



PREGNANCY RESEARCH PROJECT

The Pregnancy Research Project: A Collaborative Approach to Pregnancy Research

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BACKGROUND



“Stillbirth is the most under-studied issue in medicine today”.

“No one professional organization takes responsibility for stillbirth.”

The Lancet (2011) Stillbirth Series Executive Summary

BACKGROUND

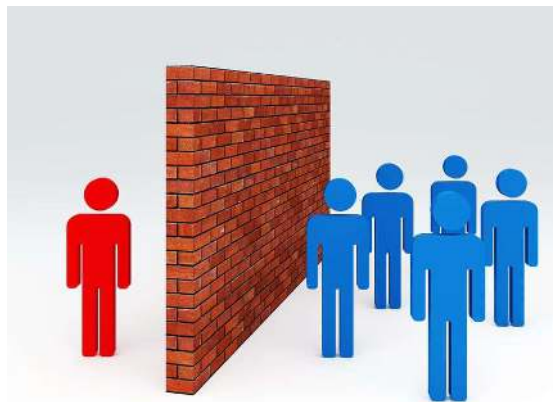


the sudden unexpected death
data enhancement and awareness act

S.2746/H.R.669



CHALLENGES



BACKGROUND



- Alzheimer's Prevention Registry (link is external)
- Breast Cancer Surveillance Consortium
- Cancer Genetics Network (link is external)
- CANCOG Registry (link is external)
- The Center for Family Research Network (link is external)
- Cardiac Risk Research Registry (CR3R) (link is external)
- Children's Health Foundation/Pediatric Autism Registry (link is external)
- Child's Risk Factor Study: Share Your Knowledge
- Collaboration with Translational Research Registry (link is external)
- Colon Cancer Family Registry
- Congenital Heart Disease Research Network Study (CHD-CRISIS) (link is external)
- Congenital Muscle Disease International Registry (CMDI) (link is external)
- Consortium for the Longitudinal Evaluation of African Americans with Early Rheumatoid Arthritis (link is external)
- Cure RFD Foundation (link is external)
- Cystic Fibrosis Foundation Patient Registry (link is external)
- Development of a National Incomparable Kidney Transplant Registry (link is external)
- Development of an Inherited Myopathologic Neuromuscular Registry (link is external)
- Development of an Inherited Family Registry (IFR) (link is external)
- Diagnostic, Clinical, and Genetic Research (DCGR) - Diagnostic Registry (link is external)
- DTG: Diagnostic and Therapeutic Registry (link is external)
- DC Connect™ The Dismal Syndrome Registry
- Dysfunctional Ovaries and Infertility Bridge (DIOIB) (link is external)
- The Environmental Polymorphisms Registry (EP) - Using DNA to Study Disease
- EUROD™ The European Osteoporosis Research Grouping and Phenotyping Network
- Familial Myotonic Dystrophy National Registry
- Foundation for Sarcoidosis Patient Registry (link is external)
- Gene Disease Registry (GDR) (link is external)
- Gene Disease Registry (GDR) (link is external)
- IMPACT Registry, Diagnostic and Interventional Cardiac Catheterization in congenital heart disease (link is external)
- International Inherited Myopathy Registry
- Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) (link is external)
- International Registry of Hereditary Spinalesclerosis (link is external)
- International Spherulosis Syndrome Registry, an SDOA (link is external) (closed to new participants)
- ITP National History Study Registry (link is external)
- Lupus Family Registry and Registry (link is external)
- Myotonic Dystrophy Patient Registry (link is external)
- National Adiposity & Visceral Adiposity Program (link is external)
- National Adiposity Research Registry (link is external)
- National and Local SLE Registries
- National Pediatric Cardiology Quality Improvement Collaborative (link is external)
- National Registry of Genetically Truncating Thoracic Aneurysm and Cardiovascular Conditions (GenACC)
- NIDA Center for Genetics Research
- NINDS National Epilepsy Study: Imaging & Balance Pathology Resource Registry (link is external)
- NIH Human Embryonic Stem Cell Registry
- DNA Neural History Patient Registry (link is external)
- NIH National Registry of U.S. Myotonic Dystrophy and U.S. Fetalocapillary Myofibrillar Myopathy (FM) (link is external)
- DNA Neural History Patient Registry (link is external)
- Neurologic Critical Care Consortium (N3C) (link is external)
- Pathologic Complete Response Registry (link is external)
- Pediatric Cardiac Hypertension and Genetic (PHCG) (link is external)
- Pediatric Pulmonary Hypertension (PPH) International Registry (link is external)
- PFO Patient Registry (link is external)
- PPROM Registry (PAPERS) (link is external)
- Progression of Comorbidity/Interventional Program
- The Prostate Cancer Registry (link is external)
- Rare Disease Critical Research Network Consortium of Gastrointestinal Disease Researcher Contact Registry (link is external)
- Research Registry for Normal Louse (link is external)
- Sanford Children's Registry
- SLE Registry
- Learn More: Neurogenetics International Registry (link is external)
- Linkage Panel for the International Registry and Registry (link is external)
- Society for Thoracic Surgeons Society, Congenital Heart Surgery Database (link is external)
- Ulcer Syndrome Registry (link is external)
- USOIRT Registry for Patients with Primary Immunodeficiency Diseases

BACKGROUND



birth/activities-ncbddd.html

CDC's National Center on Birth Defects and Developmental Disabilities Activities to Understand Stillbirth

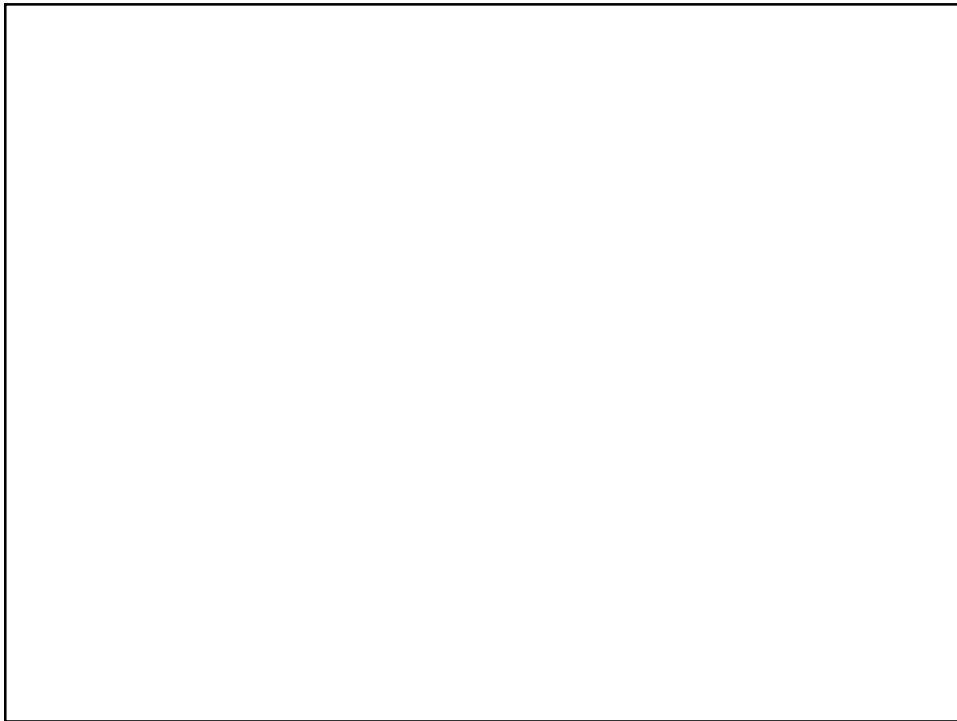
CDC's National Center on Birth Defects and Developmental Disabilities (NCBDDD) is working to learn more about the loss of a baby due to stillbirth. Read about their efforts below.

Stillbirth Surveillance Project, 2005 - 2015

From 2005 - 2015, NCBDDD supported the expansion of two birth defects tracking systems to include all stillbirths. These two tracking systems identify babies with birth defects in their study areas by having staff continually review medical records at multiple healthcare facilities. The information gathered is then reviewed by doctors and other specialists. Although time- and resource-intensive, these methods more accurately identify babies with birth defects, as compared to relying only on reports submitted by hospitals or healthcare providers. It was anticipated that by expanding these birth defects tracking systems to include all stillbirths, more accurate and complete data about stillbirths would be collected.



So instead of waiting for the government.....





In 2011 the first Stillbirth Summit brought clinicians, researchers, and families together to “think outside the box”.

One of the results of that meeting was the STARS Study:



The STARS Study



The STARS Study

STARS (Study of Trends and Associated Risks for Stillbirth) Consortium*

- Partnered with the Star Legacy Foundation and other stillbirth and parental support groups
- This unique partnership allowed bereaved parents to have direct discussions with consortium members regarding common experiences prior to their loss in order to inform the development of the survey

The goal was to investigate trends and risk factors for stillbirth

Particular interest in sleep position due to the findings of The Auckland Stillbirth Study (TASS):

- Women with a late stillbirth (28 weeks or more) were 2.5 times more likely to have gone to sleep on their back (supine position)

Stacey et al 2011

* Members of the STARS consortium listed in alphabetical order: Collins JH, Heazell AEP, Huberty JL, Kliman HJ, McGregor JA, Mitchell EA, O'Brien LM, Parast M, Peesay M, Stacey T, Warland J, Wimmer LJ.

Star Legacy Foundation
Dedicated to Stillbirth Research and Education



The STARS Study



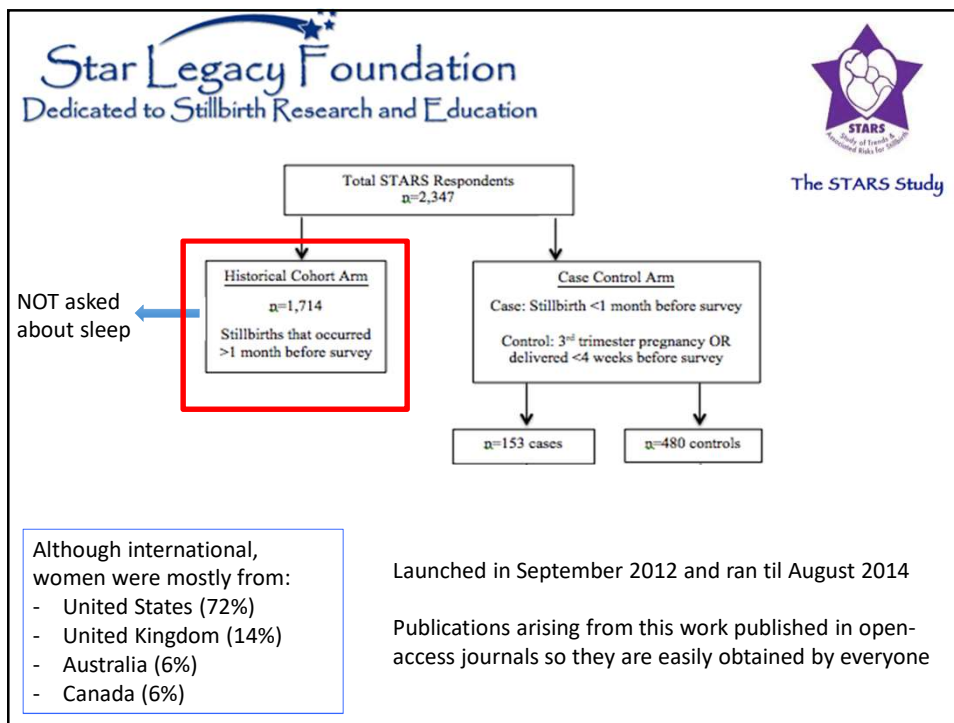
Web-based survey to investigate potentially modifiable risk factors in a large, international population.

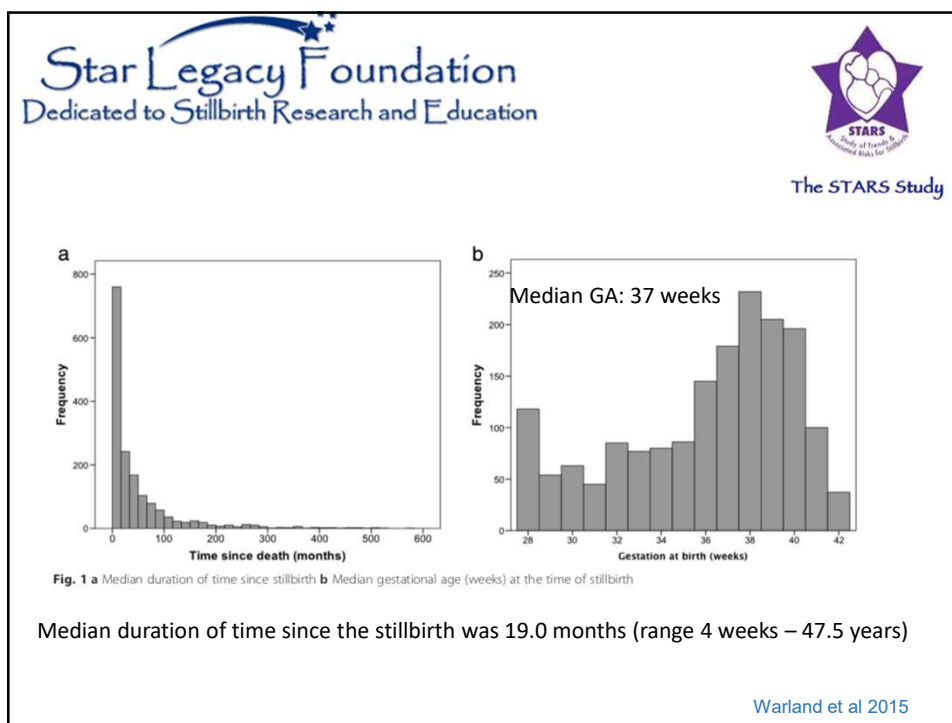
In contrast to most previous studies, our approach asked mothers directly about their behaviors, experiences, and symptoms during pregnancy.

The survey included:

- questions about established risk factors (e.g. smoking, reduced movements)
- questions relating to emerging risk factors (e.g. sleep position, gut instinct and an increase in fetal activity in the days immediately prior to the fetal demise).

Several questions in the survey were raised by bereaved parents at the 2011 Stillbirth Summit and had not been previously addressed in large-scale studies





Warland et al. *BMC Pregnancy and Childbirth* (2015) 15:172
DOI 10.1186/s12884-015-0602-4

BMC
Pregnancy & Childbirth

The STARS Study

RESEARCH ARTICLE Open Access

CrossMark

An international internet survey of the experiences of 1,714 mothers with a late stillbirth: the STARS cohort study

Jane Warland^{1*}, Louise M. O'Brien², Alexander E. P. Heazell³, Edwin A. Mitchell⁴ and the STARS consortium

Common themes reported by participants:

1. Changes in fetal movements (63% of women)
2. Gut instinct that something was wrong (68% of women)
3. Perception that demise occurred at night (40% of women)
4. Cord accident (27% of families were told a cord accident was the cause of death)
5. 55% of families disagreed with the cause of death told by clinicians

Common themes reported by participants:

1. Changes in fetal movements (63% of women)

Table 2 Frequency of unusual fetal movement

	N (%)
N = 1,714	
No change in fetal movement	480 (28.0 %)
A little bit less movement	273 (15.9 %)
Significantly less movement	522 (30.5 %)
A little bit more movement	136 (7.9 %)
Significantly more movement	146 (8.5 %)
Don't remember	103 (6.0 %)
Missing	54 (3.2 %)

Response to question "Once you were aware of your baby's usual pattern of movements was there any time that your baby's movements were unusual?"

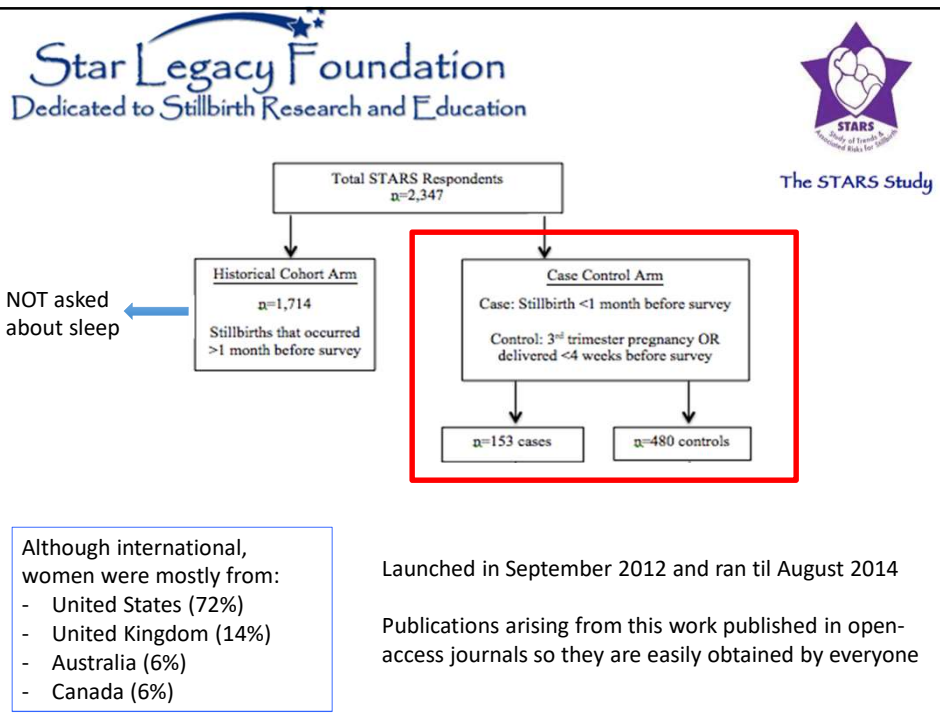


The STARS Study

"only decreased the week before birth. The day before he died he was especially busy and moving like crazy"

Significantly more women who reported increased movements, compared to those who reported reduced movements, did not worry about it (14 % vs. 6%, $p=0.001$) and fewer (61% vs. 76%, $p<0.001$) sought professional advice.

Fewer women with increased movements, compared to those with reduced movements, were either admitted or had some type of monitoring (23% vs. 33%, $p=0.002$).



RESEARCH ARTICLE

Open Access



The STARS Study

Stillbirth is associated with perceived alterations in fetal activity – findings from an international case control study

Alexander E. P. Heazell^{1,2*}, Jane Warland³, Tomasina Stacey⁴, Christin Coomarasamy⁵, Jayne Budd¹, Edwin A. Mitchell⁵ and Louise M. O'Brien⁶

In the case-control arm, median duration of time since the stillbirth was 13 days (range 1–29 days)

Women with stillbirth were:

- less likely to check fetal movements (aOR 0.54, 95%CI 0.35– 0.83)
- less likely to be told to do so by professionals (aOR 0.55, 95%CI 0.36-0.86)

Pregnancies ending in stillbirth were more frequently associated with changes in fetal movements in the preceding two weeks:

- significant reduction in fetal activity (aOR 14.1, 95%CI 7.27–27.45)
- sudden single episode of excessive fetal activity (aOR 4.30, 95% CI 2.25–8.24).

Cases described their perception of activity differently to healthy controls e.g. vigorous activity was described as “frantic”, “wild” or “crazy” compared to “powerful” or “strong”.



The STARS Study

“They told me all mothers have worries”, stillborn mother’s experiences of having a ‘gut instinct’ that something is wrong in pregnancy: Findings from an international case-control study

Jane Warland, PhD^{a,*}, Alexander E.P. Heazell, PhD^{b,c}, Tomasina Stacey, PhD^d, Christin Coomarasamy^e, Jayne Budd^{b,c}, Edwin A. Mitchell, PhD^e, Louise M. O'Brien, PhD^f

In the case-control arm, median duration of time since the stillbirth was 13 days (range 1–29 days)

Gut instinct occurred in response to a change in fetal movements for 40% of case and 26% of controls

It had been present for the whole pregnancy for 21% of cases and only n=1 control

Occurred in the night before birth in 23% of cases and 11% of controls.

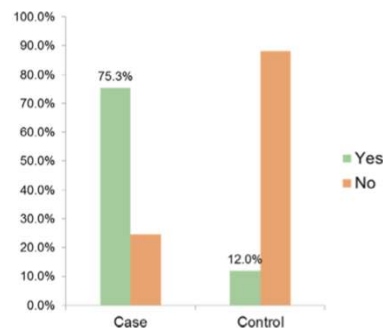


Fig. 2. Percentage response to question “During this pregnancy did you ever have a ‘gut instinct’ that something was not right?” 110 (75.3%) of the 146 stillborn cases (stillbirth less than 3 weeks prior) and only 28 (12.0%) of 234 live born controls (livebirth less than 3 weeks prior) answered yes to this question. OR 22.5 (95% CI 13.0–38.8, $p=0.001$).

Received: 18 September 2018 | Revised: 15 December 2018 | Accepted: 17 December 2018
 DOI: 10.1111/birt.12416

ORIGINAL ARTICLE

WILEY **WIRE**

Maternal sleep practices and stillbirth: Findings from an international case-control study

Louise M. O'Brien PhD¹ | Jane Warland PhD² | Tomasina Stacey PhD³ | Alexander E. P. Heazell MBChB, PhD^{4,5} | Edwin A. Mitchell MBChB⁶ | on behalf of the STARS Consortium*

The STARS Study

In the case-control arm, median duration of time since the stillbirth was 13 days (range 1–29 days)

Queried about sleep practices before pregnancy, in the previous month, and previous night (or night before stillbirth)

No differences in sleep before pregnancy in cases or controls

Stillbirths had significantly higher odds of long sleep duration >9 hours 1.8 (1.1-2.8) and significantly higher odds of NON-restless sleep 1.7 (1.0-3.0) and significantly higher odds of good/very good sleep quality OR 1.69 [95%CI 1.0-2.8]

Significantly LESS likely to wake up on the last night (aOR 2.03 [95% CI 1.24-3.34]).

Not enough position data.....

Lessons learned from STARS:

The STARS Study


- Women want to tell their stories (even decades later)
- We learned from listening to the stories
- We want to drill down deeper on some issues given the STARS findings:
 - significantly increased fetal movement
 - Intuition
- Some questions were asked of control women after delivery (e.g., gut instinct) that would have been better asked during pregnancy before the outcome was known
- A lot of hands-on work that could have been automated and more efficient
- Technical glitches from Survey Monkey made it challenging for analyses
- Would be good to have documented medical data
 - many women don't have things like BP written down, tests taken

Need to work with partners to maximize response



A banner for the STAR Legacy Foundation Pregnancy Research Project. At the top left is the STAR Legacy Foundation logo, which consists of a blue star and the text "STAR LEGACY FOUNDATION". Below this is a blue wavy line. To the left of the main title is the Pregnancy Research Project logo, which is a blue star with a white outline, surrounded by the text "PREGNANCY RESEARCH PROJECT" and "Est. 2019". The main title "PREGNANCY RESEARCH PROJECT" is in large, bold, blue letters. Below the title is a photograph of three pregnant women sitting on the floor, each with her hands on her belly.








PREGNANCY RESEARCH PROJECT

The Pregnancy Research Project will now build on the STARS study by obtaining more details in several key areas:

- sleep practices
- fetal movements
- maternal intuition

The Pregnancy Research Project collects data on:

- other stressors
- depressive symptoms
- paternal demographics
- imaging data (number and frequency of ultrasounds)
- details about previous pregnancies and their outcomes
- more detailed autopsy information

PREGNANCY RESEARCH PROJECT

You are eligible to participate if:

- You are at least 18 years of age or older
- You have had a stillbirth (pregnancy loss at or after 20 weeks gestation) at any time in the past
- You have delivered a living baby within the last five (5) years
- You are currently pregnant at 12 weeks gestation or more

The currently pregnant control group allow us have a comparison whereby outcomes are not known at the time of survey responses so that recall bias can be minimized.

NEWSLETTER SIGNUP | 952-715-7731

FOR FAMILIES FOR HEALTH PROFESSIONALS ABOUT US

STILTBIRTH SUMMIT 2019 **PREGNANCY RESEARCH PROJECT**

STAR LEGACY FOUNDATION

GET INVOLVED WHAT WE DO EVENTS OUR STARS BLOG

PODCAST OUR STORE

WELCOME TO
STAR LEGACY FOUNDATION
Because every pregnancy deserves a happy ending

DONATE

2018 GOLD

Translate »

<http://www.pregnancyresearchproject.org>

NEWSLETTER SIGNUP | 952-715-7731

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PREGNANCY RESEARCH PROJECT

The Pregnancy Research Project is a research study bringing together patients and researchers to advance knowledge and discover preventions and treatments for poor pregnancy outcomes.

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ENROLL TO PARTICIPATE

- Complete the online project questionnaire
- Allow us to gather information from your medical records

ENROLL NOW




FOR WOMEN
Learn how you can support the Pregnancy Research Project.
LEARN MORE

FOR HEALTH PROFESSIONALS
Learn how you can support the Pregnancy Research Project.
LEARN MORE

FAQS
Answers to frequently asked questions.
READ FAQS

THE PREGNANCY RESEARCH PROJECT IS A PARTNERSHIP OF:

STAR LEGACY MICHIGAN MEDICINE




STAR LEGACY
FOUNDATION

PREGNANCY
RESEARCH PROJECT

After reading the consent page with all the legal stuff.....

By clicking this link you agree to participate in this study.

..... you are linked to a REDCap database on a secure server behind Michigan Medicine HIPAA compliant firewalls



REDCap
Research Electronic Data Capture

Pregnancy Research Project - Welcome

Resize font: [Returning?](#)



STAR LEGACY
FOUNDATION
In association with




M MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN


Thank you for giving us the opportunity to learn from your experiences!

If you decide to share your experience with us today, answer for one pregnancy only. Later, after you have finished, you can always come back and answer the survey again for other pregnancies that you would like to share with us.


It can take between 30 - 45 minutes to complete the survey today, depending on your experiences and what you choose to share with us.




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PREGNANCY RESEARCH PROJECT
Est. 2019

At the end of the survey women are invited to share their prenatal and delivery records


- this requires separate consent and women will need to sign a Release of Information form which will be sent to their care provider
- medical records will provide objective information captured in real time during the pregnancy such as;
 - frequency and results of ultrasounds
 - number of presentations to healthcare providers (and why)
 - routine vital signs
 - results of autopsy (stillbirths)




At the Stillbirth Summit in 2017 we polled attendees re: medical records, and in both mothers who had experienced a stillbirth as well as those who had not, there was an overwhelmingly positive response in favor of sharing documented evidence from health care providers if this could avert another tragic outcome for a family.




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PREGNANCY RESEARCH PROJECT




**PREGNANCY
RESEARCH PROJECT**



PREGNANCY RESEARCH PROJECT
Est. 2019

Option to check a box to participate in other research – efficient way to connect families to researchers and vice versa.



We want this to be a living database which will continue to grow and ultimately be the largest, most robust dataset of its kind – which will allow to to find some answers at a population level that smaller studies cannot.

We plan to expand to other languages; while anyone anywhere in the world can take part in the survey, the medical record portion is currently only available to those in the US. That's something we are working on.

Designed to be collaborative; de-identified data will be ultimately opened up to other researchers through Star Legacy Foundation (with appropriate permissions)



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PREGNANCY RESEARCH PROJECT
Est. 2019

OPPORTUNITIES FOR PARTNERSHIP

- * Enroll in the study
- * Encourage friends, family to enroll
- * Share information where pregnant women are (clinics/organizations)
- * Brochures/social media ads/newsletters (available from Star Legacy)
- * Partnerships available
- * Add the link/embedded code to your website



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Thank you!



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