

Rights of Research Subjects

Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS) Rights of Research Subjects Fact Sheet

As a potential participant in this research study, you have the right to:

- Be informed of the nature and purpose of the study.
- Be given an explanation of the procedures to be followed in the study.
- Be given a description of any discomforts and risks reasonably to be expected from the study procedures.
- Be given an explanation of any benefits you can reasonably expect from participation.
- Be informed of medical treatment, if any, available to you during and after the study if complications should arise.
- Be given an opportunity to ask any questions concerning the study or procedures involved.
- Be informed that you may withdraw from the study at any time without penalty.
- Be given the opportunity to decide to participate or not without the use of any force or undue influence on your decision.

All information that we gather in this study will be kept confidential. This is because the study has been given a Certificate of Confidentiality by the Centers for Disease Control and Prevention. This means that anything you tell us will not have to be given out to anyone, even if a court orders us to do so, unless you say it's okay. We may share information about you with other researchers but we will never use any names in reports or publications. You should also understand that study investigators are not prevented from reporting information obtained from you to authorities in order to prevent serious harm to yourself or others.

The BD-STEPS Question and Answer sheet will give you more information about how your privacy is protected in this study. If you have questions about your rights as a subject in this research study, please call the Human Research Protection Helpline at CDC at 1-800-584-8814, leave a message including your name, phone number, and refer to protocol #2087, and someone will call you as soon as possible.