



For more information about the Organization of Teratology Information Specialists or to find a service in your area, call (866) 626-6847 or visit us online at: www.OTISpregnancy.org.

OTIS Research Study Participation

OTIS provides accurate and up-to-date information regarding possible risks from exposures in pregnancy and lactation. OTIS also contributes to the available information on medications and conditions in pregnancy by conducting and collaborating in research.

These 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 during pregnancy. Please read below to learn how you can help.

What are OTIS studies about?

OTIS studies aim to understand the effects of medications and health conditions during pregnancy. This information allows women and their health care providers to make informed choices about treatment. The goal of these studies is to improve future pregnancy outcomes for mothers and their babies. For a list of on-going OTIS studies click [here](#) or go to <http://www.otispregnancy.org/ongoing-research-studies-p135738>.

Who can participate in an OTIS Research Study?

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

Group 1: Women in this group have already taken a medication or vaccine, or have a specific health condition that is being studied (i.e. Flu vaccine, Asthma, etc). To qualify for this group you will not be asked to take any medication, nor will you be asked to discontinue any treatment; the choice for treatment will be between you and your physician.

Group 2: Some studies need women who have not taken the medication or vaccine being studied, but are affected by the same

health condition (i.e. A women who has psoriasis but is not using a medication that is being studied).

Group 3: Women in this group have not been exposed to the medication or to the health condition being studied. This group is a comparison group or control group that represents the general population. It is very important to have a women enroll in this group because the pregnancy outcomes in this group help to determine whether an exposure during pregnancy increases risks compared to a pregnancy without the exposure or health condition.

The study staff can further discuss and answer questions about participation in the studies.

Will I ever be asked to take a medication being studied?

No, you will *never* be asked to take a medication being studied. It is important for you to discuss the best treatment options for your specific condition with your health-care provider.

What will I have to do during my pregnancy if I choose to participate in an OTIS Research 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 study interviewer will ask questions about any medications you have taken during your pregnancy, prenatal tests or significant events that have occurred since the first phone call. Any information you share is kept confidential. You may be asked to record any exposures or events in a diary as your pregnancy progresses.

What happens after my baby is born?

After your baby is born there is another phone interview to gather information about the outcome of your pregnancy. You may also be asked to sign consent forms allowing yours and your child's physician 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.

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

Both miscarriage and elective termination are significant events of pregnancy and important for the study record. The study staff would ask some specific questions about the event during the phone interview and may ask if you are willing to release medical record information from your physician'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 an OTIS Research Study?

There are no costs to you, other than time, for you to participate in an OTIS Research Study.

OTIS is a not-for profit organization dependent on many organizations for funding and is not able to offer compensation for participation in most of our studies. Your participation in an OTIS Research Study makes a significant impact by helping other pregnant women and health care providers throughout the world.

How do I find out more about participating?

You can choose to be contacted by the research study staff who can give you more information about the studies. To learn more about participation, eligibility and how you can contribute to available information about exposures in pregnancy, send an email to raandpregnancy@ucsd.edu, or call OTIS at 1-866-626-6847.

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*If you have questions about the information on this fact sheet or other exposures during pregnancy, call **OTIS** at **1-866-626-6847**.*