

Dear Expectant Mother,

This letter is to inform you of a project being conducted by the Midwives Alliance of North America, called the MANA Statistics Project or MANA Stats. Your midwife contributes data to this project. After reading this letter, you will have the opportunity to ask questions and, if you so choose, to give your midwife verbal permission to enter information about your pregnancy and birth into the MANA Stats data collection system. No names or other identifiers are collected in this data registry.

Purpose. The Midwives Alliance conducts the MANA Stats Project in an effort to document the processes and outcomes associated with midwifery models of care, and to provide midwives with information they can use to maintain and improve the quality of their practices. These data may also be used for research.

1. **Activities.** In MANA Stats, each client that consents to participation is registered in an online system at the beginning of care. Your midwife then fills out an online data form describing your particular course of care.
2. **Time.** Your estimated time commitment to participate in the project is 15-20 minutes, and only involves this consent process. Your midwife enters all other data on your behalf.
3. **Risks.** Participation in this project poses no foreseeable risks to you.
4. **Benefits.** We do not expect you to benefit directly from participating in this project. However, we do expect that findings from research conducted using the MANA Stats database will help to improve maternal and infant health practices, and to guide the development of midwifery care policies in the United States and abroad.
5. **Alternatives.** There are two levels of participation in this project. First, you can choose to allow your midwife to enter your data only for her own internal quality assurance and improvement processes. In that case, your midwife would be the only person to see your data, and she would use it to do things like track her cesarean rate over time. Or, you may additionally consent to have your data included in the research database for this project. In this case, researchers who use the MANA Stats data (see #4, above) would have access to your de-identified data—however, when results are published, your data would not be reported individually, but rather in what we call “aggregate” form. For instance, the research paper might report that 93% of women had a spontaneous vaginal birth, or that 956 women used a shower during labor for pain relief. Finally, you could just opt not to have your data in MANA Stats at all. If you choose this last option, you can still get prenatal care with your current midwife.
6. **Confidentiality.** The confidentiality of your health-related information will be carefully protected. To protect your identity, your midwife will create a code for your birth (e.g., “birthcode123”), rather than using your name. Data will be kept secure to the extent permitted by the technology being used. Information collected online can be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses.
7. **Contact Information.** If you have any questions about this study, please contact the MANA Division of Research—the entity that oversees this project. (See below for contact information)

8. **Voluntariness.** If you choose to participate in the project, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to participate. You can stop at any time and still keep the benefits and rights you had before volunteering. Your decision will not affect your care or your relationship with your midwife. You may withdraw your data from this project any time prior to the final submission of the data form by your midwife to the database by contacting your midwife; she will then inform the MANA Division of Research of your withdrawal from the project.
9. **Funding.** This study receives ongoing internal funding from the Midwives Alliance Board of Directors, and varying sources of external funding, including the Foundation for the Advancement of Midwifery, Transforming Birth Fund, other foundations, and federal agencies.
10. **Conflict of Interest.** Members of the Division of Research (DOR) may also be researchers who access the data for research purposes. MANA DOR members and researchers accessing the data may also be midwives themselves or otherwise involved as midwifery or birth professionals.

Please ask any questions of your midwife about this project before making your decision about whether or not to allow your data to be entered. You may also contact the MANA Division of Research with your questions using the contact information below.

Thank you for your consideration,
 The MANA Division of Research: The MANA Statistics Project
 PO Box 373, Montvale, NJ 07645
research@mana.org or 844-626-2674

By initialing the Informed Choice for this document, you are agreeing to the following:

Dear Midwife,

*Please retain this portion in the chart so that you can log your client if she consents.
 You do not need to mail this form to MANA*

Verbal Consent (midwife reads to client)

Do you give your consent for your midwife to enter your clinical data into the MANA Statistics Project for quality insurance and quality improvement measures? Yes or No? yes no

Record date:

Do you give your consent for your midwife to enter your clinical data into the MANA Statistics Project for research purposes? Yes or No? yes no

Record date:

Birth Code _____ (for identifying client's record later when recording consent and entering data)

Thank you!
 (Remember: You do not need to mail this page to MANA)