1.	DATE ISSUED	MM/DD/YYYY	1a. SUPERSEDES AWARD NOTICE dated				
	01/14/2019		except that any additions or restrictions previously imposed remain in effect unless specifically rescinded				
2.	CFDA No.						
	93.073 - BIRTH E	DEFECTS AND DE	VELOPMENT	TAL DISABILI			
3.	ASSISTANCE TY	YPE Coope	rative Agree	ement			
4.	GRANT NO.	5 NU50DD004938	-04-00	5. TYPE OF AWA	RD		
	Formerly			Other			
4a	. FAIN NU50DD	004938		5a. ACTION TYPE	Non-Competing Continuation		
6.	PROJECT PERIO	OD MM/DD/	YYYY		MM/DD/YYYY		
	From	02/01/20	116	Through	01/31/2020		
7.	BUDGET PERIO	D MM/DD	/YYYY		MM/DD/YYYY		
	From	02/04/20	110	Through	01/31/2020		

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

CDC Office of Financial Resources

1600 Clifton Road Atlanta, GA 30329

NOTICE OF AWARD

AUTHORIZATION (Legislation/Regulations) 42 USC 241 31 USC 6305 42 CFR 52

8. TITLE OF PROJECT (OR PROGRAM)

Kentucky Population-Based Surveillance of Birth Defects and Data Utilization for Public Health Action

9a. GRANTEE NAME AND ADDRESS		9b. GRANT	EE PROJECT DIRECTOR				
Health & Family Services, Kentucky Cabinet for	Monica Clouse						
Alternate Name: Kentucky Cabinet for Health & Family Services	275 E I	Main St					
275 E Main St # 5wa		Matern	al and Child Health				
Kentucky Cabinet for Health and Family Services		Frankfo	ort, KY 40621-0001				
Frankfort, KY 40601-2321		502/564/4830 x 4394					
10a. GRANTEE AUTHORIZING OFFICIAL		10b. FEDER	AL PROJECT OFFICER				
Ms. Martie Kupchinsky		William	Paradies				
275 E Main St		Center	s for Disease Control and Prevention	1			
Frankfort, KY 40601-2321		CCHP/	NCBDDD/DBDDD/BDB				
Phone: 5025643756x3768		Atlanta	, GA 30333				
		Phone:	404-498-3919				
	ALL AMOUNTS ARE S	HOWN IN U	SD				
11. APPROVED BUDGET (Excludes Direct Assistance)		12. AWARD	COMPUTATION				
I Financial Assistance from the Federal Awarding Agency Only		a. Amount	of Federal Financial Assistance (from	n item 11 ^m)	210,000.00		
II Total project costs including grant funds and all other financial pa	articipation	b. Less Unobligated Balance From Prior Budget Periods 0.00					
a. Salaries and Wages	62,428.00	c. Less Cumulative Prior Award(s) This Budget Period					
	67.116.00	d. AMOUNT OF FINANCIAL ASSISTANCE THIS ACTION 210,00					
b. Fringe Benefits	67,116.00	13. Total Federal Funds Awarded to Date for Project Period 840,000.0					
c. Total Personnel Costs	129,544.00	14. RECOMMENDED FUTURE SUPPORT					
d. Equipment	0.00	(Subject to the availability of funds and satisfactory progress of the project):					
e. Supplies	0.00	YEAR	TOTAL DIRECT COSTS	YEAR	TOTAL DIRECT COSTS		
f. Travel	4,510.00	a. 5		d. 8			
i. Ilavei		b. 6		e. 9			
g. Construction	0.00	C. 7		f. 10			
h. Other	10,896.00	15. PROGRAM ALTERNATIVE	INCOME SHALL BE USED IN ACCORD WITH S:	ONE OF THE FOLLOWING	G		
i. Contractual	43,200.00	b. ADDITIONAL COSTS c. MATCHING					
j. TOTAL DIRECT COSTS	188,150.00						
k. INDIRECT COSTS	21,850.00		D IS BASED ON AN APPLICATION SUBMITT	ED TO, AND AS APPROVE	I ED BY, THE FEDERAL AWARDING AGENCY		
			TITLED PROJECT AND IS SUBJECT TO THE T	TERMS AND CONDITIONS	INCORPORATED EITHER DIRECTLY		
I. TOTAL APPROVED BUDGET	210.000.00	a.	The grant program legislation				
	,	b. c.	The grant program regulations. This award notice including terms and condition	ns, if any, noted below under	r REMARKS.		
m. Federal Share 210,000.00			d. Federal administrative requirements, cost principles and audit requirements applicable to this grant. In the event there are conflicting or otherwise inconsistent policies applicable to the grant, the above order of precedence shall served the great terms and enditions in contrasted the depth with a greaten when funded are drawn or attention.				
n. Non-Federal Share 0.00							
REMARKS (Other Terms and Conditions Attached -	Yes	No)					

GRANTS MANAGEMENT OFFICIAL:

Pamela Render, Grants Management Officer

2920 Brandywine Road Mailstop E09 Atlanta, GA 30341 Phone: 770-488-2712

17. OBJ C	CLASS 41.51	18a. VENDOR CODE	1610	600439B5	18b. E	IN	610600439	19. DUI	IS 927049767	2	0. CONG. DIST. 06
	FY-ACCOUNT NO.	DOCUMENT NO.		CFDA			ADMINISTRATIVE CODE	АМТ	ACTION FIN ASST		APPROPRIATION
21. a.	9-9211897	b. 16DD004938		c. 93.07	'3	d.	DD	e.	\$10,000.00	f.	75-19-0958
22. a.	9-9390BW2	b. 16DD004938		c. 93.07	'3	d.	DD	e.	\$10,000.00	f.	75-19-0958
23. a.	9-939ZRAM	b. 16DD004938		c. 93.07	'3	d.	DD	e.	\$190,000.00	f.	75-19-0958

NOTICE OF AWARD (Continuation Sheet)

PAGE 2 of 3		DATE ISSUED 01/14/2019
GRANT NO.	5 NU	50DD004938-04-00

Direct Assistance

BUDGET CATEGORIES	PREVIOUS AMOUNT (A)	AMOUNT THIS ACTION (B)	TOTAL (A + B)
Personnel	\$0.00	\$0.00	\$0.00
Fringe Benefits	\$0.00	\$0.00	\$0.00
Travel	\$0.00	\$0.00	\$0.00
Equipment	\$0.00	\$0.00	\$0.00
Supplies	\$0.00	\$0.00	\$0.00
Contractual	\$0.00	\$0.00	\$0.00
Construction	\$0.00	\$0.00	\$0.00
Other	\$0.00	\$0.00	\$0.00
Total	\$0.00	\$0.00	\$0.00

NOTICE OF AWARD (Continuation Sheet)

PAGE 3 of 3		DATE ISSUED 01/14/2019	
GRANT NO. 5 NU		50DD004938-04-00	

Federal Financial Report Cycle							
Reporting Period Start Date	Reporting Period End Date	Reporting Type	Reporting Period Due Date				
02/01/2016	01/31/2017	Annual	05/01/2017				
02/01/2017	01/31/2018	Annual	05/01/2018				
02/01/2018	01/31/2019	Annual	05/01/2019				
02/01/2019	01/31/2020	Annual	04/30/2020				

AWARD ATTACHMENTS

Kentucky Cabinet for Health & Family Services

5 NU50DD004938-04-00

- 1. Terms and Conditions
- 2. Technical Review

AWARD INFORMATION

Incorporation: In addition to the federal laws, regulations, policies, and CDC General Terms and Conditions for Non-research awards at

https://www.cdc.gov/grants/federalregulationspolicies/index.html, the Centers for Disease Control and Prevention (CDC) hereby incorporates Notice of Funding Opportunity (NOFO) number DD16-1601, entitled Population-Based Surveillance of Birth Defects and Data Utilization for Public Health Action, and application dated October 09, 2018, as may be amended, which are hereby made a part of this Non-Research award hereinafter referred to as the Notice of Award (NoA).

Approved Funding: Funding in the amount of \$210,000 is approved for the Year 04 budget period, which is February 1, 2019 through January 31, 2020. All future year funding will be based on satisfactory programmatic progress and the availability of funds.

The federal award amount is subject to adjustment based on total allowable costs incurred and/or the value of any third party in-kind contribution when applicable

Note: Refer to the Payment Information section for draw down and Payment Management System (PMS) subaccount information.

Financial Assistance Mechanism: Cooperative Agreement

Substantial Involvement by CDC: This is a cooperative agreement and CDC will have substantial programmatic involvement after the award is made. Substantial involvement is in addition to all post-award monitoring, technical assistance, and performance reviews undertaken in the normal course of stewardship of federal funds.

CDC program staff will assist, coordinate, or participate in carrying out effort under the award, and recipients agree to the responsibilities therein, as detailed in the NOFO.

- Work with CDC and other awardees to share strategies and lessons learned to improve data quality, electronic health record collection and transmission, birth defects surveillance and data standardization projects, data utilization, and other project activities.
- Participate on all cooperative agreement calls and meetings as identified by CDC program. Programs are encouraged to participate in the National Birth Defects Prevention Network (NBDPN) activities.
- Collaborate with CDC on strategies to accomplish birth defects-related performance measures.

Technical Review Statement Response Requirement: The review comments on the strengths and weaknesses of the proposal are provided as part of this award. A response to the weaknesses in these statements must be submitted to and approved, in writing, by the Grants Management Specialist/Grants Management Officer (GMS/GMO) noted in the Staff Contacts section of this NoA, no later than 30 days from the budget period start date. Failure to submit the required information by the due date, March 1, 2019, will cause delay in programmatic progress and will adversely affect the future funding of this project.

FUNDING RESTRICTIONS AND LIMITATIONS

Funding Opportunity Announcement (FOA) Restrictions:

- Awardees may not use funds for research.
- Awardees may not use funds for clinical care.
- Awardees may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, awardees may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
 Reimbursement of pre-award costs is not allowed.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
 - See http:// www.cdc.gov /grants /additional requirements /index.htm l#ar12 for detailed guidance on this prohibition and http://www. cdc.gov/ grants /documents/Anti- Lobbying _Restrictions_ for CDC _Grantees_July _2012.pdf
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

Indirect Costs:

Indirect costs are approved based on the recipient's approved Cost Allocation Plan dated June 7, 2018.

REPORTING REQUIREMENTS

Performance Progress and Monitoring: Performance information collection initiated under this grant/cooperative agreement has been approved by the Office of Management and Budget under OMB Number 0920-1132, "Performance Progress and Monitoring Report", (or Expiration Date 8/31/2019. The components of the PPMR are available for download at: https://www.cdc.gov/grants/alreadyhavegrant/Reporting.html.

Required Disclosures for Federal Awardee Performance and Integrity Information System (FAPIIS): Consistent with 45 CFR 75.113, applicants and recipients must disclose in a timely manner, in writing to the CDC, with a copy to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Subrecipients must disclose, in a timely manner in writing to the prime recipient (pass through entity) and the HHS OIG, all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. Disclosures must be sent in writing to the CDC and to the HHS OIG at the following addresses:

CDC, Office of Grants Services Keisha Thompson, Grants Management Specialist Centers for Disease Control **Chronic Disease and Birth Defects Services Branch** 2960 Brandywine Road Atlanta, Georgia 30341

Email: dwt6@cdc.gov (Include "Mandatory Grant Disclosures" in subject line)

AND

U.S. Department of Health and Human Services
Office of the Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201

Fax: (202)-205-0604 (Include "Mandatory Grant Disclosures" in subject line) or

Email: MandatoryGranteeDisclosures@oig.hhs.gov

Recipients must include this mandatory disclosure requirement in all subawards and contracts under this award.

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371. Remedies for noncompliance, including suspension or debarment (See 2 CFR parts 180 and 376, and 31 U.S.C. 3321).

CDC is required to report any termination of a federal award prior to the end of the period of performance due to material failure to comply with the terms and conditions of this award in the OMB-designated integrity and performance system accessible through SAM (currently FAPIIS). (45 CFR 75.372(b)) CDC must also notify the recipient if the federal award is terminated for failure to comply with the federal statutes, regulations, or terms and conditions of the federal award. (45 CFR 75.373(b))

PAYMENT INFORMATION

The HHS Office of the Inspector General (OIG) maintains a toll-free number (1-800-HHS-TIPS [1-800-447-8477]) for receiving information concerning fraud, waste, or abuse under grants and cooperative agreements. Information also may be submitted by e-mail to hhstips@oig.hhs.gov or by mail to Office of the Inspector General, Department of Health and Human Services, Attn: HOTLINE, 330 Independence Ave., SW, Washington DC 20201. Such reports are treated as sensitive material and submitters may decline to give their names if they choose to remain anonymous.

Payment Management System Subaccount: Funds awarded in support of approved activities have been obligated in a newly established subaccount in the PMS, herein identified as the "P Account". Funds must be used in support of approved activities in the NOFO and the approved application. All award funds must be tracked and reported separately.

The grant document number identified on the bottom of Page 1 of the Notice of Award must be known in order to draw down funds.

PROGRAM OR FUNDING SPECIFIC CLOSEOUT REQUIREMENTS

The final programmatic report format required is the following.

Final Performance Progress and Monitoring Report (PPMR): This report should include the information specified in the NOFO and is submitted 90 days following the end of the period of performance via www.grantsolutions.gov. At a minimum, the report will include the following:

- Statement of progress made toward the achievement of originally stated aims.
- Description of results (positive or negative) considered significant.
- List of publications resulting from the project, with plans, if any, for further publication.

Additional guidance may be provided by the GMS and found at: https://www.cdc.gov/grants/alreadyhavegrant/Reporting.html

CDC Staff Contacts

Grants Management Specialist: The GMS is the federal staff member responsible for the day-to-day management of grants and cooperative agreements. The GMS is the primary contact of recipients for business and administrative matters pertinent to grant awards.

GMS Contact:

Keisha Thompson, Grants Management Specialist Center for Disease Control and Prevention (CDC) Office of Grants Services (OGS) 2960 Brandywine Road MS.E-01 Atlanta, GA 30341

Telephone: 770-488-2681 Email: dwt6@cdc.gov

Program/Project Officer: The PO is the federal official responsible for monitoring the programmatic, scientific, and/or technical aspects of grants and cooperative agreements, as well as contributing to the effort of the award under cooperative agreements.

Programmatic Contact:

William Paradies, Project Officer
Centers for Disease Control and Prevention
National Center on Birth Defects and Developmental Disabilities
4770 Buford Hwy, MS E-86
Atlanta, GA 30341-3717
Telephone: 404-498-3919

Telephone: 404-498-3919 Email: wep2@cdc.gov

Grants Management Officer: The GMO is the federal official responsible for the business and other non-programmatic aspects of grant awards. The GMO is the only official authorized to obligate federal funds and is responsible for signing the NoA, including revisions to the NoA that change the terms and conditions. The GMO serves as the counterpart to the business officer of the recipient organization.

GMO Contact:

Pamela Render, Grants Management Officer

Centers for Disease Control and Prevention Office of Grants Services 2960 Brandywine Road Atlanta, Georgia 30341 Telephone: 770-488-2712 Email: PRender@cdc.gov

Technical Reviewer Evaluation Report FOA #CDC-RFA-DD16-1601: Population-Based Surveillance of Birth Defects and Data Utilization for Public Health Action

Year 4: Annual Performance Report / Non-Competing Continuation 2/1/2019 – 1/31/2020 Cooperative Agreement Number: U50 DD004938

Applicant: Kentucky Cabinet for Health & Family Services

Principal Investigator: Monica Clouse, MPH

Address: 275 E Main St

HS-2WA

Frankfort, KY 40601-2321

Phone: 502-564-4830 x4394 Email address: monica.clouse@ky.gov

Year 4 Year 4

Requested Recommended

 New Funds:
 \$210,000
 \$210,000

 Year 3 Est. Unobligated:
 \$\frac{0}{2}\$
 \$\frac{5}{2}\$

 Total Budget:
 \$210,000
 \$210,000

CDC Technical Reviewer: Kathryn Arnold / Leslie O'Leary Date: December 3, 2018

Brief overview/summary of proposed continuation year activities

1. Comments on current year performance/progress in meeting the purpose and goals of the recipient:

- The recipient continues to enhance its population-based birth defects surveillance by improving data quality, timeliness, and utilization for public health action. The recipient uses the surveillance data to 1) build recipient capacity by disseminating information to partners, 2) increase referral to services for affected individuals, 3) enhance surveillance of newborn screening of critical congenital heart defects (CCHDs), and develop data-driven prevention strategies for at-risk populations.
- The Principal Investigator (PI) has established due dates for data submission from their 10 data sources and sends reminders to data sources if needed. Thus far in 2018, the PI has not had to send reminders to any of the 10 data sources that provide data to the Kentucky Birth Surveillance Registry (KBSR), which is an improvement compared to 2017 when the PI had to contact one the of the data sources.
- In April 2018, the recipient implemented quality check reports for stillbirth and live birth certificate data to ensure birth defects are coded correctly and populates the "All Defect" screen in KBSR.
- Since data from the cytogenetics lab are still received as hard copy, the recipient implemented a data entry protocol which improved timeliness.

- In February 2018, the epidemiologist working on the KBSR moved to another Maternal and Child Health (MCH) program. The PI, who is trained as an epidemiologist, will serve in this capacity for the remainder of the cooperative agreement.
- The NBDPN Data Sources Descriptive Assessment Tool was used to improve the completeness of data received from two of the recipient's data sources (i.e., two university genetics clinics) and the recipient plans to develop individualized quality improvement plans for the remaining eight data sources by January 31, 2019.
- The timeliness of case ascertainment continues to improve. In 2016, the average age of cases reported to KBSR was 164 days. In 2017, the average age was 144 days. In 2018, the average age to date is 125 days.
- To improve case completeness KBSR stopped abstracting cases with substance exposure and no birth defects. This change will reduce the number of eligible cases and allow the abstractors to focus on conditions recommended by NBDPN, thus improving the recipient's case completeness.
- Since the PI is the only KBSR employee at this time, the recipient plans to train MCH nurses to abstract cases. The PI and a senior nurse abstractor will conduct quality checks on 10% of the abstracted cases to ensure accuracy and consistency across abstractors. In addition, quality checks will be done on 5% of cases that were abstracted at a medical facility (i.e., five birthing hospitals).
- KBSR continues to engage with many partners including, but not limited to, the Office for Children with Special Health Care Needs (OCSHCN), Environmental Public Health Tracking Network (EPHTN), Kentucky Folic Acid and Perinatal Partnership (KFAP) and the Division of Women's Health.
- KBSR, in collaboration with the Division of Women's Health, plans to launch a birth defects prevention awareness campaign.
- KBSR developed a video of a Kentucky family raising a child with spina bifida. The video was posted to the Cabinet's Facebook page and YouTube on March 3, 2018 for World Birth Defects Day.
- KBSR developed a report of cases (n=139) for referral to First Steps. Although all cases met the recipient goal of referral within 15 days, the days to case creation increased from 2.9 days in 2016 to 7.9 days due to staff turnover and implementation of the new report, which now includes diagnostic information from all data sources.
- KBSR abstracted 92% of cases with a targeted primary or secondary cardiovascular anomaly for the time period (2013-2017), which exceeded their abstraction target of 90%.

2. Comments on new budget year objectives as to being realistic, specific and measurable.

- Although a few of the activities for Year 4 have changed (i.e., three deleted and two added, page 48 of 175), the overall objectives have remained the same and are realistic, specific, and measurable.
- 3. Identify and discuss any proposed changes in long-term objectives, methods of operation, and need for financial support, and the likelihood that such modifications will lead to achievement of project objectives.
 - No major changes in the long-term objectives were proposed. The recipient will continue

to improve its surveillance, capacity development, and data utilization activities.

- 4. Human Subject Issues: Does the project adequately address the Human Subject requirements of Title 45 CFR 46 for the protection of human subjects? Specifically, comment on pending or now approved Human Subject Assurances and cite documentation of all IRB actions.
 - Since the cooperative agreement pertains to birth defects surveillance activities, IRB approval is not necessary.

5. Comment on the continuation year budget request: Discuss whether the budget is reasonable, clearly justified, and consistent with the intended use of funds.

- The Year 4 budget is reasonable, clearly justified, and consistent with the intended use of funds. For Year 4 budget period, we recommend a total of \$210,000 comprised of FY 2019 new funds
- In-Kind Support: The recipient identified in-kind support from collaborating partners, but did not quantify the amount. By obtaining other sources of funding, it is encouraging that the recipient demonstrates their commitment to the goals and objectives of the FOA.
- We verified the arithmetic accuracy, allowability, and reasonableness of the budget justification.

6. Summary of Strengths:

- The recipient continues to monitor the timeliness, accuracy, and quality of the surveillance data. Specific examples of the recipient's monitoring includes established due dates for data submission by the data sources, and quality check reports to ensure birth defects are coded correctly.
- The recipient continues to successfully improve the timeliness of case ascertainment, most likely the result of automatic upload of data to KBSR's database.
- The percent of remote abstractions, either using hospital-based systems, KHIE, or direct transmission of records, increased from 54% in 2015 to 78% in 2018. In addition, the recipient plans to work with an additional six hospitals to obtain KHIE access.
- KBSR data were used in a research project at the University of Kentucky. Results from the project were presented as a poster at the 2018 NBDPN Annual Meeting. The data were also used for a student's dissertation and more recently, a researcher from the University of Louisville requested KBSR data for a grant proposal on maternal proximity to fly coal ash and adverse birth outcomes.
- KBSR data were used to identify service gaps for children with special healthcare needs and presented to OCSHCN.
- KBSR continues to work closely with First Steps. In 2018, KBSR referred 139 cases to First Steps. Although the average time to referral increased from 2.9 days in 2016 to 7.9 days in 2018, the recipient goal of referral within 15 days was met.

7. Summary of Weaknesses and Concerns:

- In February 2018, the epidemiologist moved to another MCH program. In addition, the nurse abstractor/referral coordinator position is vacant. Although the recipient plans to fill the nurse abstractor/referral coordinator position, it is unclear how the recipient will accomplish the Year 4 activities given the PI appears to be the only person currently working on the project.
- The number of cases abstracted through KHIE will be reduced because the KHIE is beginning to transition to a new vendor and will be unavailable from September 2018 to January 2019. It is unclear how the recipient will "catch-up" on abstractions.
- Among cases referred to First Steps, the number that "moved out of state" (Table 2, page 48 of 175) increased from 0.6 % in 2016 to 19.4 % in 2018, which is a substantial increase. Does KBSR know why there has been such an increase in the number of cases that moved out of state?
- Some of Year 3 activities had to be delayed or postponed due to vacant positions (i.e., referral coordinator/abstractors).

8. Recommendations:

- The recipient should inform CDC when the nurse abstractor/referral coordinator position is filled and provide CDC with a plan that outlines how the activities of the cooperative agreement will be accomplished by January 31, 2020.
- Since the KHIE will be down from September 2018 January 2019, reducing the number of case abstractions that will occur during this time, the recipient is encouraged to develop and implement a plan for "catching-up" on case abstractions once the KHIE is available.
- The recipient is encouraged to develop alternate strategies to reduce the number of cases in First Steps' "Unable to Contact" category.