



Best Practices for States Considering the Midwives Alliance Statistics Project (MANA Stats) for Legislative or Regulatory Midwifery Data Collection & Reporting

The **purpose** of this document is to provide basic guidance to state organizations and regulatory agencies considering the use of MANA Statistics to fulfill mandatory midwifery data collection and reporting requirements.

What is MANA Statistics? MANA Statistics (MANA Stats) is one of the largest perinatal data registries for midwife-attended births in the community setting (home and birth centers). The project is administered by the Midwives Alliance of North America (MANA), the professional organization for all midwives in the United States. Data collection began in 2004 and continues today. More information on the methodology and history of this data registry can be found in this published article:

<https://www.ncbi.nlm.nih.gov/pubmed/24479670>

Information on the process by which midwives may enroll, and their requirements once enrolled, are available on www.manastats.org

The following are recommended best practices for implementing mandatory data collection. These guidelines are designed to assist in the development of language and processes that are in compliance with the federal regulations for research data registries and that ensure protection for research subjects.

- *Statute should include generic language for mandatory reporting requirements.* Details should be left to administrative rules since they can be more easily amended as needed.
- *Do not name the database to be used in statute or rules.* Instead, state requirements as “participation in a nationally validated perinatal data registry” or similar language. An example of successful language can be found in Appendix A of this document.
- *The reporting system must allow MANA Stats to remain in compliance with research standards for human subjects.* MANA Stats is a research data registry. This means that all project components follow Institutional Review Board (IRB) protocols for the ethical and non-coercive treatment of human subjects in research. This requires midwives to obtain consent for data collection from each client/patient. IRB protocols dictate that clients/patients cannot be required to participate in MANA Stats, even if their midwife’s state requires mandatory data collection. As such, states must provide an alternative reporting mechanism for data from clients who decline to have their data entered into MANA Stats. An example of what an alternative reporting mechanism may look like is included in Appendix B.

- *All data in the MANA Stats data registry is de-identified and should be reported to states in the aggregate.* To facilitate this, midwives can print their Annual Summary Report from the MANA Stats site at any time. This report can be for a calendar year or a specified 12-month period. The report may be limited if desired to births occurring within one state. It includes annual caseload numbers and standard perinatal outcomes for clients who began labor in the midwife's care. Contact support@manastats.org for a sample report. To remain in compliance with federal regulations for human subjects research, *MANA Stats will never provide data directly to regulatory agencies.*
- *State midwifery organizations are strongly encouraged to contract with the MANA Stats data collection team* to provide information and proactive support to state midwives regarding the enrollment process and requirements of MANA Stats participation, especially the need to log all clients prospectively, and to complete all data forms in a timely manner. The data collection team can be reached at support@manastats.org
- *To support midwife compliance with state reporting requirements, states will be asked to provide their own data doulas. Please contact support@manastats.org to learn more*

Early contact is the key to success! The Midwives Alliance Division of Research (DOR) recommends that representatives from state midwifery organizations and regulatory agencies contact the DOR early in the process (before draft language is written) to ensure successful collaboration and feasibility. We are happy to review draft language to ensure compliance with research standards and best practices and, where needed, provide support to policymakers with questions. The DOR can be reached at research@mana.org.

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Appendix A: Sample Regulatory Language on Mandatory Data Collection from Washington State

- Washington State Statute regarding Licensed Midwife License Renewal Requirements- [RCW 18.50.102](#):
 - “Proof of participation in data submission on perinatal outcomes to a national or state research organization, as detailed in rule;”
- Washington Administrative Code on Data Submission requirements- [WAC 246-834-370](#):
 - (1) As a condition of renewing a license, a licensed midwife shall report data on all courses of care for every mother and newborn under the midwife's care to a national or state research organization approved by the department. If the mother declines to participate in the collection of data, the midwife shall follow the protocol of the approved national or state research organization.
 - (2) The licensed midwife shall verify compliance by submitting an attestation to the department annually with the license renewal.
 - (3) For auditing purposes, written confirmation of full participation in data collection from the approved state or national research organization shall suffice.
 - (4) The midwife must keep her/his data and participation records; data and participation records will not be submitted directly to the department.

Appendix B: Sample Alternative Reporting Mechanisms for Clients that Decline Participation in MANA Statistics

Please visit <http://www.oregon.gov/oha/PH/HLO/Pages/Board-Direct-Entry-Midwifery-License.aspx> and click on “DEM Client Declined MANA Reporting” form under “Application, renewal and information update forms” for a sample alternative reporting mechanism from the State of Oregon.