



MotherToBaby

Medications & More During Pregnancy & Breastfeeding
Ask The Experts

Fact Sheet

by the **Organization of Teratology Information Specialists (OTIS)**

For more information about us or to find a service in your area,
call **(866) 626-6847**. Visit us online at **www.MotherToBaby.org**.

Find us! Facebook.com/MotherToBaby or @MotherToBaby on Twitter

Research Study Participation

OTIS provides accurate and up-to-date information on possible risks from exposures in pregnancy and breastfeeding via our MotherToBaby information service. OTIS also contributes information on exposures from medications and vaccines as well as health conditions in pregnancy by doing research either on our own or in partnership with other research teams. Our MotherToBaby Pregnancy Studies need the participation of pregnant women to help provide information to women all over the world. You can participate even if you are not taking any medication or have not received any vaccines during pregnancy. Please read below to learn how you can help.

What are MotherToBaby Pregnancy Studies about?

MotherToBaby Pregnancy Studies aim to understand the effects of medications, vaccines, and health conditions during pregnancy. This information allows women and their health care providers to make more informed choices about treatment during pregnancy. The goal of these studies is to improve future pregnancy outcomes for mothers and their babies. For a list of our ongoing studies, visit <https://mothertobaby.org/pregnancy-studies/>.

Who can participate in a MotherToBaby Pregnancy Study?

Different studies have different needs or requirements to participate. These requirements depend on what is being studied. Study participants fall into one of the following groups:

Group 1 – Specific Medication/Vaccine Exposure:

Pregnant women in this group have taken the specific medication or vaccine that is being studied (e.g., got the flu vaccine; took albuterol for asthma, etc.).

Group 2 – Women with a Specific Health Condition:

Some studies need pregnant women who have not taken the medication or vaccine being studied, but who are affected by the same health condition as women in Group 1 (e.g., a woman with asthma who has not had to take any medication while pregnant; a woman who has psoriasis but is not using a medication that is being studied). These women are eligible to be in Group 2.

Group 3 – Women without Specific Medication/Vaccine Exposure or a Specific Health Condition:

Pregnant women in this group have not been exposed to the medication or vaccine being studied and they do not have the health condition being studied. This group is a comparison or “control” group. It is very important to have women enroll in this group because the pregnancy outcomes in this group help to determine whether an exposure during pregnancy (i.e., the medication, vaccine, or health condition being studied) increases risks compared to a pregnancy without any of these exposures.

If I participate, will I be asked to take a medication or get a vaccine?

No. Our studies are observational, which means you will not be asked to take any medications or vaccines or change any part of your routine. Even while you are participating, the decisions for your medical care and treatment will remain between you and your health care provider.

What will I have to do during my pregnancy if I choose to participate in a MotherToBaby Pregnancy Study?

Once you agree to participate, information about your medical history and your pregnancy will be gathered during an initial telephone interview. Depending on what study you enroll in and how far along you are in your pregnancy, there may be additional telephone interviews during your pregnancy. During these interviews, the

interviewer will ask questions about any medications you have taken during your pregnancy and any prenatal tests or significant events that have occurred since the prior phone call. You will also be asked to record any exposures or events in a diary as your pregnancy progresses. Any information you share is kept confidential.

What happens after my baby is born?

After your baby is born, an interviewer will call you to gather information about the outcome of your pregnancy. You will be asked to sign consent forms allowing your health care provider and your child's health care providers to release copies of your medical records. Some of the studies also provide an examination with a pediatrician specially trained in dysmorphology (the area of medicine concerned with the study of birth defects). This examination is offered to you for free and will not require you to travel. Information obtained from your medical record, your child's medical record, and from the pediatric examination is kept confidential.

Suppose I agree to participate and then have a miscarriage or choose to terminate my pregnancy – what happens then?

It is important for the study to be aware of and record information about miscarriages and terminations. If you were to report having a miscarriage or terminating your pregnancy, the study staff would ask some questions about your pregnancy during the phone interview, and may ask if you are willing to release medical record information from your health provider's office.

What if I agree to participate and later change my mind?

Because your participation is voluntary, you are free to withdraw from the study at any time.

Are there any costs for me to participate? Do I get paid for participating in a MotherToBaby Pregnancy Study?

Participating in a MotherToBaby Pregnancy Study will not cost you anything, other than the time to participate. Some, but not all, studies are able to offer compensation for each interview you complete. Most importantly, your participation in a MotherToBaby Pregnancy Study makes a significant impact by helping future pregnant women, their babies, and health care providers throughout the world.

How do I find out more about participating?

You can choose to be contacted by MotherToBaby Pregnancy Studies staff who can give you more information about the studies and determine if you would be eligible to participate. To learn more:

- **Call toll-free:** 877-311-8972 (8am-5pm Pacific)
- **Email:** mothertobaby@ucsd.edu
- **Visit:** <https://mothertobaby.org/join-study/>

November, 2015