



STAR LEGACY
FOUNDATION

PREGNANCY RESEARCH PROJECT

Organizational & Individual Partnership Opportunities

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Pregnancy Research Project

The Pregnancy Research Project is a collaborative source of data for researchers interested in improving pregnancy outcomes. Databases exist for many health conditions, but pregnancy does not currently have this type of information available. Studies during and immediately after pregnancy are viewed as challenging, yet many women who have had a poor pregnancy outcome want their experience to be used to prevent future tragedies.

Why is this an important project?

In order for health professionals to identify prevention methods, interventions, or models of care, they rely on research that guides their work. Research during pregnancy has always been a challenge for ethical reasons. Researchers often report that the most time-consuming and expensive aspects of their work are enrolling individuals to participate in a study. It is not always easy to find people who meet the criteria for a specific study and are willing to contribute. Conversely, Star Legacy Foundation regularly hears from women who want their pregnancy experiences to benefit other families. It is rare that we are able to match them with studies that are able to use their information.

This project is designed to answer many questions about pregnancy health, but also to create a central location where women can contribute their information that may be used in dozens of research studies, and where researchers can obtain data for their studies in a matter of days or weeks instead of years. A unique aspect is that it will combine the mother's personal observations and knowledge with the items documented in the medical record to create a more robust and holistic picture of the pregnancy.

How it works

Women who have ever had a stillbirth in the past or women who are currently at least 12 weeks pregnant or have had a pregnancy that lasted at least 12 weeks gestation in the last 5 years are eligible to enroll. Their participation will involve completing a survey and requesting their medical records be sent to the project. The survey will focus on details about the pregnancy that are not typically documented in the medical record. The medical records requested will include prenatal office visits, laboratory and imaging, hospitalizations, delivery, and neonatal records.

Trained medical abstractors will enter the information from the medical records into a database and link their survey answers into the same database. Researchers will later be able to request de-identified data points for women who meet the criteria of their IRB-approved study.



Eligibility

Eligible individuals will have had a stillbirth in the past or are currently at least 12 weeks pregnant or have had a pregnancy that lasted at least 12 weeks within the last 5 years. During the initial phases of the project, the participants must be able to complete the consent form and survey in English (online, written, or verbal) and their medical records must exist in English. Expansion of the consent and maternal survey into additional languages will be part of phase II, and inclusion of medical records in languages other than English will be part of phase III.

Enrollment

Women will be able to enroll and participate online, in-person at project events or through partnering organizations, or by requesting a phone interview.

Data Security

All data will be housed in a secure dropbox location at the University of Michigan and/or locked file in a locked office for paper records. After abstraction, hard copies of records or surveys will be destroyed. The database will be housed through the Redcap system at the University of Michigan which has a strong record of quality and security for medical and research information. Researchers requesting information must provide evidence of IRB approval and oversight and the request will be reviewed by the Medical Steering Team for the Pregnancy Research Project. All information will be de-identified before being shared with any research team. The Pregnancy Research Project Coordinator and the abstractor assigned to a participant's case will be the only individuals with access to identifiable information.

Funding

Financial support for the Pregnancy Research Project is provided by the Star Legacy Foundation, a 501(c)(3) organization based in Eden Prairie, Minnesota, and through in-kind contributions by the University of Michigan. Additional funding will be pursued through grants, donations, sponsoring partnerships, and fees for data.

All financial support of the Pregnancy Research Project will support the costs of maintaining the database, abstracting records, enrolling new participants, monitoring quality and safety, and analyzing data.

Oversight

The Star Legacy Foundation Board of Directors will manage administrative, financial, and legal components of the project. The Medical Steering Team will serve as the Clinical Experts, manage the scientific and ethical components, review/approve requests for data, and oversee



publication. Additionally, they will annually review the project and quality assurance reports and determine if any adjustments are needed.

Ethics approval and oversight is provided by the University of Michigan Institutional Review Board. IRB # HUM00134286

Partnering Organizations

Star Legacy Foundation is seeking partnerships with organizations to increase the number of participants, involve a wide diversity of individuals and circumstances in the study, improve access to the data by researchers, expedite the data availability, and encourage collaboration for this and future maternal child health endeavors.

Partners

Pregnancy Research Project Partners are asked to:

- Encourage participation in the project by eligible individuals
- Offer enrollment information to eligible individuals at the organization's physical location or events held by the organization

The Pregnancy Research Project will support these partners by:

- providing regular updates on the status of the project
- placing the partner name on project website
- providing enrollment information cards to be given to eligible individuals

Supporters

Pregnancy Research Project Supporters are Partners who are willing to further support the project by:

- Providing a letter of support that can be used for IRB approval and/or grant applications
- Placing the Pregnancy Research Project Partner logo on organizational website once the project is launched
- Including details about the project on the organization's website, social media accounts, newsletters, and similar communication methods once the project is launched

The Pregnancy Research Project will provide for Supporting organizations:

- Placement of the organization's logo of partnering organizations on the project website
- Text and logos to be used in communications about the project
- Acknowledgement in Star Legacy Foundation communication channels



Sponsors

Organizations and individuals who wish to contribute to the financial support of the Pregnancy Research Project are welcome! All Sponsors are expected to participate at the level of a Supporter in addition to the financial contribution.

Presenting Sponsor **\$ 100,000**

The Presenting Sponsor organization/individual will be recognized in the title of the project on all marketing materials, websites, and communication and are eligible for a display table at the Stillbirth Summit. Star Legacy Foundation will also issue a press release announcing the partnership. Presenting Sponsors are eligible for 2 researchers to obtain data for research purposes at a 100% discount per year of sponsorship.

Platinum Sponsor **\$ 50,000**

Platinum Sponsors will be recognized prominently on the project website, marketing materials, and communication and are eligible for a display table at the Stillbirth Summit. Star Legacy Foundation will also issue a press release announcing the partnership. Platinum Sponsors are eligible for 1 researcher to obtain data for research purposes at a 100% discount and 1 researcher to obtain data for research purposes at a 50% discount per year of sponsorship.

Gold Sponsor **\$ 25,000**

Gold Sponsors will have their logo placed on the project website, marketing materials, and communication and are eligible for a display table at the Stillbirth Summit. Gold Sponsors are eligible for 2 researchers to obtain data for research purposes at a 50% discount per year of sponsorship.

Silver Sponsor **\$ 10,000**

Silver Sponsors will have their logo placed on the project website and communication and are eligible for a display table at the Stillbirth Summit. Silver Sponsors are eligible for 1 researcher to obtain data for research purposes at a 50% discount per year of sponsorship.

Bronze Sponsor **\$ 5,000**

Bronze Sponsors will have their logo placed on the project website. Bronze Sponsors are eligible for 1 researcher to obtain data for research purposes at a 25% discount per year of sponsorship.



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Questions

For more information, visit www.starlegacyfoundation.org/prp or contact us at prp@starlegacyfoundation.org, 952-715-7731.