DATA ACCESS POLICY & PROCEDURES

Introduction

The American Association of Birth Centers (AABC) *Perinatal Data Registry* (PDR) is an online data registry for the collection of data on normal birth. The purposes of the registry are to:

1. Help improve and maintain quality of care of childbearing families;
2. Provide for ongoing and systematic collection of data on normal birth; and
3. Facilitate research on maternity care practices that support optimal birth.

The AABC encourages the use of its PDR data by both those facilities and individuals who have contributed data to the PDR and by outside researchers, and strives to ensure that this data use remains both ethical and purposeful. Emphasis is on data use that will promote quality maternity care.

The purpose of this document is to (1) define the procedures by which interested parties can gain access to the data in the registry and (2) outline a process to assure that any publication derived from the registry is a high quality report such that the data are accurately presented, not prejudicial to any person or facility, nor in violation of the confidentiality of any person or facility.

Ethical Standards

Successful applicants who intend to use material obtained from the PDR have the responsibility to seek honestly, and promulgate ethically, the truth in all phases of work. This responsibility extends to all phases of research and creative activity which may result from data obtained from the PDR.

The AABC Research Committee and the AABC Board of Directors will oversee the development of scientific project applications, abstracts, manuscripts or presentations derived from PDR data. They subscribe to the following principles in considering research and creative activities:

1. Scientific integrity will be inherent in all anticipated activity.
2. Fabrication and falsification of information that an applicant claims is based on PDR data is unethical.
3. Intentional selection or treatment of data to present views known by the applicant to be false is unethical.
4. Dissemination of tangible information under the applicant's name which is derived from data from another individual's work without due credit is plagiarism.

5. Applicants must list co-authors of a work to be disseminated in any form, but only with the co-author's express consent. The unwarranted inclusion of co-authors who have not been substantially involved in the work is unethical.
6. Observations must be recorded in a manner such that individual facilities and human subjects cannot be identified, either directly or through inference.
7. Observations should be recorded in a manner such that conclusions cannot be judged as prejudicial to any facility or individual.

The Process to Obtain Data

When straight facts (e.g. for benchmarking or policy-making purposes) are required from the PDR, necessitating no interpretation of data, this is considered a *Routine Data Request*. A request for data requiring or leading to any interpretation or extensive analysis (e.g. for the testing of hypotheses or from which conclusions will be drawn) is considered a *Scientific Data Request.* Forms for requesting data are available at www.birthcenters.org in the Research & Data section.

In making the data available to individuals and entities, AABC is only bound by its responsibility to guard the confidentiality of patients and sites. No other responsibility is assumed by AABC about the data.

Routine Data Request:

For a routine data request, the individual must submit (by mail or e-mail) a completed *Routine Data Request* form (Attachment A) to the AABC at 3123 Gottschall Road, Perkiomenville, PA 18074 or to pdr@birthcenters.org. Whenever possible, the AABC will respond to all such requests within 30 working days. A copy of the request and response shall be forwarded simultaneously by the Executive Director to the AABC BOD and to the Research Committee Chairperson.

Routine data requests will be approved for the release of aggregate data or a subset of data, for example state-wide or regional data. No request will be approved for the data of an individual PDR contributor, either facility or individual, or for data from which an individual contributor may be identified.

Scientific Data Request:

For a scientific data request, the principal investigator must complete *Scientific Data Request* for (Attachment B) and submit by mail or email it to the AABC at 3123 Gottschall Road, Perkiomenville, PA 18074 or to pdr@birthcenters.org. **The application must be typed and include all required information. The application must include the principal investigator's signature, verifying that she/he will abide by all publication policies.**

Investigators submitting a scientific data request must include a copy of Institutional Review Board (IRB) approval for their study The IRB at the institution of each requester is responsible for determining whether the project satisfies the requirements for protection of human subjects. Alternately, the investigator may elect to seek IRB approval from the Duke University Medical Center's IRB. **An IRB**

letter stating that the proposed study is exempt from review may be acceptable for a request of the de-identified data set. The IRB, whether within or outside of the U.S., must operate under the Office of Human Research Protections (OHRP)–approved assurance. The Web Site for OHRP provides information regarding the process to obtain project assurances (http://www.hhs.gov/ohrp/). Investigators who do not agree to sign the *Scientific Data Request,* or do not submit an IRB approval or letter confirming exemption from review, will not be sent the data set.

If review is required, the requester should inform the IRB to review each of the following items in considering approval of the request:

1. Does the Study's informed consent permit use of these data for research purposes by investigators who were not part of the original study?
2. If the answer to (1) is no, is the protection of privacy so great, and the risk to the participants so low, as to merit waiver of informed consent?
3. Have all reasonable personal identifying items been removed from the data set, or modified appropriately?
4. Will the recipient investigators provide appropriate safeguards for protection of participant privacy?
5. Has the recipient investigator signed the data distribution agreement with the AABC pledging to protect confidentiality and to use the data in the manner specified in the agreement?

A copy of the IRB approval document, including the OHRP assurance number, or a letter stating project is exempt from review, should be sent to the AABC along with the signed *Scientific Data Request* form.

The requests will be reviewed for scientific merit and potential to contribute to the purposes of the PDR registry project. In addition, the amount of resources necessary to fulfill the request, source of request for data, and intended use of requested information will be taken into consideration. The AABC will also seek to avoid duplication of research efforts and/or publications.

The AABC will provide the investigator with prior notification of the charges to be assessed for the data request. These charges will be based upon the volume of data requested and the anticipated time involved in supplying the data. AABC members will be assessed for approved data requests at a discounted charge.

All scientific data requests must be approved by both the Research Committee and by the AABC Board of Directors. Outside consultation may be sought if needed to obtain the appropriate expertise for review of the scientific data request.

Approval for use of the AABC dataset includes only the analysis for which the investigator originally submitted a request. Any additional data analysis for a different research project requires submission of a new data use request. There will be no fee for a subsequent request if no additional data are requested.

Abstracts, Manuscripts and Presentations:

No publication or major presentation shall be made by any party regarding the results of any data analysis without going through the appropriate AABC approval processes outlined below. **The approval process for abstracts, manuscripts, and presentations is independent of the approval process for data request.**

Prior to the release of any PDR data (e.g. in the form of an abstract, manuscript, or presentation) to any audience, approval must be obtained from the AABC BOD. An electronic copy of the proposed abstract, manuscript, or presentation, including the required *Publication Request* form (Attachment C), must be submitted to the AABC. These applications will be disseminated to the AABC Research Committee and the BOD for review. Applicants may be required to present the presentation to the AABC BOD prior to approval of the publication request.

Any proposed abstracts or manuscripts resulting from research from PDR data will be submitted by the author(s) to the AABC for review at least 30 days prior to the date of submission for publication. Any presentations will be submitted at least 30 days prior to the date of submission for acceptance.

Each author of any abstract, manuscript, or presentation (subsequently referred to as "the work") should have participated sufficiently in the work to take public responsibility for its content, meaning that any author listed can defend the work's content, including the data and the conclusions based on them.

"Sufficient participation" should include: 1) Conceptualization of the work, and/or analysis and interpretation of the data; 2) Participating in writing the article by contributing to , drafting, or revising it for critically important content; and 3) review and approval of the entire contents of the final work before it is submitted for publication. The primary author should be the person who actually did most of the work and who actively wrote and referenced most of the paper.

The AABC BOD may give constructive criticism without denying the publication request application. The AABC BOD and Research Committee will have ten working days (for abstracts) and twenty working days (for manuscripts and presentations) to forward an approval/disapproval to the author by e-mail or in writing.

Any disagreements about the use of the data will be resolved by a good faith effort by both parties. If the dispute cannot be resolved, the AABC may withdraw the use of its name or reference to the PDR in the final publication or presentation.

Priorities in selecting journals/forums for publications submission will be given to peer-reviewed journals as well as presentations and publications of abstracts at national and international professional meetings.

The AABC and the facilities or practices contributing data to the PDR should receive a standard acknowledgement in the final abstract, manuscript, or presentation. This shall read as follows: "The authors gratefully acknowledge the efforts of the American Association of Birth Centers as well as those individuals and facilities contributing data to the AABC *Perinatal Data Registry*." In all cases

where journal policies permit, each individual facility and practice who contributed data to the PDR shall be acknowledged.

The primary author should keep the AABC apprised of all events following submission (i.e., acceptance or rejection). Copies of the reprinted article will be sent to the AABC office. Requests for copies of manuscripts will not be considered until the manuscript is in press.

The AABC will maintain an up-to-date bibliography and repository of all publications or major presentations pertaining to the PDR or resulting from analysis of PDR data. Lead authors are responsible for providing the AABC office with the most recent version of all publications.

Indemnification

AABC shall not be liable for any damages or loss whatsoever to any person or legal entity arising from the use of PDR data. Any person who uses these data agrees to indemnify, defend and hold harmless AABC and AABC's officers, directors, employees, agents and contractors from and against all loss, damages, claims, demands, liabilities and causes of action of any kind arising from use of the AABC data.

No Outside Use of Data

User agrees not to convey these data to any other person or entity outside the data user's collaborative group working on the project for which the data have been requested. AABC prefers to be the direct source of data so that our collaborators have the most current and accurate data.

In no event shall any PDR data be used for commercial purposes. Users agrees not to reproduce, sell, or redistribute the original data, or provide to colleagues, or place the materials for download on a website. Any sale, loan, or offering for use of these data, in whole or in part, is prohibited.

Approved 4.9.2010; Revised 2.7.2014; Revised 4.18.2015;

Reviewed by Research Committee 1.21.2019

ATTACHMENT A: Routine Data Request Form

ROUTINE DATA REQUEST

INDIVIDUAL REQUESTING INFORMATION:_____

INSTITUTION:_____ DEPARTMENT:_____

ADDRESS:_____

PHONE:_____ FAX:_____ E-MAIL:_____

DATE OF REQUEST:_____ DATE NEEDED: _____

INFORMATION REQUESTED (Please list the specific variables that should be included in the dataset):

PURPOSE OF INQUIRY:

PREFERRED FORMAT:

- ☐ ELECTRONIC
- ☐ HARD COPY
- ☐ SPREADSHEET
- ☐ REPORT WITH NARRATIVE

Please return the completed and signed form to:

American Association of Birth Centers
3123 Gottschall Road | Perkiomenville, PA 18074
Fax 215-234-8829 | pdr@birthcenters.org

Attachment B: Scientific Data Request

Scientific Data Request
Application for Data from the AABC Perinatal Data Registry

PROJECT TITLE: _____

PRINCIPAL INVESTIGATOR: _____

TITLE: _____

INSTITUTION: _____

ADDRESS: _____

PHONE: _____ FAX: _____

E-MAIL: _____

I understand that approval for use of the AABC dataset includes only the analysis for which the investigator originally submitted a request.

I agree to:

- Use the dataset only for the approved project.
- Not to convey these data to any other person or entity outside the collaborative group working on the project for which the data have been requested.
- Not to publish or publically present data provided from the American Association of Birth Centers Perinatal Data Registry without prior approval by the AABC Board of Directors.
- Guard the confidentiality of any data provided to us from the AABC Perinatal Data Registry.

PRINCIPAL INVESTIGATOR: _____ DATE: _____

(PRINT) _____

The following must be submitted with this data request form:

- Biosketch for primary investigator and collaborating researchers (use attached form)
- Description of project, including abstract, methods, and research questions
- Evidence of IRB approval or exemption
- Appendix E: Checklist of variables being requested

Please return the completed and signed form to:

American Association of Birth Centers
3123 Gottschall Road | Perkiomenville, PA 18074
Fax 215-234-8829 | pdr@birthcenters.org

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED 3 PAGES.

NAME:

INSTITUTION/COMPANY

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement (describe previous research activities, qualifications and resources to conduct this project)

B. Positions and Employment

C. Previous or Ongoing Research

D. Publications

Attachment C: Publication or Presentation Request

Request for Permission to Publish or Present Perinatal Data Registry Research

TITLE:_____

PRIMARY AUTHOR: _____

CO-AUTHORS: _____

JOURNAL/CONFERENCE: _____

SUBMISSION DEADLINE: _____

TITLE & DATE OF ORIGINAL SCIENTIFIC DATA REQUEST: _____

Please return the completed and signed form to:

American Association of Birth Centers
3123 Gottschall Road
Perkiomenville, PA 18074
Fax 215-234-8829
pdr@birthcenters.org

Attachment D: Fee Schedule for Data Access Requests

Routine Data Request

- $250 (includes up to 15 variables; fees for requests with additional variables will be assessed on an individual basis)
- Complimentary for PDR contributing practices and AABC committees

Sliding Fee Scale for Scientific Data Request:

PDR Outcome Data

- $1,500 – demographic information and 5 variables
- $2,500 – demographic information and 10 variables
- $3,500 – demographic information and 20 variables
- $5,000 – demographic information and more than 20 variables

PDR Outcome Data – STUDENTS

- $1,000 – PhD students
- $500 – Masters level students

PDR Birth Center Profile Data (most recent year)

- $1,599 - Researchers
- $500 - PhD Students
- $250 - Masters Level Students

5.8.19

Attachment E: AABC PDR 3.0 List of Variables
Note: Indicate which of your research questions each variable will address

Part 1 - Initial OB Visit

*Required Field in the PDR

Research Question	Select	PDR Variable
	☐	Age *
	☐	Primary Payment Method *
	☐	Secondary Insurance
	☐	Years of Education (Total # of Years) (GED=12) *
	☐	Maternal Ethnicity *
	☐	Maternal Race *
	☐	If Hispanic, specify: *
	☐	Marital or Partner Status *
	☐	Mother's Occupation
	☐	Family History
	☐	Medical History * (24 response choices)
	☐	If Substance Abuse selected, specify:
	☐	Psychosocial History (14 response choices)
	☐	Mother's Pregravid or Early Pregnancy Weight *
	☐	Mother's Height *
	☐	Calculated BMI
	☐	Gravidity *
	☐	Basic Parity *
	☐	Detailed Parity *
	☐	Pregnancy History * (24 answer choices)
	☐	Number of Previous Cesarean Births *
	☐	Number of Previous VBACs *
	☐	Planned Place of Birth for Current Pregnancy *
	☐	Weeks of Gestation at Start of Prenatal Care
	☐	Weeks Gestation at Initial Visit to Birth Center or Midwifery Practice

Part 1A-VBAC Data

Research Question	Select	PDR Variable
	☐	Did you obtain operative note from previous cesarean birth?
	☐	Uterine incision
	☐	Uterine closure
	☐	Surgical Infection after cesarean birth(s)?
		Primary reason for previous cesarean according to operative note
	☐	Interval from most recent cesarean birth to current EDD

Part 1B – Third Trimester Review

Research Question	Select	PDR Variable
	☐	Intended Place of Birth in 3rd Trimester

Part 2 - Antepartum Course

Research Question	Select	PDR Variable
	☐	Number of Prenatal Visits in the Birth Center *
	☐	# of Prenatal Visits with Other Providers
	☐	Other Provider/Services
	☐	Prenatal Classes
	☐	Psychosocial Pregnancy Issues
	☐	If Substance Abuse selected above, specify:
	☐	Activity during pregnancy
	☐	Prenatal Testing (Only those done as OUTPATIENT)
	☐	If ultrasound(s) done, please indicate
	☐	If ultrasound for cervical length, indicate:
	☐	Breech Version Procedure(s)
	☐	Cervical Ripening
	☐	If herbals or homeopathics, specify:
	☐	Drugs Prescribed/Recommended
	☐	If progesterone, specify:
	☐	If herbals or homeopathics, specify:
	☐	Number of Antepartum Hospitalizations
	☐	Primary Indication for Antepartum Hospitalization

Research Question	Select	PDR Variable
	☐	Primary Antepartum Care Provider *
	☐	Prenatal Complications * (29 answer choices)
	☐	If infection specify:
	☐	If Non-Reassuring Fetal Testing specify:
	☐	Number of days spent in ICU *
	☐	If maternal death prior to the onset of labor, please provide details. *
	☐	How is client planning to feed her baby? *
	☐	Antepartum Transfer *
	☐	Primary Indication for Attrition Medical: *
	☐	Primary Indication for Attrition Non-Medical: *
	☐	Primary Indication for AP Medical Referral: * (21 answer choices)
	☐	Gestation age at AP Medical Referral *

Part 3 - Intrapartum Course

Research Question	Select	PDR Variable
	☐	
	☐	Weight at final prenatal visit *
	☐	Place of First Admission to IP Care *
	☐	Labor Status on Admission
	☐	Cervical Dilation on Admission
	☐	Cervical Effacement on Admission
	☐	Fetal Station on Admission
	☐	Fetal Position on Admission
	☐	Frequency of Uterine Contractions on Admission
	☐	Duration of Uterine Contractions on Admission
	☐	Intensity of Uterine Contractions to Palpation on Admission
	☐	Frequency of Uterine Contractions on Admission
	☐	Duration of Uterine Contractions on Admission
	☐	Intensity of Uterine Contractions to Palpation on Admission
	☐	Induction of Labor *
	☐	Primary Indication for Induction of Labor * (18 answer choices)

Research Question	Select	PDR Variable
	☐	Location in which each method of induction was used
	☐	If herbals or homeopathics for induction of labor, specify:
	☐	Augmentation of Labor
	☐	Primary Indication for Augmentation of Labor
	☐	Indicate methods Used for augmentation of labor in any location
	☐	If herbals or homeopathics used for augmentation of labor, specify:
	☐	Monitoring During Labor
	☐	If Intermittent Auscultation Only, Specify
	☐	If Continuous Electronic, Specify
	☐	Intake during labor, check all that apply
	☐	Pain Relief - Non-Pharmacologic, check all used in any location:
	☐	Water Immersion Variables (7)
	☐	Pain Relief - Pharmacologic used in any location:
	☐	Other procedures used during intrapartum in any location:
	☐	Pushing during 2nd stage (directed/physiologic/passive descent)
	☐	Calculated Gestational Age
	☐	Place of Birth *
	☐	Type of Birth *
	☐	Primary Indication for Cesarean Birth *
	☐	Was cesarean birth designated as emergent by provider?
	☐	Mother's Position for Birth
	☐	Fetal Position at Birth
	☐	If breech, specify:
	☐	Water Birth (No, Yes)?
	☐	Placenta delivered under water?
	☐	Support for Labor
	☐	Primary Attendant for Birth *
	☐	Episiotomy *
	☐	Perineum Care

Research Question	Select	PDR Variable
	☐	Laceration
	☐	Intrapartum Transfer *
	☐	Primary Indication for Pre-Admit IP Referral * (16 response choices)
	☐	Primary Indication for IP Referral * (17 response choices)
	☐	Primary Indication for Emergency IP Transfer * (6 response choices)
	☐	Length of Time from Decision to Transfer to Arrival in Receiving Unit: *
	☐	Length of Time in Hospital Prior to Delivery *
	☐	Mode of Transport for IP Transfer *
	☐	Length of 1st stage of labor
	☐	Length of the 2nd stage of labor
	☐	Length of the 3rd stage of labor
	☐	Indicate if Active Management of 3rd Stage
	☐	Indicate all interventions used for 3rd stage management
	☐	Time from Rupture of Membranes to Birth
	☐	Character of Amniotic Fluid
	☐	Intrapartum Complications * (32 answer choices)
	☐	Length of stay in ICU *
	☐	If maternal death in labor, please provide details.*
	☐	Did mother receive prophylactic corticosteroids to promote fetal lung maturity?
	☐	If client received tocolytics during labor, select indication
	☐	If Uterine Rupture, specify: *
	☐	If Surgical Injury, specify: *
	☐	Postpartum Transfer *
	☐	Primary Indication for PP Transfer * (8 answer choices)
	☐	Primary Indication for Emergency PP Transfer * (5 answer choices)
	☐	Length of time from decision to transfer to arrival in receiving unit *
	☐	Length of Time in Hospital Prior to Treatment

Research Question	Select	PDR Variable
	☐	Mode of Transport for PP Transfer *
	☐	Postpartum Complications * (16 answer choices)
	☐	Length of stay in ICU after postpartum admission *
	☐	If maternal death postpartum, please provide details.*
	☐	Postpartum Procedures in any location (10 answer choices)
	☐	Specify herbals or homeopathics used immediately postpartum, please select all used
	☐	Specify use of oxytocics:
	☐	Length of Maternal Postpartum Stay at Birth Center or Hospital
	☐	Type of Newborn Transfer *
	☐	Primary Indication for Newborn Transfer * (10 answer choices)
	☐	Newborn Transferred to: *
	☐	Length of time from decision to transfer to arrival in receiving unit *
	☐	Length of Time in Hospital Prior to Treatment
	☐	Mode of Transport for Newborn Transfer *
	☐	Newborn procedures in any setting (19 answer choices)
	☐	Specify type of Vitamin K (IM/oral)
	☐	If PPV please specify:
	☐	If PPV, select duration
	☐	If septic work-up, specify:
	☐	Newborn Admission to NICU after Hospital Birth *
	☐	If newborn admitted to NICU, please select time of admission *
	☐	Length of newborn's stay in NICU *
	☐	Newborn Length of Stay in Birth Center or Hospital for newborn who was NOT admitted to NICU
	☐	Was newborn length of stay longer than maternal length of stay?
	☐	Pregnancy Outcome: *
	☐	Outcome of Singleton Pregnancy or First Twin*
	☐	If fetal death intrapartum, please provide details.*
	☐	If neonatal death, please provide details*

Research Question	Select	PDR Variable
	☐	Newborn Complications * (25 answer choices)
	☐	If congenital anomalies, specify: *
	☐	Gender Singleton or 1st twin
	☐	Calculated Birth Weight in Grams
	☐	Apgar Score (1 & 5 minutes, 10 minutes if indicated)
	☐	Repeat variables for 2nd twin
	☐	Infant feeding method initiated after birth *
	☐	Newborn's Length of Stay in Transfer Site *
	☐	Infant Feeding Method at Discharge *

Part 4 - Postpartum Course

Research Question	Select	PDR Variable
	☐	Postpartum Follow-up *
	☐	Select all follow-ups attempts made *
	☐	Please indicate if any of the following length of stay situations occurred (Baby>mother, mother >48 hours after vagina birth or >72 hours after cesarean birth)
	☐	Number of Home Visits by Birth Center
	☐	Number of Home Visits by Outside Agency
	☐	Number of Maternal Post-Partum Visits in Midwifery Practice or Birth Center
	☐	Number of Maternal Postpartum Visits to Other Providers for Postpartum Issues
	☐	Number of Infant Visits in Midwifery Practice or Birth Center
	☐	Number of provider initiated phone calls
	☐	Maternal Re-admission before 6 weeks *
	☐	Primary Indication for Maternal Re-Admission * (6 answer choices)
	☐	Length of Stay during Maternal Re-Admission
	☐	Newborn Re-Admission before 6 weeks *
	☐	Primary Indication for Newborn Re-Admission Before 6 weeks * (5 answer choices)
	☐	If infection specify (suspected or confirmed)

Research Question	Select	PDR Variable
	☐	Age of Newborn at Re-Admission (days)
	☐	Length of Stay for Newborn Re-Admission
	☐	Maternal Problem Up to 6 weeks Postpartum * (12 answer choices)
	☐	Perineal Discomfort (per mother)
	☐	Resumption of Sexual Intercourse
	☐	Emotional Well-Being (per mother)
	☐	Edinburgh Postnatal Depression Screen score
	☐	Birth Control Method after Postpartum Visit
	☐	Newborn Problems Up to 6 weeks * (8 answer choices)
	☐	If congenital anomalies, specify:
	☐	Infant feeding method at 6weeks

PRINCIPAL INVESTIGATOR: _____ DATE: _____

(PRINT) _____