Data Use Agreement

Florida Birth Defects Registry

Please email signed and completed 1) Data Use Agreement Form and 2) Application for the Use of Data from the Florida Birth Defects Registry (FBDR) Form to FBDR@FLHealth.gov with a copy of permission obtained from Florida Department of Health Division of Public Health Statistics and Performance Management and the Agency for Health Care Administration (AHCA).

This Agreement ("Agreement") for the use of data from the Florida Birth Defects Registry ("FBDR") is entered into by the Florida Department of Health, Division of Community Health Promotion ("Department"), and _____, ("Requestor").

Pursuant to the Agreement, the data provided from the FBDR shall only be used for the specific purposes for which it was requested and supplied, and it shall not be copied or redistributed in any manner to any third party.

Requestors within DOH, county health department staff, or their contractors must receive approval from the DOH Division of Public Health Statistics and Performance Management and AHCA prior to completing an Agreement for the Use of Data from the FBDR. Before data can be released and research commenced, the research protocol must first be reviewed and approved by Human Research Protection Program (Institutional Review Board) at the DOH (381.86, Florida Statutes, Institutional Review Board). No research may occur at the Department that has not been approved by the DOH IRB. Information about creating an application for review of research by the DOH IRB may be found at: http://www.floridahealth.gov/provider-and-partner-resources/research/irb/irb-basic-info.html.

Requestors with a college or university affiliation must have a full-time faculty member as data custodian, and must first receive approval from their university Institutional Review Board (IRB). Upon approval by the university IRB, the applicant must complete data use agreements with the DOH Bureau of Vital Statistics, and AHCA prior to applying to the DOH FBDR Coordinator for data. Once the approvals have been obtained from the aforementioned entities the Requestor must complete the DOH Agreement for the Use of FBDR Data and submit this and all other data use agreements to the DOH FBDR Coordinator for review and approval. Before data can be released and research commenced, the research protocol must first be reviewed and approved by Human Research Protection Program (Institutional Review Board) at the DOH (381.86, Florida Statutes, Institutional Review Board). No research may occur at the Department that has not been approved by the DOH IRB. Information about creating an application for review of research by the DOH IRB may be found at: http://www.floridahealth.gov/provider-and-partner-resources/research/irb/irb-basic-info.html.

RECITALS

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Exhibit 1

1. The Department collects and maintains confidential data in the FBDR from which it has prepared one or more electronic files beginning with the year 1998.

2. Data in the FBDR is confidential and exempt from the provisions of Section 119.07, Florida Statutes.

3. This confidential FBDR data is for use by authorized Requestor(s) for scientific and epidemiologic research as described in Section 381.003   Florida Statutes.

4. The Department has received and approved an Application for the Use of Data from the FBDR (Exhibit 1). The Application is incorporated as a part of this Agreement.

5. The Requestor(s) agrees to protect the confidentiality of the FBDR data and any reports containing the data. Protection includes the use of password protections and storage of the data in areas with restricted access.

6. The Requestor(s) agrees not to share the data externally or internally unless specifically authorized and upon completion of the research outlined in the Application the Requestor(s) shall destroy the data file.

7. The Requestor(s) agrees not to link the FBDR data file to any other data file obtained from any other source and not to attempt to contact any individuals or their families referenced in the FBDR file. The Requestor(s) further agrees not to prepare or publish reports derived from the FBDR data that would lead to the identification of individuals or their families

8. The Requestor(s) shall acknowledge the "Florida Department of Health, Florida Birth Defects Registry" as a source of data in all publications and shall provide the Coordinator of the FBDR with a copy of all research papers or reports using FBDR data.

9. The Requestor(s) shall identify a designated data custodian whose responsibility shall be to insure the appropriate use, security and confidentiality, and destruction of FBDR data at the appropriate time upon completion of research.

10. The law governing this Agreement shall be Florida Law and the venue for disputes over this Agreement shall be a State Court of Competent Jurisdiction in Leon County, Florida.

11. Requestor(s) agrees that he or she (they) has the authority to bind Investigator's Institution as to the terms of this Agreement.

12. This Agreement begins upon the date it is fully executed and ends upon completion of the performance by the parties.

13. The above recitals are true and correct and incorporated as if fully stated herein.

Exhibit 1

IN WITNESS WHEREOF, the parties hereto executed this _____ page Agreement, with Exhibit 1, on the dates stated below.

REQUESTOR

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Organization: _____

DATA CUSTODIAN

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Organization: _____

FLORIDA DEPARTMENT OF HEALTH

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Signature: _____

Printed Name: _____

Title: _____

Date: _____

Exhibit 1

Application for the Use of Data

from the

Florida Birth Defects Registry

Please email signed and completed 1) Application for the Use of Data from the Florida Birth Defects Registry (FBDR) Form and 2) Data Use Agreement Form to FBDR@flhealth.gov with a copy of permission obtained from Florida Department of Health Division of Public Health Statistics and Performance Management and the Agency for Health Care Administration.

Please complete this section with details specific to the proposed research project.

I. APPLICANT INFORMATION.

Name of Applicant: _____ Date: _____

Phone: _____ E-mail: _____

Applicant's Organization/Address: _____

Database Requested: FBDR _____ Confidential _____ Non-Confidential

Database Specification: _____ Years (1998 to most current)

_____ Statewide or _____ County(ies) of Interest (Please list)

_____

_____

_____

_____ Conditions (Please specify. See section IV)

_____

_____

_____

Provide File Format (i.e., SAS,)_____
Data transfer specification (i.e., CD, or upload via secure FTP site)_____

Title of Study: _____

Exhibit 1

Please provide written answers to the questions below in the space provided or on a separate attachment if additional space is required. (Use separate page if necessary.)

A.   Is the requested data needed for work being performed under contract to DOH? If yes, who is the DOH contract manager?

B.   Is this the first application submitted by Requestor to the FBDR in connection with this study? If not, indicate the previous application number or month and year of application.

C.   What are the organization's qualifications and experience at maintaining and using confidential data?

D.   Who in the organization or its sub-contractors will have access to FBDR data and who will be the custodian or official monitor of the data?   Provide names and job titles for all individuals who will have access to the data. (For university applicants, the data custodian must be a full-time faculty member.)

E.   What safeguards will be taken to ensure the confidentiality of the data? Describe both electronic and physical security measures.

F.   What specific data elements, records, and time periods are needed and why is each necessary for the successful completion of the project or study? (Please see list of available variables)

G.   Describe any proposed linkages to other data files including the source of these files and the linking methodology.

H.   When will the use of FBDR data be finished and how will the data be disposed of after the completion of the project?

II. PROJECT SUMMARY.
Please attach a study protocol with responses to the following:

- A statement of the problem area addressed by the study/research;
- The goals, objectives, and timetable of the study/research;
- A description of the analyses to be performed using FBDR data including specific testable hypotheses if any;
- An explanation of what work will be performed by any sub-contractors or affiliated organizations and how control of the project will be maintained;
- A listing of all sources of data; and
- A description of how and when research results will be released.

Exhibit 1

III. Data Variables.

Variable name	Type	Length	Description	Value labels
1. yearcertno	Char	15	4 digit-year and state file number	
2. bth_int	Num	3	Months between current and previous pregnancy outcome	
3. BMI*	Num	2.1	Maternal BMI	
4. bth_mo	Num	2	Infant's birth month	
5. bth_ord	Num	2	Order of birth for multiple gestations	
6. bth_yr	Num	4	Infant's birth year	
7. bw_gm	Num	6	Birth weight in grams	
8. calc_gestage	Num	2	Calculated gestational age	
9. cdob	Date	mdy10.	Infant's date of birth	
10. county	Num	3	Mother's resident county	Attachment B
11. diab_nonspecific	Num	1	Maternal diabetes	0='None'
				1='Yes'
				88='N/A'
				99='Unknown'
12. diab_Chronic	Num	1	Maternal pre-pregnancy diabetes	0='None'
				1='Yes'
				88='N/A'
				99='Unknown'
13. diab_gestational	Num	1	Maternal gestational diabetes	0='None'
				1='Yes'
				88='N/A'
				99='Unknown'
14. dlnmb	Date	mdy10.	Date last normal menses began	
15. D_age	Num	3	Age of infant at death	
16. D_agecode	Num	1	Age code of infant at death	0='years'
				2='months'
				4='days'
				5='hours'
				6='minutes'
				99='unknown'
17. Facility_level	Num	1	From AHCA level of NICU beds	Attachment C
18. factype_code	Num	2	Type of birthing facility	1='Hospital'
				2='Birth Center'
				3='Home Birth-planned or unplanned'
				4='Clinic/Dr office'
				5='Enrourte/other'
				99='Unknown'
19. fage	Num	3	Paternal age at delivery	
20. fdob	Date	mdy10.	Father's date of birth	

Exhibit 1

21. feduc	Num	2	Father's education level at delivery	1='8 grade or less'
				2='9-12 grade no diploma'
				3='High school diploma/GED'
				4='Some college no degree'
				5='Associate Degree'
				6='Bachelors Degree'
				7='Advanced degree'
				99='Unknown/Missing'
22. fethn	Num	2	Father's ethnicity	0='Non-Hispanic'
				1='Mexican'
				2='Puerto Rican'
				3='Cuban'
				4='Central/So Amer'
				5='Other Hispanic'
				6='Haitian'
				99='Unknown'
23. frace	Num	2	Father's race	1='White'
				2='Black'
				3='American Indian'
				4='Chinese'
				5='Japanese'
				6='Hawaiian'
				7='Filipino'
				8='Other Asian/Pacific Islander'
				9='Other Race'
				20='Multiple race'
				99='Unknown'
24. ga_clin	Num	3	Clinical estimate of gestation in weeks	
25. hyptn_chronic	Num	1	Maternal hypertension	0='None'
				1='Yes'
				88='N/A'
				99='Unknown'
26. hyptn_preg	Num	1	Pregnancy-related hypertension	0='None'
				1='Yes'
				88='N/A'
				99='Unknown'
27. hyptn_eclampsia	Num	1	eclampsia hypertension	0='None'

Exhibit 1

					1='Yes' 88='N/A' 99='Unknown'
28. Inf_death	num	1	Infant has linked death certificate	0='No' 1='Yes'	
29. Kotelchuck*	Num	2	Calculated Kotelchuck score		
30. lbl	Num	2	Previous number of live births living		
31. lbd	Num	2	Previous number of live births dead		
32. mage	Num	3	Maternal age at delivery		
33. married	Num	1	Mother's marital status at delivery	0='No' 1='Yes' 2='Widow' 99='Unknown'	
34. mbircountry	Char	9	Mother's country of birth	'United States' 'Puerto Rico' 'Virgin Islands' 'Guam' 'Candada' 'Cuba' 'Mexico' 'Remainder' 'Unknown'	
35. mdob	Date	mdy10.	Mother's date of birth		
36. meduc	Num	2	Mother's education level at delivery	1='8 grade or less' 2='9-12 grade no diploma' 3='High school diploma/GED' 4='Some college no degree' 5='Associate Degree' 6='Bachelor's Degree' 7='Advanced degree' 99='Unknown/Missing'	
37. methn	Num	2	Mother's ethnicity	0='Non-Hispanic' 1='Mexican' 2='Puerto Rican' 3='Cuban' 4='Central/So Amer' 5='Other Hispanic' 6='Haitian'	

Exhibit 1

					99='Unknown'
38. mode	Num	1	Method of delivery		1='Vaginal'
					2='Caesarean'
					99='Unknown'
39. mrace	Num	2	Mother's race		1='White'
					2='Black'
					3='American Indian'
					4='Chinese'
					5='Japanese'
					6='Hawaiian'
					7='Filipino'
					8='Other Asian/Pacific Islander'
					9='Other Race'
					20='Multiple race'
					99='Unknown'
40. msmoke	Num	1	Mother's smoking status		0='No'
					1='Yes'
					2=Quit during pregnancy'
					99='Unknown'
41. m_hgt*	Num	3	Maternal height in inches (births after 3/2004)		
42. othterms	Num	2	Number of other pregnancy outcomes		
43. pay *	Num	1	Delivery payment source		1='Medicaid'
					2='Private Insurance'
					3='Self-pay'
					8='Other'
					9='Unknown'
					88='Not Available'
44. plurality	Num	2	Plurality		
45. pnc_mon*#	Num	2	Month of pregnancy PNC began		
46. pnc_visits*#	Char	2	Total number of PNC visits		
47. pre_preg_wt*	Num	3	Maternal pre-pregnancy weight in lbs		
48. rgindex*	Num	2	Calculated RGindex		Attachment C
49. sex	Num	2	Infant sex		1='Male'
					2='Female'
					99='Unknown'

*   Data only available for live births after March 2004
#   Variable created by combining data fields from different birth certificate versions

IV.Birth Defect Conditions.

Numeric Variable Coded as '1' if the infant has been identified with the selected birth defect condition; otherwise the cell will be coded with 0; indicating the infant does not have the birth defect selected. The following is a list of "reportable" birth defect conditions with inclusion/exclusion criteria:

Birth Defects ‡	Varaible Name	ICD-9-CM Codes †	ICD-10-CM Codes	Comments
Central Nervous System				
Anencephalus	anencephaly	740.0 - 740.1	Q00.0 - Q00.1	
Spina Bifida without anencephalus	spinabifida	741.0, 741.9	Q05.0 - Q05.9, Q07.01,	w/o 740.0 - 740.10 or w/o Q00.0 - Q00.1
Holoprosencephaly	holoprosencephaly	742.2	Q04.2	
Encephalocele	encephalocele	742.0	Q01.0 – Q01.9	
Eye				
anophthalmia/microphthalmia	anophthalmia_microphthalmia	743.0, 743.1	Q11.0 – Q11.2	
Congenital cataract	congenital_cataract	743.30 – 743.34	Q12.0	
Aniridia	aniridia	743.45	Q13.1	
Ear				
Anotia/Microtia	anotia_microtia	744.01, 744.23	Q16.0, Q16.1, Q17.2	
Cardiovascular				
Congenital Heart Defects (CHD)	CHD	* Does not include Atrial septal defects		
Critical Congenital Heart Defects (CCHDs)-Primary	CCHD_ox	**Common_Truncus, DTGA, TOF, Pulmonary_Atresia, HLHS, TAPVR, Tricuspid_atresiastenosis		
Critical Congenital Heart Defects (CCHDs)-Expanded	CCHD_all	*** See footnote		
Common Truncus	common_truncus	745.0	Q20.0	
Transposition of the Great Arteries (TGA)	TGA	745.10, 745.12, 745.19	Q20.3, Q20.5	
Dextro-TGA	DTGA	745.10	Q20.3	
Double Outlet Right Ventricle (DORV)	DORV	745.11	Q20.1	
Tetralogy of Fallot (TOF)	TOF	745.2	Q21.3	
Common Ventricle or Single Ventricle	common_ventricle	745.3	Q20.4	
Ventricular Septal Defect (VSD)	ventricular_SD	745.4	Q21.0	probable cases included
Atrial Septal Defect (ASD)	atrial_SD	745.5	Q21.1	
Atrioventircular Septal Defect	Endocardial_cushion	745.60, 745.61, 745.69	Q21.2	
Pulmonary Valve Atresia and Stenosis		746.01, 746.02	Q22.0, Q22.1	
Pulmonary valve atresia	pulmonary_atresia	746.01	Q22.0	
Tricuspid Valve Atresia and Stenosis	tricuspid_atresiastenosis	746.1	Q22.4	
Ebstein's Anomaly	ebstein_anomaly	746.2	Q22.5	
Aortic Valve stenosis	aortic_valve	746.3	Q23.0	
Hypoplastic Left Heart Syndrome (HLHS)	HLHS	746.7	Q23.4	
Coarctation of Aorta (Hypoplasia of aortic arch)	coarc_aorta	747.10	Q25.1	
Interruption of aortic arch	interruption_arch	747.11	Q25.1, Q25.4	
Total Anomalous Pulmonary Venus Return (TAPVR)	TAPVR	747.41	Q26.2	

Exhibit 1

Birth Defects ‡	Varaible Name	ICD-9-CM Codes †	ICD-10-CM Codes	Comments
Orofacial				
Cleft palate without cleft lip	CPwoCL	749.0	Q35.0 – Q35.9	
Cleft lip with and without cleft palate	CLwoCP	749.1	Q36.0 – Q36.9,	
Cleft lip with cleft palate	CL_w_CP	749.2	Q37.0 – Q37.9	
Choanal atresia	choanal_atresia	748.0	Q30.0	
Gastrointestinal				
Esophageal atresia/ tracheoesophageal fistula	Esophageal_atresiafistula	750.3	Q39.0 – Q39.4	
Rectal and large intestinal atresia/stenosis	Rectal_intestine_atresiastenosis	751.2	Q43.1	
Biliary atresia	biliary_atresia	751.61	Q44.2 - Q44.3	
Genitourinary				
Renal agenesis/hypoplasia	renal_agenesishypoplasia	753.0	Q60.0 – Q60.6	
Bladder exstrophy	bladder_extrsophy	753.5	Q64.1	
Congenital Posterior urethral valves	urethral_valve	753.6	Q64.2	
Small intestinal atresia	small_intestine_atresia	751.1	Q41.10-41.19	
Hypospadias	Hypospadia	752.61	Q54.0 – Q54.9 (excluding Q54.4)	
Musculoskeletal				
Reduction deformity, any limb	limb_defect	755.2, 755.3, 755.4	Q71, Q72, Q73	
Cloacal extsrophy	cloacal_exstrophy	751.5	Q43.7	
Gastroschisis	gastro	756.79 or 756.73	Q79.3	756.69 only if procedure code = 54.71
Omphalocele	omphalocele	756.72	Q79.2	
Clubfoot	clubfoot	754.51, 754.70	Q66.0, Q66.89	
Diaphragmatic hernia	diaphragmatic_hernia	756.6	Q79.0 – Q79.1	
Chromosomal				
Trisomy 13	tri_13	758.1	Q91.4 – Q91.7	
Down syndrome	downs	758.0	Q90.0 – Q90.9	
Trisomy 18	tri_18	758.2	Q91.0 – Q91.3	
Deletion 22 a 11	D22q11	758.32	Q93.81	
Turner syndrome	turner	758.6	Q96.0	
Other				
Infants diagnosed with at least one selected birth	new_BD	****All birth defect categories listed		
Neonatal abstience syndrome (NAS)	NAS	779.5, 760.72		
‡ All definitions need to be considered enlight of the strengths and limiations of the FBDR				
† ICD-9 and ICD-10 codes used for categorization have undergo revision annual-codes presented reflect most recent FBDR data				
*** Includes CCHD_ox and DORV, Common Ventricle, Ebstein's anomaly, Coarctation of the Aorta, Interrupted aortic arch				

Exhibit 1

Attachment B
Vital Statistics Florida County Code Data Dictionary

11	ALACHUA		46	LEE
12	BAKER		47	LEON
13	BAY		48	LEVY
14	BRADFORD		49	LIBERTY
15	BREVARD		50	MADISON
16	BROWARD		51	MANATEE
17	CALHOUN		52	MARION
18	CHARLOTTE		53	MARTIN
19	CITRUS		23	MIAMI-DADE
20	CLAY		54	MONROE
21	COLLIER		55	NASSAU
22	COLUMBIA		56	OKALOOSA
24	DESOTO		57	OKEECHOBEE
25	DIXIE		58	ORANGE
26	DUVAL		59	OSCEOLA
27	ESCAMBIA		60	PALM BEACH
28	FLAGLER		61	PASCO
29	FRANKLIN		62	PINELLAS
30	GADSDEN		63	POLK
31	GILCHRIST		64	PUTNAM
32	GLADES		65	ST JOHNS
33	GULF		66	ST LUCIE
34	HAMILTON		67	SANTA ROSA
35	HARDEE		68	SARASOTA
36	HENDRY		69	SEMINOLE
37	HERNANDO		70	SUMTER
38	HIGHLANDS		71	SUWANNEE
39	HILLSBOROUGH		72	TAYLOR
40	HOLMES		73	UNION
41	INDIAN RIVER		74	VOLUSIA
42	JACKSON		75	WAKULLA
43	JEFFERSON		76	WALTON
44	LAFAYETTE		77	WASHINGTON
45	LAKE		99	UNKNOWN

Exhibit 1

Attachment C

Facility_Level Data Values - Based upon Florida's Agency for Health Care Administration and Florida's DOH, Children Medical Services

0=Births <25 and no Level 2 Neonatal Intensive Care Beds nor Level 3 Neonatal Intensive Care Beds

1=Births 25+ and no Level 2 Neonatal Intensive Care Beds nor Level 3 Neonatal Intensive Care Beds

2=Level 2 Neonatal Intensive Care Beds are Present

3=Level 3 Neonatal Intensive Care Beds are Present

99997= Other/Unspecified

99999 = Unknown

Rgindex Data Values

1=Intensive Care Utilization - Prenatal Care Started in 1st Trimester

2=Intensive Care Utilization - Prenatal Care Started in 2nd Trimester

3=Intensive Care Utilization - Prenatal Care Started in 3rd Trimester

4=Adequate Prenatal Care Utilization - Prenatal Care Started in 1st Trimester

5=Intermediate Prenatal Care Utilization - Prenatal Care Started in 1st Trimester

6=Intermediate Prenatal Care Utilization - Prenatal Care Started in 2nd Trimester

7=Inadequate Prenatal Care Utilization - Prenatal Care Started in 1st Trimester

8=Inadequate Prenatal Care Utilization - Prenatal Care Started in 2nd Trimester

9=Inadequate Prenatal Care Utilization - Prenatal Care Started in 3rd Trimester

10=No Prenatal Care Utilization

11=Missing Prenatal Care Criteria

88=Unable to calculate