18
   - Serum IntegratedScreen™ – detects 80% of ONTD, 87% of Down syndrome, and 90% of trisomy 18
   - AFP4® – detects 80% of ONTD, 81% of Down syndrome, and 80% of trisomy 18
   - MSAFP – detects 80% of ONTD, no information about Down syndrome or trisomy 18
3. Not all affected fetuses can be detected: some will be missed by any of these screening tests.
4. Some women with normal fetuses will have abnormal screening results.
5. Abnormal screening results may indicate the need for further testing, such as ultrasound and/or CVS or amniocentesis.

DNA Testing

BIA

1. The purpose of my DNA test is to determine whether I, or my fetus if fetal testing is ordered, have mutation(s) or genetic alterations known to be associated with the following genetic condition or disease: _____.
2. This testing is done on a small sample of blood; in some cases a mouthwash sample can be used. For the fetus, testing is done on amniotic fluid, CVS or fetal blood.
3. Mutations and alterations are often different in different populations. I understand that the laboratory needs accurate information about my family history and ethnic background for the most accurate interpretation of the test results.
4. When DNA testing shows a mutation or alteration, then the person is a carrier or is affected with the condition or disease tested for, or, in the case of cancer genetic testing, the person is a carrier of a mutation or alteration that may be associated with an increased risk for certain cancer(s) compared to the general population. Consulting a doctor or genetic counselor is recommended to learn the full meaning of the results and to learn if the additional testing might be necessary.
5. When the DNA testing does not show a known mutation or alteration, the chance that the person is a carrier or is affected is reduced or, in the case of cancer genetic testing, the person's risk for certain cancer(s) compared to the general population will depend on additional personal factors. There is still a chance to be a carrier or to be affected because the current testing cannot find all the possible changes within a gene.
6. In some families, DNA testing might discover non-paternity (someone who is not the real father), or some other previously unknown information about family relationships, such as adoption.

Genetic Amniocentesis

1. The purpose of amniocentesis is to detect certain birth defects, including most fetal chromosome disorders and neural tube defects.
   My reason for having amniocentesis is _____.
2. Before the amniocentesis I will have an ultrasound to help locate the placenta and fetus. Ultrasound may also detect twins, incorrect dating of the pregnancy, and some, but not all, physical defects in the fetus.
3. Amniocentesis involves inserting a needle through the woman's abdomen into the fluid in her uterus. A small amount of fluid (less than 1 ounce) is taken out. There may be some discomfort when the needle is inserted.
4. There are serious complications in less than 1% of amniocentesis procedures. The most serious complication is miscarriage. Other possible, but rare, serious complications include hemorrhage, infection, or injury to the fetus. Minor complications include cramping, vaginal spotting, slight leakage of amniotic fluid, and soreness where the needle was inserted. Early amniocentesis (12-15 weeks gestation) may have a slightly higher risk than standard amniocentesis (after 15 weeks gestation) for pregnancy loss, amniotic fluid leakage, and culture failure.
5. Fewer than 1 in 100 amniocenteses need to be repeated because not enough fluid is obtained the first time. Occasionally, even though fluid is obtained, a diagnosis cannot be made, and the amniocentesis needs to be repeated or further testing might be necessary.
6. The standard testing performed on an amniotic fluid sample is chromosome analysis, which can identify over 99% of chromosomal disorders, and AFP (alpha-fetoprotein) analysis, which can identify over 90% of open neural tube defects. Testing for other conditions will not be performed unless indicated in (1) above.
7. Normal test results do not guarantee the birth of a normal child. As in any laboratory test, there is a small possibility of error, and maternal cells may contaminate the sample. In addition, 3-5% of all pregnancies have birth defects which cannot be detected by testing amniotic fluid or by ultrasound examination.

Additional items of consent/refusal applicable to any of the above screening/testing

1. In the case of twins or other multiple fetuses, the results may pertain to only one of the fetuses.
2. In the case of abnormal diagnostic results, the decision to continue or to terminate the pregnancy is entirely mine.
3. The decision to consent to, or to refuse any of the above procedures/testing is entirely mine.
4. No test(s) will be performed and reported on my sample other than those authorized by my doctor; and any unused portion of my original sample will be destroyed within 2 months of receipt of the sample by the laboratory.
5. My doctor may release my pregnancy outcome or ultrasound and amniocentesis results to Laboratory Corporation of America® Holdings (LCAH), its subsidiaries and affiliated companies to be used for statistical analysis of the laboratory's performance.
6. LCAH, its subsidiaries and affiliated companies will disclose the test results ONLY to the doctor named below, or to his/her agent, unless otherwise authorized by the patient or required by law.
7. My signature below indicates that I have read, or had read to me, the above information and I understand it. I have also read or had explained to me the specific disease(s) or conditions(s) tested for, and the specific test(s) I am having, including the test descriptions, principles, and limitations. I have had the opportunity to discuss the purposes and possible risks of this testing with my doctor or someone my doctor has designated. I know that genetic counseling is available to me before and after the testing. I have all the information I want and all my questions have been answered.

YES: I REQUEST that Dr./or an associate physican _____ perform amniocentesis and/or the genetic screening or testing marked above.
I understand and accept the consequences of this decision.

Patient Signature	Date	Obtained by

NO: I DECLINE to have amniocentesis, and/or the genetic screening/testing offered to me. I understand and accept the consequences of this decision.

Patient Signature	Date	Obtained by

California, Georgia, and New York have statutes requiring laboratories to send confidential results of certain genetic tests to state or federal health agencies for monitoring the detection of birth defects.

It is a standard of care for physicians to obtain informed consent for genetic testing. This model consent form is designed to address the requirements of New York State Civil Rights Law Section 79-L and Massachusetts General Law Chapter 111, Section 70G. Laboratory Corporation of America® Holdings (LCAH), its subsidiaries and affiliated companies require that all reproductive genetic testing sent to any of our laboratories be accompanied by the signed attestation on the front of this Test Requisition Form. Relevant educational materials are also available through LCAH.

BRCAssure™ Test Components	Comprehensive *BRCA1/2* Analysis: Includes full gene sequencing and duplication/deletion testing of *BRCA1/2* genes	Ashkenazi Jewish *BRCA* Panel: Includes screening for three known pathogenic variants; two in *BRCA1* gene, one in *BRCA2* gene

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