Healthy Brain and Child Development

Participating in the largest, long-term study of early brain and child development in the United States

I recently came across a patient named Jamie when she asked some interesting questions about a new study she had heard about on child development. Jamie is pregnant with her second baby and got a flyer from the Healthy Brain and Child Development study (HBCD). The HBCD is a national study being carried out at 27 sites in different parts of the country, with two sites at MotherToBaby locations including Emory University and UC San Diego. At first, she was undecided if she wanted to volunteer. It is a large-scale, long-term project with the goal to better understand how child development is affected by exposure to social and environmental experiences and conditions. She would be one of the 7,000 mother/infant pairs contributing their time and effort to this project.

Here were some questions that she was thinking about before deciding to join the research project. With so many research sites across the nation, you may be asking yourself these questions, too:

What is the HBCD goal and where is this study?

Most of the HBCD sites are at universities and hospitals that have a history of working with pregnant women and their babies. The study was developed by the National Institutes on Health, part of the US public health service. The goal is to understand children's brain development. HBCD aims to recruit 7000 pregnant women. Researchers will follow them, as well as their babies, over the first 10 years of life. They'll keep track to gather more information on how prebirth and after birth events affect the development of children's brain, more specifically, their cognitive and emotional functioning. The information that is collected (data) and will be stored at NIH. The data is made available to scientists who will use this information to improve our understanding of children's growth and adjustment. All information will be "deidentified". That means, to protect confidentiality, there will be NO information that could identify individual mothers or children in the stored data.

Who can participate?

HBCD will include pregnant women across the United States from both rural and metropolitan areas. Recruitment takes place during pregnancy with the first visit in the second trimester. HBCD enrolls women, 18 years and older, from different ethnic and racial groups based on the population of the sites where recruitment is taking place. They are able to include Spanish speakers by having staff who are bilingual. The study is interested in mother's health and exposures during pregnancy, as well as the caregiving environment that can predict how well children grow. As a result, they are looking for all kinds of women to participate, from the general population as well as those who use alcohol, tobacco, stimulants and opioids.

What will participation involve?

Parents will answer a series of questions through surveys and interviews. Mothers and babies will also provide urine and blood samples. In addition, HBCD is monitoring babies' sleep in the newborn period and taking "pictures" of children's brains as they develop using MRI and electroencephalograms (EEG) periodically over time. As they get older, babies' development and behavior will be tested to monitor how they are progressing.

There are several study visits in the first year after the baby arrives and then once a year until they are 10 years old. Families will be reimbursed for their time and travel expenses.

Jamie went to the HBCD website to answer some of her questions (Home – UCSD – Healthy Brain and Child Development (hbcdstudy.org)) and she also got in touch with the Project Coordinator at our HBCD site to ask more about the schedule and the MRI. She was satisfied with the answers and decided that she would like to make a contribution to children's futures by participating in HBCD. She has already completed her first visit and is looking forward to seeing us again when her son in born. Jamie shared with us that she wants to be part of HBCD because she understands how important understanding brain development and behavior is for both children and their families.

MotherToBaby experts know how important research is and supports the efforts of the HBCD study. You can learn more about MotherToBaby's own studies to consider as well here.

Healthy Brain and Child Development

How Does Lupus Impact Pregnancy?

Many pregnant people with systemic lupus erythematosus (or SLE, a type of lupus) and lupus nephritis will have healthy babies. However, some people experience complications. With your help, we can capture more information about how lupus can affect pregnancy.

> *"Our observational research program collects important information about lupus and its treatment during pregnancy. This information will be used by healthcare providers and future parents to better manage lupus during pregnancy."*
>
> *— Christina Chambers, PhD, MPH, Lead Investigator, MotherToBaby Pregnancy Studies*

Our lupus study includes:

- 1-3 phone interviews during your pregnancy and at least 1 interview after you have your baby.
- Your permission to obtain a copy of your and your baby's medical records from your healthcare providers.
- An opportunity to receive a specialized, non-invasive exam of your baby with a study doctor

You can help us better understand lupus and its treatment in pregnancy. Will you become our partner and join the Lupus & Pregnancy Study?

JOIN NOW

Healthy Brain and Child Development

Help Us Understand the Possible Effects of Benlysta® in Pregnancy

Many people need to take medication during pregnancy to appropriately manage a chronic health condition. In some cases, avoiding or stopping medication use during pregnancy may be more harmful than taking medication. Yet fewer than 10% of medications have enough information to determine their safety for use in pregnancy — this is where you come in!

MotherToBaby is currently enrolling pregnant women in a study examining the use of Benlysta® (belimumab) to treat systemic lupus erythematosus (or SLE, a type of lupus) or active lupus nephritis (lupus-related kidney inflammation) during pregnancy.

Are you currently pregnant? Did you take Benlysta® at any point in your current pregnancy? If you answered “yes” to both of these questions, then you have the opportunity to help us learn more about Benlysta®.

> *“There is a huge need to generate more data for all of the drugs that people who are pregnant need to take.”*
>
> *— Christina Chambers, PhD, MPH, Lead Investigator, MotherToBaby Pregnancy Studies*

Will you take the next step and become our partner? Make an impact on the health of future families today by joining our Benlysta® & Pregnancy Study!

JOIN A STUDY

REFER A PATIENT

Healthy Brain and Child Development

When you think medication or vaccine safety, you think clinical drug trials. Right?! Clinical drug trials are research studies designed to gather information to determine whether a new medication or vaccine is safe and effective in people.

However, what most people don't know is that pregnant women are excluded from these studies when a new drug is being developed. Essentially, this means that once a medication is approved by the US Food & Drug Administration (FDA), it's prescribed to patients (including those who are or could become pregnant) with little to no information on the safety of the drug if used during pregnancy. Currently, less than 10% of medications approved by the FDA have enough information to determine their risk when used in pregnancy! To address this gap, the FDA may require observational studies, called pregnancy exposure registries, to be conducted on newly approved medications or vaccines to determine safety in pregnancy.

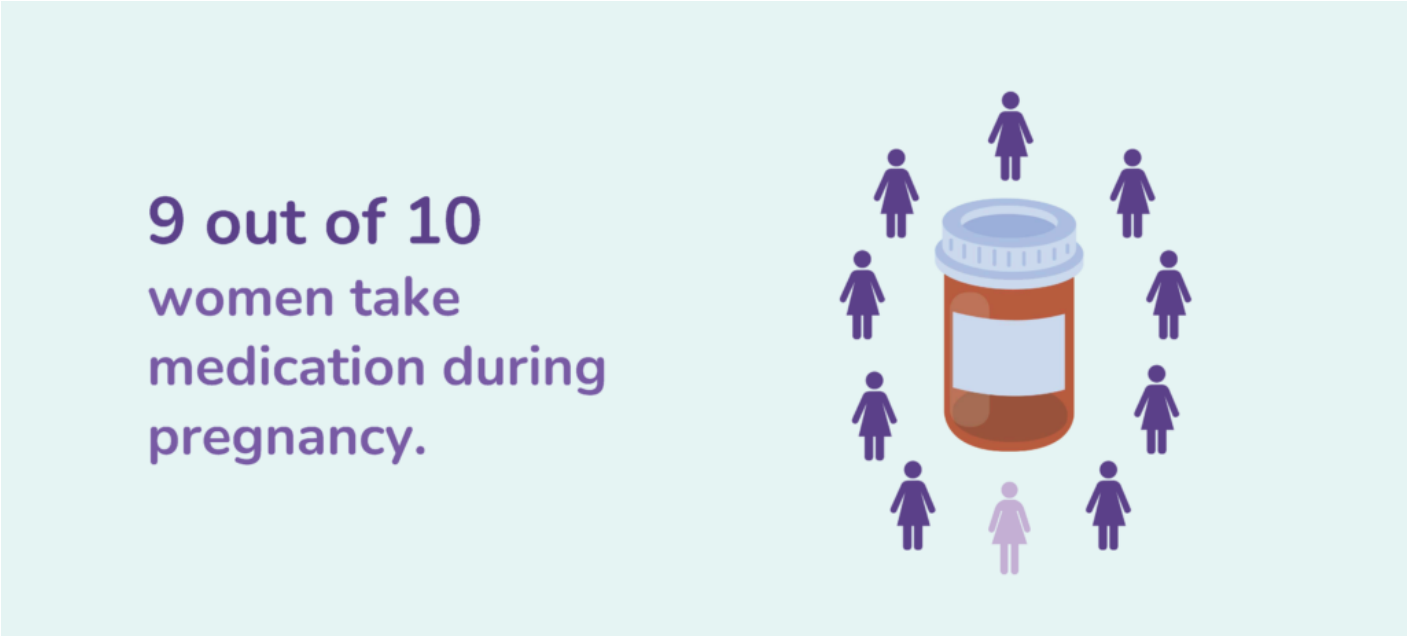
What are pregnancy exposure registries?

Pregnancy exposure registries are observational studies that collect health information on exposure to medical products such as drugs and vaccines during pregnancy. "Observational" means that study participants are **never** asked to take a new medication or to change any existing medications. After enrolling in the study they are simply followed by researchers through the remainder of their pregnancy, often by completing interviews or surveys or by allowing the researchers to access their medical records.

Why are pregnancy exposure registries important?

Pregnant women represent an important segment of the population, with over 6 million pregnancies occurring per year the U.S. alone. Additionally, studies have shown that 9 out of 10 women take medication during pregnancy – these women deserve to know if the medications they are taking will have any effect on their pregnancy, and pregnancy

exposure registries are how we gather this information.



This information is used by pharmaceutical companies when listing safety information on drug labels. It is also helpful for healthcare providers to determine treatment plans for their pregnant patients. In many cases, pregnancy exposure registries have provided reassurance – and in some cases have raised red flags – on whether a medication is safe to take during pregnancy.

Why not just stop taking medications before you become pregnant?

It's a common misconception that quitting a medication during pregnancy will be safer for the mom and her baby. In fact, for many chronic health conditions (such as asthma or seizure disorders), it's safer for both mom and baby if the condition is well-managed. Some pregnant women may also experience acute conditions (like an infection) or develop complications during pregnancy that require medication. Physicians and pregnant women have the difficult task of balancing the risks and effects of an unmanaged condition during pregnancy versus the potential risks and benefits of starting or continuing to take a medication during pregnancy. Having enough information about the safety of the medication when used in pregnancy would make this task a whole lot easier.

And let's not forget: nearly half of all pregnancies in the U.S. may be unintended, which means that women may be exposing their pregnancy to a medication without realizing it because they weren't planning the pregnancy and won't know they are pregnant until they miss their first menstrual period.

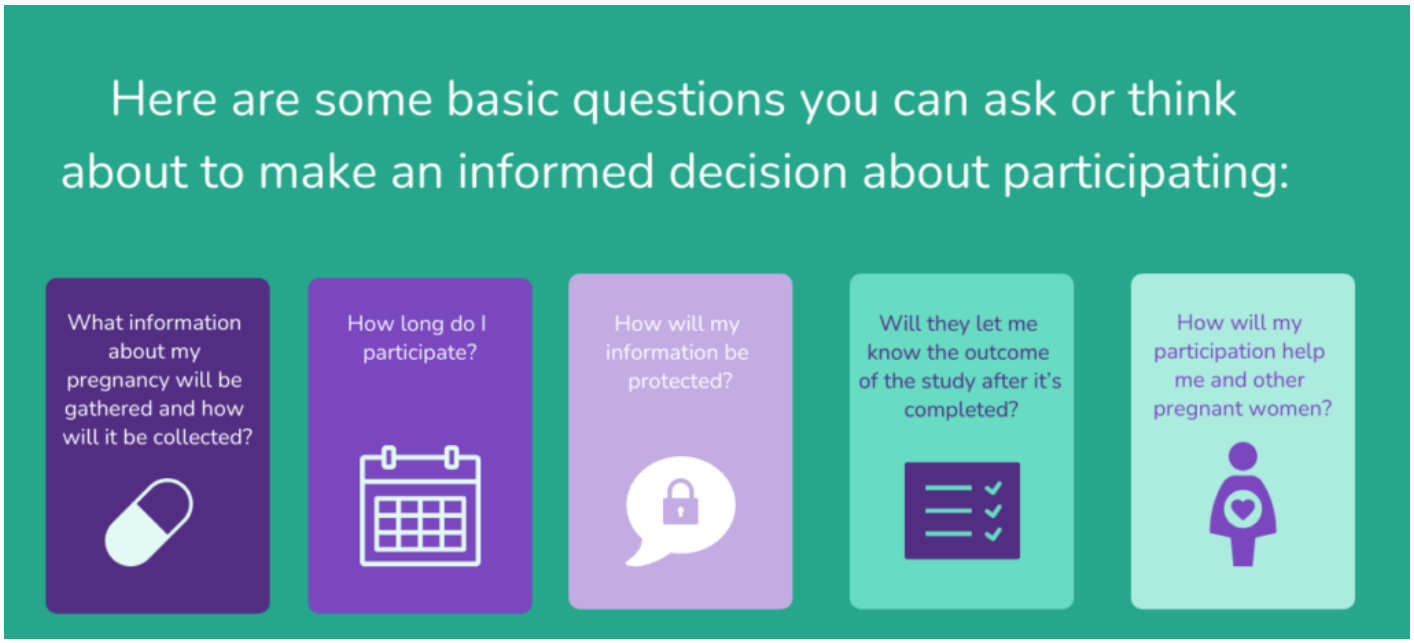
How are registries organized/structured?

It's worth repeating: Pregnancy registries are **strictly observational**. Researchers will follow participants throughout their pregnancy and sometimes after the child has been born regardless of the woman's healthcare routine.

Researchers collect data about the pregnancy from the woman and/or (with the woman's permission) from her medical records. The type of data collected, communications and length of participation vary from one registry to another, so it's important you find out all the details about the study before you join.

Here are some basic questions you can ask or think about to make an informed decision about participating:

- What information about my pregnancy will be gathered and how will it be collected?
- How long do I participate?
- How will my information be protected?
- Will they let me know the outcome of the study after it's completed?
- How will my participation help me and other pregnant women?



Who participates?

Pregnancy registries are generally designed to compare pregnant women who have been exposed to the medication/vaccine of interest to those who have not been exposed. Depending on the registry, participants can include women who:

- Have taken a specific medication or vaccine during a current or recent pregnancy.
- Are pregnant and have not taken the medication being studied, but have the same health condition being treated by the medication being studied.
- Are pregnant, have not taken the medication being studied, and do not have the same health condition being studied.

Where can I find a registry to join?

There are a variety of organizations that run pregnancy registries. A great place to start is by asking your healthcare provider. You can also look on the US FDA Pregnancy Registry site.

What makes MotherToBaby pregnancy registries different?

Here at MotherToBaby, we run several pregnancy exposure registries, called MotherToBaby Pregnancy Studies. Our studies are unique in a few different ways:

- Participants have access to our trained experts to answer questions on any exposures during pregnancy and breastfeeding – all at no cost to you.
- Some of our studies offer a free in-home examination of your infant and a consultation with an expert pediatric specialist who can answer any questions you might have about your child's growth and development.
- When you enroll in a study that includes free developmental follow-up for your child, you'll receive reports after each screening, which will provide you with information about how your child is developing relative to other children his/her age.

Interested in learning more about what it's like to participate in our studies? Meet Mariah, a study participant and maternal health advocate mom of 4. She shares her experience here.

If you or someone you know is interested in joining one of our pregnancy studies, we'd be happy to talk you through the process and answer any questions you may have.

- **Call 877.311.8972 or email MotherToBaby@health.ucsd.edu**

You can also browse through our ongoing studies here.

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Healthy Brain and Child Development

By Beth Kiernan, MPH, Interviewer & Teratogen Information Specialist, MotherToBaby

"When my RA started flaring 6 or 7 weeks postpartum, I got to the point that I could barely lift my own baby….We need more research on medications used in pregnancy as well as during breastfeeding!"

I want you to meet Mariah, a participant in our MotherToBaby Rheumatoid Arthritis Study. I chatted with Mariah to learn about her experience being pregnant with a chronic medical condition and to find out what motivated her to participate in our study. As a Baby Blog reader, you are probably aware that MotherToBaby provides information on exposures during pregnancy and breastfeeding. What you might not know is that we also conduct observational research on certain heath conditions and their treatments, with the goal of providing moms like Mariah (and like you!) with better information about health and medications in pregnancy. This month's Baby Blog focuses on the role of research at MotherToBaby and puts a spotlight on those who make our program possible: the women who decide to share their pregnancy experience with us.

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BETH: Mariah, thank you so much for talking with me about pregnancy research and your involvement with MotherToBaby! As an advocate for moms with rheumatoid arthritis (RA) and the creator of the popular blog, Mamas Facing Forward, you are inspiring women with chronic illness across the globe who are or want to become pregnant.

MARIAH: I'm so glad to be here and to talk more about pregnancy research! Since being diagnosed with RA, I've taken an interest in medical research–both personally and professionally. It's been interesting to see my RA treatment options expand dramatically between my first pregnancy and my third, which were only about six years apart.

BETH: In general, the medical community knows little about the effects of taking most medications in pregnancy, because pregnant women are often not included in studies that determine the safety of new medicines. What initially interested you about MotherToBaby Pregnancy Studies?

MARIAH: Medication use during pregnancy needs to be studied because of the potential risks for the developing baby! Professionally, I cover developing research for Rheumatology Network so I have a good understanding of the different types and stages of medical research. But even with this background, when I first joined MotherToBaby's study, I didn't understand what "observational research" meant. My biggest concern was: Would I have to take a study drug–or change my usual treatment in any way?

BETH: This is the most common question–or confusion–that I hear from women! How would you describe what observational research is and what would you say is the difference between a clinical trial and observational studies, like MotherToBaby's pregnancy registries?

MARIAH: I've learned that observational means the study "observes" what a participant does, but doesn't advise or require a treatment course or change. There is no tested drug or placebo like in a clinical trial. A pregnancy registry is a study that collects health and medication information from pregnant women and their newborns, and then compares outcomes to unexposed women and their babies. While in the study, I made my own treatment decisions with my doctor, which is logical since she knows my health history best. But because MotherToBaby provides evidence-based information about medications in pregnancy, you also helped me learn more about my medications and specific

pregnancy data, which then guided the conversations I had with my doctor before pregnancy and during the flare I had at about 23 weeks.

BETH: I'm glad that we were able to help you during this flare! So what ultimately motivated you to join a MotherToBaby Pregnancy Study?

MARIAH: I've actually participated in two research studies through MotherToBaby, and my main motivation was due to the lack of information on medications during pregnancy. At the beginning of my second pregnancy, I wasn't taking any medications to control my RA and I ended up flaring very badly—to the point where I was having difficulty caring for myself and my then almost two-year-old son. Though I know oftentimes TNF inhibitors are discontinued in the third trimester (call MotherToBaby to find out why!), my rheumatologist and I made the decision to use one so we re-started Enbrel near the end of my second trimester and continued through the remainder of my pregnancy. After making such a difficult decision, I called MotherToBaby right away to enroll in the study because I wanted future moms to have the benefit of my data when it came time for them to make a similar difficult decision.

While planning to become pregnant again, my rheumatologist, perinatologist, and I decided to switch me from Rituxan to Cimzia prior to conception, and decided that I would remain on Cimzia through my entire pregnancy and while nursing. I joined the Cimzia & Pregnancy Study as soon as I found out I was pregnant with my third baby. I'm still involved, in fact, my third baby just turned one and we just got a birthday card in the mail from MotherToBaby! I think it's fantastic to have such a caring group of researchers committed to providing better information for pregnant women living with chronic illnesses.

BETH: Did you have any initial hesitations about joining a MotherToBaby study?

MARIAH: At first, I wondered if study participation would take too much time. I had a toddler at home, I worked, and I was pregnant again**.** I found out that typically a woman spends about two hours total in phone interviews in the first year, and then just ten minutes per year by phone if enrolled in a multi-year study.

My husband was concerned about privacy. I asked how my personal information would be safeguarded, and who would have access to my medical records. I asked if the study collected my insurance information or social security number–it does not. Results will be published but without revealing my identity. The studies are coordinated out of the University of California San Diego, and their Human Research Protections Program oversees the privacy and security protocols, so there is an extra layer of oversight and protection. Also, pharmaceutical companies are required to sponsor this research but they don't have access to my personal data, and all research is done independently.

Women may feel wary about the idea of participating in research during pregnancy. What has made me feel even more secure is that doctors familiar with MotherToBaby have recommended joining your studies. The studies are not experimental so I didn't find any likely risk, nor is there any cost to me. So this, coupled with the research benefiting other moms like me, made me feel like it was something that I could support pretty easily.

BETH: What was the process of enrolling like for you?

MARIAH: I answered questions about my health history, prenatal test results, some demographic info, and then made a list of exposures during the pregnancy, such as prescription and over-the-counter medications, caffeine, illnesses and other environmental exposures.

BETH: I know you've mentioned the main reason for your enrollment was due to the lack of information about medications during pregnancy. Can you tell us more about how you and your healthcare team navigated your treatment options during pregnancy?

MARIAH: As I mentioned before, my treatment options changed dramatically between my first and third pregnancies. During my first, I spoke to my obstetrician and rheumatologist about my RA medications. I didn't do much research on my own at the time (there were fewer online resources, blogs, and social media connections then too!) but rather I trusted the information being given to me by my doctors. My obstetrician knew almost nothing about RA treatments and deferred completely to my rheumatologist. Based on the data available at the time, I used nothing but prednisone during that pregnancy.

When my RA started flaring 6 or 7 weeks postpartum, I got to the point that I could barely lift my own baby. At three months, I made the heartbreaking decision to wean my son so that I could re-start Enbrel, because at the time my rheumatologist did not think there was enough data available for it to be safe enough to breastfeed while taking that medication. I did manage to find one blog at the time where a mom talked about making the decision to use Enbrel

while nursing, but as much as I personally wanted to continue breastfeeding I couldn't find adequate information to make me comfortable with the idea.

BETH: I'm so sorry to hear about your struggle breastfeeding. Unfortunately, this experience is very common. We also provide information to moms about breastfeeding exposures, and many of our research participants also provide a sample of breastmilk to Mommy's Milk so we can learn more about medications and breastfeeding.

MARIAH: Yes, we need more research on medications used in pregnancy as well as during breastfeeding! So jump forward to two years later during my second pregnancy, my rheumatologist and I decided that the data had improved enough–and that the uncontrolled inflammation I was experiencing was a greater risk to me and my baby than the potential risk of the Enbrel. I used Enbrel during the end of that pregnancy and through three months of breastfeeding. Though I must say that I made this decision under a fair amount of duress because I was feeling very, very poorly at the time. I assumed I would manage my second pregnancy the same way I managed my first, so when I started flaring badly I did not have a treatment plan in place. This was another situation where I more or less trusted my rheumatologist's advice. Unfortunately, Enbrel lost its effect for me after my second pregnancy and I weaned my second son at three months as well, and began to search for another treatment option.

For my third pregnancy, I consulted my rheumatologist and a perinatologist prior to trying to conceive. I also did a lot more of my own research. I looked to what MotherToBaby had to say about the medications we were considering and found some research studies to read. I was lucky to have doctors who also did their research. My perinatologist didn't know much about Cimzia so she researched it before meeting with me. She shared her research with me and explained how the molecular structure of Cimzia was missing the part that is responsible for crossing the placenta, making it one of the better options for use during pregnancy.

BETH: Wow! That is a lot to navigate –for you and your healthcare providers. As you have shown us, every pregnancy and treatment plan is different! What is one thing you would like pregnant women or moms dealing with a chronic illness to learn from your experience?

MARIAH: When it comes to considering the use of medications during pregnancy, public opinion tends to push the idea that a woman ought to "sacrifice" herself for the sake of her baby during a pregnancy, so it can be difficult for many women to dodge that pressure and to consider medication at all while pregnant. MotherToBaby can help illuminate both the potential benefits and potential challenges of taking a drug while pregnant or breastfeeding. I'm glad to talk about these issues, and recommend paths to women that may make their decisions easier!

BETH: Thank you so much for talking with us today and for sharing your experience, Mariah. I think many women will be interested in hearing how you navigated pregnancy and motherhood while living with a chronic illness. So many women grapple with medication questions during pregnancy, and whether they decide to participate in our studies or not, we are glad you are here to help them through it on your blog and as an RA patient advocate. Any last words about pregnancy & research?

MARIAH: I recommend you ALL THE TIME – and have benefited firsthand from the research studies!

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If you are pregnant and interested in participating in a study, contact MotherToBaby to see if you qualify! We enroll pregnant women taking certain medications or living with chronic health conditions like rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's and ulcerative colitis, multiple sclerosis, asthma, high cholesterol, and eczema. We also enroll women without any of these conditions or medication exposures. You can view a list of all our ongoing studies here: https://mothertobaby.org/ongoing-studies. We look forward to speaking with you!

Beth Kiernan, MPH, is a Teratogen Information Specialist with MotherToBaby Pregnancy Studies, a series of observational research studies about medications and health conditions during pregnancy. The studies are conducted by the non-profit Organization of Teratology Information Specialists (OTIS). Beth is based at the University of California San Diego, and is a married mother of four children.

About MotherToBaby

MotherToBaby is a service of the Organization of Teratology Information Specialists (OTIS), and a suggested resource by many agencies including the Centers for Disease Control and Prevention (CDC). If you have questions about exposures during pregnancy and breastfeeding, please call MotherToBaby toll-FREE at 866-626-6847 or try out MotherToBaby's new text information service by texting questions to (855) 999-3525. You can also visit MotherToBaby.org to browse a library of fact sheets about dozens of viruses, medications, vaccines, alcohol, diseases, or other exposures during pregnancy and breastfeeding or connect with all of our resources by downloading the new MotherToBaby free app, available on Android and iOS markets.