Title: Parental exposure to ionizing radiation and birth defects
Award number: 1R03OH10315
Principal Investigator: Dorothy Kim Waller, PhD
Co-Investigator: Charles Beasley, PhD
Affiliation: School of Public Health, UT Health, Houston
State: Texas
e-mail address: kim.waller@uth.tmc.edu
Telephone: 713-500-9155
Physical Address: Dr. Kim Waller, 1200 Pressler Avenue, Suite E643, Houston, Texas, 77030.
Start and End Dates: September 1st, 2012 – August 31st 2014.
Date of Report: November 18th 2014

Abstract

Methods - We studied 38,009 mothers who participated in the National Birth Defects Prevention Study (NBDPS) between 1997 and 2009. Mothers with potential exposure to ionizing radiation from occupational sources or from diagnostic x-rays or CT scans focused on the urinary tract, pelvis, spine to total body during pregnancy were identified based on maternal interviews that described occupations, workplaces, job activities and diagnostic tests.

Occupational Exposures - There was no association between mothers who had potential exposure to ionizing radiation from occupational sources and 39 categories of NBDPS birth defects in aggregate (AOR= 0.88; 95% CI= 0.74 - 1.05). Mothers with this type of exposure did have a significantly increased risk for 4 of 39 categories of birth defects and a significantly protected risk for 1 of 39 categories of birth defects.

These results should be interpreted cautiously because our measurement of exposure is qualitative. Also, some of these associations may be due to occupational exposures that are correlated with ionizing radiation and some may be due to chance.

Overall, these findings suggest that women who are occupationally exposed to ionizing radiation during pregnancy have the same frequency of infants with structural birth defects (in aggregate) as unexposed women. It appears that most exposures to occupational sources of ionizing radiation are low and that the majority of pregnant women who work with ionizing radiation are not at increased risk of structural birth defects due to this exposure.

Exposure to Radiologic Exams – Mothers exposed to radiologic exams that delivered ionizing radiation to the urinary tract, lower back, abdomen, pelvis or total body during the first trimester of pregnancy had no increase in all NBDPS birth defects in aggregate (OR= 1.0; 95% CI= 0.6 – 1.6). They did have a significantly increased risk for 2 of 22 categories of structural birth defects. These results should be interpreted cautiously because multiple statistical tests were conducted and exposure to radiographic exams was based on maternal report, requiring mothers to distinguish between ultrasound, ionizing radiation and magnetic resonance imaging. The categories of birth defects that were associated with this exposure did not correspond to those that were associated with occupational exposures to radiation.

Overall, 0.9 % of mothers reported exposure to a radiographic exam that met the study criteria. The levels of pelvic radiation that occur due radiographic exams are generally much higher than the level of ionizing radiation that mothers are exposed to in their occupations. Although, our findings may be explained by chance, the finding that almost 1.0% of pregnant

women have this type of radiographic exposure suggests that a larger study of these exposures would be useful and would hopefully provide greater certainty regarding the safety of radiographic diagnostic exams during early pregnancy.

Final Progress Report – Section 1

Significant Findings

Frequency of exposures - Overall, 2.5% of case mothers and 2.7% of control mothers were in occupations with suspected exposure to ionizing radiation. Among these exposed mothers, over 85% were health care workers. Also, 0.9 % of case mothers and 0.8 % of control mothers were exposed to ionizing radiation during the first trimester of their pregnancy from diagnostic tests that were focused on the urinary tract, pelvis, lower back or total body.

Risk of birth defects among mothers whose work during the periconceptional period involved potential for exposure to ionizing radiation (specific aim 3) - These mothers had no increase in the risk of all study birth defects, when they were analyzed as an aggregate (group). After adjusting for potential confounding factors, they did have a significantly elevated increase in the risk of 4 of 39 specific birth defects (isolated hydrocephaly (10 exposed mothers out of 251 cases), isolated anotia/microtia (10 exposed mothers out of 299 cases), isolated colonic atresia (4 exposed mothers out of 21 cases), and isolated omphalocele (9 exposed mothers out of 253 cases). For comparison there were 183 exposed mothers out of 6,304 control mothers. Given that we assessed 39 different birth defects, by chance alone we expected to see a significantly elevated increase in the risk of approximately one birth defect.

We also assessed the aggregate risk of all NBDPS birth defects stratified by the following 8 sources of occupational exposure to ionizing radiation: fluoroscopy, nuclear medicine, CT scan, planar x-rays (including portable), dental x-rays, animal x-rays, working with ionizing radiation in a research institute and flight crew. Among these 8 categories, we only observed an increased risk of all birth defects in aggregate among the mothers who worked with fluoroscopy. They had a twofold increase in risk that was not statistically significant. Out of 17,317 cases in this analysis, 37 mothers worked with fluoroscopy compared with 7 mothers working with fluoroscopy out 6,304 controls.

Although, based on small numbers and therefore imprecise, our findings of a non-significant association between occupations that work with fluoroscopy and a twofold increase in birth defects (in aggregate) may merit some attention as fluoroscopy is known to deliver particularly high levels of radiation to patients and health care workers.

Our results for this study may be explained by chance, by other occupational exposures that occur among health care workers, by bias due to increased utilization of prenatal diagnosis among health care workers and for some or all of the four birth defects identified, these associations may represent effects of exposure to ionizing radiation.

Risk of birth defects among mothers who reported exposures to ionizing radiation during the <u>first trimester</u> from diagnostic x-rays or CT scans focused on the urinary tract, pelvis, lower back or total body (specific aim 1) - These mothers had no increase in the risk of all study birth defects, when they were analyzed as an aggregate (group). After adjusting for potentially confounding factors, they did have a significantly elevated increase in the risk of 2 of

22 specific birth defects (isolated dandy walker malformation (2 exposed mothers out of 67 cases) and isolated d-transposition of the great arteries (5 exposed mothers out of 486 cases). In comparison, 24 of 7668 control mothers had one of these exposures. These results may be explained by chance or by confounding from the illness or accident for which the diagnostic tests was ordered. Alternatively, one or both of these associations may represent effects of exposure to ionizing radiation.

Risk of birth defects among mothers who reported exposures to ionizing radiation during the three months prior to conception from diagnostic x-rays or CT scans focused on the urinary tract, pelvis, lower back or total body (specific aim 1) - After adjusting for potentially confounding factors, we observed no elevated increase in the risk of any of the 22 birth defects that we assessed.

Consistency of the categories of birth defects associated with maternal exposure to ionizing radiation – There was no overlap in the categories of birth defects associated with maternal exposure to ionizing radiation from occupational sources and exposures from x-rays and CT scans. There was also no overlap with categories of birth defects associated with maternal exposure to ionizing radiation in our study and previous studies. This is consistent with what would be expected if some or all of the significant associations that we observed in the two studies above are due to chance or bias.

Translation of Findings -Overall, we did not find any clear increase in risk of birth defects among mothers who were occupationally exposure to ionizing radiation and therefore we are not recommending any actions to protect workers. Although, based on small numbers and therefore imprecise, our findings of a non-significant association between occupations that work with fluoroscopy and a twofold increase in birth defects (in aggregate) may merit some attention. The fact that fluoroscopy is known to deliver particularly high levels of radiation to patients and health care workers, suggests that an association between fluoroscopy and birth defects might be plausible. However, workers who are exposed to fluoroscopy are usually also exposed to anesthetic gases and high levels of stress.

Outcomes / Impact - Question: How did this study lead to improvements in occupational safety and health ? Answer: We did not find any clear evidence of increased risk of birth defects due to occupational exposures to ionizing radiation. Thus, we are not proposing any recommendations for improvement in occupational safety and health. Question: How can findings of this study guide future investigations and research? Answer: We suggest that future investigations be focused on workers with the greatest potential for high exposures to ionizing radiation, including those who work near fluoroscopy (including speech pathologists), those who are members of flight crews and industrial radiographers.

Final Progress Report – Section 2

Scientific Report for Specific Aim 3

Specific Aim: To assess the association between maternal exposure to occupational sources of ionizing radiation during the periconceptional period and 39 categories of birth defects using a large population-based study of birth defects.

Background: Ionizing radiation (IR) is known to be carcinogenic and mutagenic, but relatively little is known about the association between maternal occupational exposure to IR and birth defects. Existing studies of maternal occupational exposure to IR and birth defects are generally limited to one occupation, and include very small numbers of birth defects resulting in low statistical power. To date, there are two population-based studies of occupational exposure to IR and all birth defects. A cohort study conducted in Germany, included 3,816 pregnant women who were defined as exposed to IR because they wore dosimeters. They reported a small increase in birth defects in aggregate among exposed mothers. However, their results were imprecise with only 4 cases of birth defects among exposed mothers. The other study is the Baltimore-Washington Infant Study which assessed the association between maternal occupational exposure to IR and congenital cardiac defects including 4,390 congenital cardiac defects and 3,572 controls. As this was a case control study it was substantially more precise. They assessed exposure by maternal recall of occupation and work activities and they reported an association between maternal exposure to occupational sources of ionizing radiation and one type of cardiac defect.

Methods: We studied 38,009 mothers who participated in the National Birth Defects Prevention Study and delivered between 1997 and 2009. We assessed odds ratios [ORs] for the association between maternal occupations with potential exposure to IR and 39 birth defects. Mothers text responses to questions about her occupation and work activities were scanned for the presence of over 100 character strings such as "radio" that suggested they may have worked in an occupation with a high potential for exposure. Responses from mothers that were positive on this scan were then read by three of the investigators to identify those mothers who had an occupation with potential for exposure to ionizing radiation. Two investigators also read responses from a random sample of 1,000 unexposed mothers to ensure than mothers whose responses suggested they were exposed were not being overlooked by the computer scan.
Results: We observed significant ORs for isolated hydrocephaly (AOR = 2.1; 95% CI = 1.1 - 4.2), isolated anotia/microtia (AOR= 2.0; 95% CI= 1.0 - 4.0), isolated colonic atresia (COR = 7.5; 95% CI= 2.5 - 22.3), isolated omphalocele (AOR= 2.3; 95% CI= 1.1 - 4.6) and isolated anencephaly (COR=0.23; 95% CI =0.06 – 0.94). We also observed an elevated OR for the association between mothers with occupational exposure to fluoroscopy and birth defects in aggregate (AOR= 2.0; 95% CI= 0.9 - 4.6) that was not statistically significant.

Conclusion: We observed that maternal occupations with potential exposure to IR were associated with a significantly increased risk for 4 of 39 birth defects and a significantly protected risk for 1 of 39 birth defects. These results should be interpreted cautiously because our measurement of exposure is qualitative, some of these associations may be due to

occupational exposures that are correlated with IR and may be due to chance. However, these findings serve as the first evaluation of these relationships in a large study and may be useful for generating hypotheses for future studies.

Scientific Report for Specific Aim 1

Specific Aim: To assess the association between maternal exposure to radiologic exams during the periconceptional period and 22 categories of birth defects using a large population-based study of birth defects.

Background: This is the first large epidemiologic study of maternal exposures to radiographic exams during the periconceptional period and birth defects. Although, physicians attempt to avoid using radiographic exams on pregnant women, the level of exposures that women receive from them are generally thought to be below the threshold that causes birth defects.

Methods: We studied 27,809 case mothers and 10,200 control mothers who participated in the National Birth Defects Prevention Study and delivered between 1997 and 2009. Maternal exposure to radiologic exams that delivered ionizing radiation to the urinary tract, lumbar spine, abdomen, pelvis or total body were identified based on the mother's report of type of radiologic exams, organ or body part scanned and the month during which the exam occurred.

Results: Overall, 0.9 % of mothers reported exposure to a radiographic exam during the periconceptional period that met the study criteria. We calculated odds ratios separately for exposures occurring during the 3 months before conception and during the first trimester. Assessing confounding for 13 co-variates, we observed significant associations between maternal exposure during the first trimester and isolated dandy walker malformation (odds ratio [OR] =7.73; 95% confidence interval [CI] = 1.81- 33.0) and isolated d-transposition of the great arteries (OR= 3.8; 95% CI= 1.4 – 10.3). We observed no association between maternal exposures during the 3 months before conception and any of the 22 birth defects.

Conclusion: Maternal exposure to radiologic exams that delivered IR to the urinary tract, lumbar spine, abdomen or pelvis was associated with an increased risk for 2 of 22 birth defects. These results should be interpreted cautiously because multiple statistical tests were conducted and measurements of exposure were based on maternal report. However, our results may be useful for generating hypotheses for future studies.

Scientific Report for Specific Aim 2

Specific Aim -To assess the association between paternal exposure to occupational sources of ionizing radiation during the periconceptional period and 39 categories of birth defects using a large population-based study of birth defects.

This aim was not completed – We found that the data for paternal occupational exposures was poor. Only half of mothers are married and many do not report any information on the infants father. When the information was present it was based on the mother's knowledge of the fathers occupation and was therefore much less detailed than the

information on mothers exposure. It is possible that paternal exposure to radiation immediately before conception might result in birth defects with clear genetic causes. Unfortunately, these types of birth defects are excluded from the National Birth Defects Prevention Study. Given the type of birth defects included in this study, it is less likely that we would observe an association between paternal exposures to ionizing radiation and birth defects.

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
	Female	Male	Female	Male	
American Indian/ Alaska Native					0
Asian	1900				0
Native Hawaiian or Other Pacific Islander					0
Black or African American	4561				0
White	23185		8362		0
More Than One Race					0
Total	**29646**	**0**	**8362**	**0**	**38008**

This is a study of pregnant women and their infants. The table was filled out for the women in the study. Each woman also has an infant. Infants are approximately 50% male and 50% female and of the same race/ethnicity as their mother.

Publications

1. Lim H, Agopian AJ, Whitehead LW, Beasley CW, Langlois PH, Emery RJ, Waller DK and the National Birth Defects Prevention Study (2014). Maternal occupational exposure to ionizing radiation and major structural birth defects. (In Press for Birth Defects Research Part A)
2. Lim H, Beasley CW, Whitehead LW, Emery RJ, Agopian AJ, Langlois PH, Waller DK and the National Birth Defects Prevention Study (2014). Maternal exposure to radiographic exams and major structural birth defects. (Under Review)

Inclusion of Children – Yes. The study subjects are mothers who recently delivered infants and their infants.

Materials Available for Other Investigators – None.

End of Report

18-Nov-14

MEMORANDUM

TO: Waller,Kim

FROM: Dee Wise
Post-Award Finance Team

Attached is a copy of the Report of Expenditures for your grant which is submitted to the granting agency ninety days from the end of the budget period. Please take the time to review this report against the records that you maintain. If any discrepancies exist, please contact the Post-Award Finance Team immediately; otherwise, please sign the space provided indicating your agreement with this report. Your cooperation in returning this to the Post-Award Finance Team wiithin ten (10) working days is appreciated.
If we have not received your reply in the specified time, it will be necessary to assume your agreement and forward the report to the granting agency.

Unobligated balance:

Direct Cost	$389.72
Indirect Cost	$201.93
Restricted Funds	$0.00
Total	$591.65

Kim Waller
Principal Investigator

November 18, 2009
Date

Enclosure

FINANCIAL STATUS REPORT WORKSHEET

Project Number...	0009229/0009235	Project Period...	09/01/12	to 08/31/14
Grant Number.......	5R03OH010315-02	Report Period...	09/01/12	to 08/31/14
Investigator...........	Waller,Kim	Agency............	CDC	
Analyst.......... PAF/	Dee Wise	UTHSCH		

Expense Cat.	Obj.	Budget	Expenses Incept. to 08/31/14	Expenses Incept. to 00/00/00	Reversing Adjusting Entries	Current Adjusting Entries	Current Year Expenses	Unliq. Obligations/ Indirect Cost	Adjusted Current Yr Expenses	Adjusted Free Balance
FACULTY SALARY	**61001**	37,619.19	36,143.30	0.00	0.00	0.00	36,143.30	0.00	36,143.30	1,475.89
A&P SALARY	**61002**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CLASSIFIED SALARY	**61003**	38,220.60	39,403.93	0.00	0.00	0.00	39,403.93	0.00	39,403.93	(1,183.33)
OTHER WAGES	**61004**	3,733.61	3,733.61	0.00	0.00	0.00	3,733.61	0.00	3,733.61	0.00
Other Wages	*61004*	3,733.61	3,733.61	0.00	0.00	0.00	3,733.61	0.00	3,733.61	0.00
Faculty Stipend/Fellowship	*69155*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Student Stipend/Fellowship	*69156*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BENEFITS	**61005**	18,987.60	18,655.44	0.00	0.00	0.00	18,655.44	0.00	18,655.44	332.16
MAINTENANCE & OPER.	**61006**	150.00	150.00	0.00	0.00	235.00	150.00	0.00	385.00	(235.00)
Maintenance & Oper	*61006*	150.00	150.00	0.00	0.00	235.00	150.00	0.00	385.00	(235.00)
Stipends/No Bene-students	*69161*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Tuition & Fees	*67679*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Patient care earning IDC	*67248*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Space Leases	*67470*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TRAVEL	**61007**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Domestic Travel	*61007*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Foreign Travel	*67121*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
UTILITIES	**61008**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CAPITAL EXPENDITURES	**61009**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PATIENT COSTS	**61012**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Patient care no IDC	*69651*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
RETURN BAL/RESTRICTED	**61013**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
RES. SUBCONTRACTS	**61014**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Costs Earning IDC	*69759*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Costs Not Earning IDC	*69778*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SUB-TOTAL		98,711.00	98,086.28	0.00	0.00	235.00	98,086.28	0.00	98,321.28	389.72
								0.00		
INDIRECT COSTS	61015	51,329.00	51,004.97	0.00	0.00	122.20	51,127.17	(0.10)	51,127.07	201.93
RETRN BAL/RESTRICTED	61013	0.00								0.00
TOTAL COST		150,040.00	149,091.25	0.00	0.00	357.20	149,213.45	0.00	**149,448.35**	591.65

FINANCIAL STATUS REPORT WORKSHEET

Project Number...	0009229/0009235	Project Period...	09/01/12 to 08/31/14
Grant Number.....	5R03OH010315-02	Report Period...	09/01/12 to 08/31/14
Investigator.....	Waller,Kim	Agency.....	CDC
Analyst..... PAF/	Dee Wise	UTHSCH	

INDIRECT COST CALCULATION FOR EXPENDITURES

MTDC FOR GRANT YEAR *				98,321.28
MTDC AT RATE 2 (Enter if there are two rates)				0.00
RATE 1	0.000	98,321.28	0.00	
RATE 2 (current)	0.000	0.000	0.000	
MAXIMUM INDIRECT COST		0.00	0.00	0.00
TOTAL INDIRECT COST (from page 1)				51,127.17
POTENTIAL INDIRECT COST ADJUSTMENT				(0.10)
INDIRECT COST FREE BALANCE FROM LEDGERS				201.83
ACTUAL INDIRECT COST ADJ. (JOURNAL VOUCHER)				(0.10)

INDIRECT COST CALCULATION FOR ENCUMBRANCES

ADJUSTED INDIRECT COST FREE BALANCE	201.93
MTDC ENCUMBRANCE (from page 1)	0.00
LESS: PATIENT CARE ENCUM. EXCLUDED FROM IND. CST	0.00
CURRENT INDIRECT COST RATE	0.000
MAXIMUM INDIRECT COST ENCUMBRANCE	0.00
MTDC ENCUMBRANCE USED FOR CALCULATION	0.00
CURRENT INDIRECT COST RATE	0.000
ACTUAL INDIRECT COST ENCUMBRANCE	0.00

REV CHECK	DIRECT COST	INDIRECT CST	TOTAL COST
AWARD	98,711.00	51,329.00	150,040.00
ENCUM.	0.00	0.00	0.00
CARRYOVER	0.00	0.00	0.00
TOTAL	98,711.00	51,329.00	150,040.00
FSR REV.	98,711.00	51,329.00	150,040.00
VARIANCE	0.00	0.00	0.00

EXPLANATION:

EXP CHECK	INDIRECT CST	TOTAL COST
BOOK EXP.	51,127.17	149,091.25
BOOK ADJ.	(0.10)	357.10
TOTAL	51,127.07	149,448.35
FSR EXP.	0.00	149,448.35
VARIANCE	51,127.07	0.00

* TOTAL DIRECT COSTS		98,321.28
LESS: PAT COST/RES	0.00	
TUIT & FEES	0.00	
SPACE LEASES	0.00	
EQUIPMENT	0.00	
RSCH SUBC EXM	0.00	
		0.00
MTDC FOR GRANT YEAR		98,321.28

FINANCIAL STATUS REPORT WORKSHEET

Project Number...	0009229/0009235	Project Period...	09/01/12	to	08/31/14
Grant Number.....	5R03OH010315-02	Report Period...	09/01/12	to	08/31/14
Investigator.....	Waller,Kim	Agency.....	CDC		
Analyst..... PAF/	Dee Wise	UTHSCH			

DATA FOR ELECTRONIC TRANSMISSION OF FSR:

ADD

GRANT NO.: 5R03OH010315-02

(005) RECIPIENT ID: 0009229/0009235	
(10B) TOTAL OUTLAYS THIS PERIOD	149,448.35
(10C) PROGRAM INCOME	0.00
(10F) NON-FEDERAL SHARE OF OUTLAYS	0.00
(10H) UNLIQUIDATED OBLIGATIONS	0.00
(10 I) NON-FEDERAL UNLIQ. OBLIG.	0.00
(10Z) PREV. BUDGET PERIOD CARRYOVER REQUEST	0.00
(10X) GRANTEE CARRYOVER REQUEST	591.65
(11B) INDIRECT COST RATE 1	0.000
(SPACEBAR)	
(11C) BASE FOR RATE 1	0.00
(11G) INDIRECT COST RATE 2	0.000
(SPACEBAR)	
(11H) BASE FOR RATE 2	0.00
(11E) FEDERAL SHARE INDIRECT COST	0.00

(12) REMARKS:

PRINCIPAL INVESTIGATOR: Waller,Kim

591.65 WILL BE CARRIED FORWARD TO THE NEXT BUDGET PERIOD IF UNDER THE EXPANDED AUTHORITIES AND F.D.P. ('R' GRANTS EXCEPT FOR R10,R18,R43 AND R44).

ENCUMBRANCES: DIRECT COST	0.00
INDIRECT CST	0.00
TOTAL	0.00

REVIEWED BY: _____

_____

DATA FOR NON-ELECTRONIC FILING OF FSR:

1. FEDERAL AGENCY: CDC
2. GRANT #: 5R03OH010315-02
5. ACCOUNT #: 0009229/0009235
8. PROJECT PERIOD 09/01/12 to 08/31/14
9. REPORT PERIOD 09/01/12 to 08/31/14

10. STATUS OF FUNDS:

A. NET OUTLAYS PREVIOUSLY REPORTED	0.00
B. TOTAL OUTLAYS THIS REPORT PERIOD	149,448.35
C. LESS: PROGRAM INCOME CREDITS	0.00
D. NET OUTLAYS THIS REPORT PERIOD	149,448.35
E. NET OUTLAYS TO DATE	149,448.35
F. LESS: NON-FEDERAL SHARE OF OUTLAYS	0.00
G. TOTAL FEDERAL SHARE OF OUTLAYS	149,448.35
H. TOTAL UNLIQUIDATED OBLIGATIONS	0.00
I. LESS: NON-FED. UNLIQ. OBLIGATIONS	0.00
J. FEDERAL SHARE OF UNLIQ. OBLIG.	0.00
K. TOTAL FED. OUTLAYS & UNLIQ. OBLIG.	149,448.35
L. TOTAL CUMULATIVE AMOUNT AUTHORIZED	150,040.00
M. AMOUNT OF UNOBLIGATED BALANCE	**591.65**

(Amt. Paid to date-Expended to date-Encumbrances)

11. INDIRECT COST

RATE 1:	0.000	BASE	0.00	0.00
RATE 2:	0.000	BASE	0.00	0.00
TOTAL:				0.00

12. REMARKS:

PRINCIPAL INVESTIGATOR: Waller,Kim

591.65 WILL BE CARRIED FORWARD TO THE NEXT BUDGET PERIOD IF UNDER THE EXPANDED AUTHORITIES AND F.D.P. ('R' GRANTS EXCEPT FOR R10,R18,R43 AND R44).

UNOBLIGATED BALANCE LESS RESTRICTED AMOUNT: 591.65

FINANCIAL STATUS REPORT WORKSHEET

Project Number...		0009229	Project Period...	09/01/12	to 08/31/14
Grant Number......		5R03OH010315-02	Report Period...	09/01/12	to 08/31/14
Investigator...........		Waller,Kim	Agency............	CDC	
Accountant...........	PAF/	Dee Wise	UTHSCH		

Expense Cat.	Obj.	Budget	Expenses Incept. to 08/31/14	Expenses Incept. to 00/00/00	Reversing Adjusting Entries	Current Adjusting Entries	Current Year Expenses	Unliq. Obligations/ Indirect Cost	Adjusted Current Yr Expenses	Adjusted Free Balance
FACULTY SALARY	**61001**	30,560.19	29,299.64	0.00	0.00	0.00	29,299.64	0.00	29,299.64	1,260.55
A&P SALARY	**61002**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CLASSIFIED SALARY	**61003**	38,220.60	39,403.93	0.00	0.00	0.00	39,403.93	0.00	39,403.93	(1,183.33)
OTHER WAGES	**61004**	3,733.61	3,733.61	0.00	0.00	0.00	3,733.61	0.00	3,733.61	0.00
Other Wages	*61004*	3,733.61	3,733.61	0.00	0.00	0.00	3,733.61	0.00	3,733.61	0.00
Faculty Stipend/Fellowship	*69155*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Student Stipend/Fellowship	*69156*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
BENEFITS	**61005**	17,645.60	17,326.43	0.00	0.00	0.00	17,326.43	0.00	17,326.43	319.17
MAINTENANCE & OPER.	**61006**	150.00	150.00	0.00	0.00	235.00	150.00	0.00	385.00	(235.00)
Maintenance & Oper	*61006*	150.00	150.00	0.00	0.00	235.00	150.00	0.00	385.00	(235.00)
Stipends/No Bene-students	*69161*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Tuition & Fees	*67679*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Patient care earning IDC	*67248*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Space Leases	*67470*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TRAVEL	**61007**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Domestic Travel	*61007*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Foreign Travel	*67121*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
UTILITIES	**61008**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
CAPITAL EXPENDITURES	**61009**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PATIENT COSTS	**61012**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Patient care no IDC	*69651*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
RETURN BAL/RESTRICTED	**61013**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
RES. SUBCONTRACTS	**61014**	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Costs Earning IDC	*69759*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Costs Not Earning IDC	*69778*	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
*PLACE HOLDER*******		0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SUB-TOTAL		90,310.00	89,913.61	0.00	0.00	235.00	89,913.61	0.00	90,148.61	161.39
								0.00		
INDIRECT COSTS	61015	46,960.00	46,755.25	0.00	0.00	122.20	46,877.45	(0.17)	46,877.28	82.72
RETRN BAL/RESTRICTED	61013	0.00								0.00
TOTAL COST		137,270.00	136,668.86	0.00	0.00	357.20	136,791.06	0.00	**137,025.89**	244.11

FINANCIAL STATUS REPORT WORKSHEET

Project Number...	0009229			Project Period...	09/01/12 to 08/31/14
Grant Number.....	5R03OH010315-02			Report Period...	09/01/12 to 08/31/14
Investigator.....	Waller,Kim			Agency.....	CDC
Accountant..... PAF/	Dee Wise			UTHSCH	

INDIRECT COST CALCULATION FOR EXPENDITURES

MTDC FOR GRANT YEAR *				90,148.61
MTDC AT RATE 2 (Enter if there are two rates)				0.00
RATE 1	0.520	90,148.61	0.00	
RATE 2 (current)	0.520	0.520	0.520	
MAXIMUM INDIRECT COST		46,877.28	0.00	46,877.28
TOTAL INDIRECT COST (from page 1)				46,877.45
POTENTIAL INDIRECT COST ADJUSTMENT				(0.17)
INDIRECT COST FREE BALANCE FROM LEDGERS				82.55
ACTUAL INDIRECT COST ADJ. (JOURNAL VOUCHER)				(0.17)

INDIRECT COST CALCULATION FOR ENCUMBRANCES

ADJUSTED INDIRECT COST FREE BALANCE	82.72
MTDC ENCUMBRANCE (from page 1)	0.00
LESS: PATIENT CARE ENCUM. EXCLUDED FROM IND. CST	0.00
CURRENT INDIRECT COST RATE	0.520
MAXIMUM INDIRECT COST ENCUMBRANCE	0.00
MTDC ENCUMBRANCE USED FOR CALCULATION	0.00
CURRENT INDIRECT COST RATE	0.520
ACTUAL INDIRECT COST ENCUMBRANCE	0.00

REV CHECK	DIRECT COST	INDIRECT CST	TOTAL COST
AWARD	90,310.00	46,960.00	137,270.00
ENCUM.	0.00	0.00	0.00
CARRYOVER	0.00	0.00	0.00
TOTAL	90,310.00	46,960.00	137,270.00
FSR REV.	90,310.00	46,960.00	137,270.00
VARIANCE	0.00	0.00	0.00

EXPLANATION:

EXP CHECK	INDIRECT CST	TOTAL COST
BOOK EXP.	46,877.45	136,668.86
BOOK ADJ.	(0.17)	357.03
TOTAL	46,877.28	137,025.89
FSR EXP.	46,877.28	137,025.89
VARIANCE	0.00	0.00

* TOTAL DIRECT COSTS		90,148.61
LESS: PAT COST/RES	0.00	
TUIT & FEES	0.00	
SPACE LEASES	0.00	
EQUIPMENT	0.00	
RSCH SUBC EXM	0.00	
		0.00
MTDC FOR GRANT YEAR		90,148.61

FINANCIAL STATUS REPORT WORKSHEET

Project Number...	0009229		Project Period...	09/01/12	to 08/31/14
Grant Number.....	5R03OH010315-02		Report Period...	09/01/12	to 08/31/14
Investigator.....	Waller,Kim		Agency.....	CDC	
Accountant..... PAF/	Dee Wise		UTHSCH		

DATA FOR ELECTRONIC TRANSMISSION OF FSR:

ADD

GRANT NO. : 5R03OH010315-02

(005) RECIPIENT ID: 0009229	
(10B) TOTAL OUTLAYS THIS PERIOD	137,025.89
(10C) PROGRAM INCOME	0.00
(10F) NON-FEDERAL SHARE OF OUTLAYS	0.00
(10H) UNLIQUIDATED OBLIGATIONS	0.00
(10 I) NON-FEDERAL UNLIQ. OBLIG.	0.00
(10Z) PREV. BUDGET PERIOD CARRYOVER REQUEST	0.00
(10X) GRANTEE CARRYOVER REQUEST	0.00
(11B) INDIRECT COST RATE 1	0.520
(SPACEBAR)	
(11C) BASE FOR RATE 1	90,148.62
(11G) INDIRECT COST RATE 2	0.520
(SPACEBAR)	
(11H) BASE FOR RATE 2	0.00
(11E) FEDERAL SHARE INDIRECT COST	46,877.28

(12) REMARKS:

PRINCIPAL INVESTIGATOR: Waller,Kim

0.00 WILL BE CARRIED FORWARD TO THE NEXT BUDGET PERIOD IF UNDER THE EXPANDED AUTHORITIES AND F.D.P. ('R' GRANTS EXCEPT FOR R10,R18,R43 AND R44).

ENCUMBRANCES: DIRECT COST	0.00
INDIRECT CST	0.00
TOTAL	0.00

REVIEWED BY: _____

_____

DATA FOR NON-ELECTRONIC FILING OF FSR:

1. FEDERAL AGENCY: CDC
2. GRANT # : 5R03OH010315-02
5. ACCOUNT #: 0009229
8. PROJECT PERIOD 09/01/12 to 08/31/14
9. REPORT PERIOD 09/01/12 to 08/31/14

10. STATUS OF FUNDS:

A. NET OUTLAYS PREVIOUSLY REPORTED	0.00
B. TOTAL OUTLAYS THIS REPORT PERIOD	137,025.89
C. LESS: PROGRAM INCOME CREDITS	0.00
D. NET OUTLAYS THIS REPORT PERIOD	137,025.89
E. NET OUTLAYS TO DATE	137,025.89
F. LESS: NON-FEDERAL SHARE OF OUTLAYS	0.00
G. TOTAL FEDERAL SHARE OF OUTLAYS	137,025.89
H. TOTAL UNLIQUIDATED OBLIGATIONS	0.00
I. LESS: NON-FED. UNLIQ. OBLIGATIONS	0.00
J. FEDERAL SHARE OF UNLIQ. OBLIG.	0.00
K TOTAL FED. OUTLAYS & UNLIQ. OBLIG.	137,025.89
L. TOTAL CUMULATIVE AMOUNT AUTHORIZED	137,270.00
M. AMOUNT OF UNOBLIGATED BALANCE	**244.11**

(Amt. Paid to date-Expended to date-Encumbrances)

11. INDIRECT COST

RATE 1:	0.520	BASE	90,148.62	46,877.28
RATE 2:	0.520	BASE	0.00	0.00
TOTAL:				46,877.28

12. REMARKS:

PRINCIPAL INVESTIGATOR: Waller,Kim

0.00 WILL BE CARRIED FORWARD TO THE NEXT BUDGET PERIOD IF UNDER THE EXPANDED AUTHORITIES AND F.D.P. ('R' GRANTS EXCEPT FOR R10,R18,R43 AND R44).

UNOBLIGATED BALANCE LESS RESTRICTED AMOUNT: 244.11

Form Approved Through 08/31/2015
OMB No. 0925-0002

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Procedure for Submission of Final Invention Statement and Certification (For Grant or Award) Form HHS 568

A Final Invention Statement and Certification (Form HHS 568) shall be executed and submitted within 90 days following the expiration or termination of a grant or award. The Statement shall include all inventions which were conceived or first actually reduced to practice during the course of work under the grant or award, from the original effective date of support through the date of completion or termination. The Statement shall include any inventions reported previously for the grant or award as part of a non-competing application. This reporting requirement is applicable to grants and awards by Department of Health and Human Services in support of research.

The Final Invention Statement and Certification does not in any way relieve the person responsible for the grant or award, or the institution, of the obligation to assure that all inventions are promptly and fully reported directly to the National Institutes of Health, as required by terms of the grant or award. Information regarding the reporting of inventions, including the reporting form to be followed, may be obtained from the Office of Policy for Extramural Research Administration, Division of Extramural Inventions and Technology Resources, 6705 Rockledge Drive MSC 7980, Bethesda, Maryland 20892-7980, Telephone: (301) 435-1986.

The original of the completed Final Invention Statement and Certification is to be returned to the awarding component that funded the grant or award. The entire grant or award number must appear in the designated box on the form. The period covered by the Final Invention Statement is the project period of the grant or award at a particular grantee institution. If no inventions were involved, insert the word "None" in the first block under item Title of Invention. Each Statement requires the signature of an institution official authorized to sign on behalf of the institution.

Privacy Act Statement. The NIH maintains application and grant records as part of a system of records as defined by the Privacy Act: NIH 09-25-0036, *Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH*: http://oma.od.nih.gov/ms/privacy/pa-files/0036.htm.

Form Approved Through 08/31/2015
OMB No. 0925-0002

Department of Health and Human Services

Final Invention Statement and Certification

(For Grant or Award)

DHHS Grant or Award No.

R03 OH 0 10315

A. We hereby certify that, to the best of our knowledge and belief, all inventions are listed below which were conceived and/or first actually reduced to practice during the course of work under the above-referenced DHHS grant or award for the period

_____ through _____.

original effective date *date of termination*

B. Inventions (Note: If no inventions have been made under the grant or award, insert the word *"NONE"* under Title below.)

NAME OF INVENTOR	TITLE OF INVENTION	DATE REPORTED TO DHHS
NULL		
(Use continuation sheet if necessary)		

C. Signature — This block ***must*** be signed by an official authorized to sign on behalf of the institution.

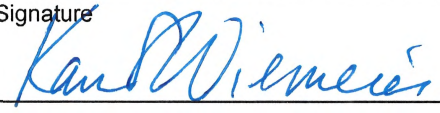
Title

Director, Contracts

Typed Name

Karen Niemeier

Signature



Date

11/19/2014

Name and Mailing Address of Institution

The University of Texas Health Science Center at Houston
Sponsored Projects Administration
7000 Fannin, UCT 1006
Houston, TX 77030

TANGIBLE PERSONAL PROPERTY REPORT
Final Report SF-428- B

Federal Grant or Other Identifying Number Assigned by Federal Agency (Block 2 on SF-428).

1. **Report** (Select all that apply)

a. ___ Federally-owned Property (List on Supplemental Sheet SF-428S or recipient equivalent and complete Section 2a below.)

b. ___ Acquired Equipment with acquisition cost of $5,000 or more for which the awarding agency has reserved the right to transfer title (List on Supplemental Sheet SF-428S or recipient equivalent and complete Section 2b below.)

c. ___ Residual Unused Supplies with total aggregate fair market value exceeding $5,000 not needed for any other Federally sponsored programs or projects. *(Complete Section 2c below)*

d. ___ None of the above

2. Complete relevant section(s)	**For Agency Use Only**
2a. **Federally-owned Property** *(Select one or more.)* (i) ___ Request transfer to Award _____ (ii) ___ Request Federal Agency disposition instructions (iii) ___ Other *(Provide detail in Block **3** or attach request)*	Agency response to requested disposition of Federally owned property: (i) Recipient request approved___ denied ___ (ii) Dispose in accordance with attached instructions ___.
2b. **Acquired Equipment** *(Select one or more.)* (i) ___ Request unconditional transfer of title with no further obligation to the Federal Government. (ii) ___ Request Federal Agency disposition instructions Note: If the awarding agency does not provide disposition instructions within 120 days the recipient may continue to use the equipment for Federally supported projects or dispose in accordance with the applicable property standards.	Agency response to requested disposition of acquired equipment: (i) Recipient request approved___ denied ___ (ii) Dispose in accordance with attached instructions ___ Authorized Awarding Agency Official Signature: / Date: Name: / Phone: Title / Email

2c. **Reportable Residual Unused Supplies**

(i) __ Sale proceeds or __ Estimate of current fair market value ..... $_____

(ii) Percentage of Federal participation ..... _____%

(iii) Federal share ..... $_____

(iv) Selling and handling allowance ..... $_____

(v) **Amount remitted to the Federal Government**..... $_____

3. Comments Null

FINAL REPORT ATTACHMENT TO SF-428

Agency use only

OMB Approval Number: 3090-0289
Expiration Date: 4/30/2013

A. General Instructions:

This Attachment is to be used by recipients when required to provide a final property report for closeout of Federal assistance awards. The Attachment allows recipients to request specific disposition of Federally-owned property and acquired equipment. The attachment also provides a means for calculating and transmitting appropriate compensation to the awarding agency for residual unused supplies.

Requirements for final reporting are based on individual award provisions and the type of property. Generally, at the end of a Federal assistance award, recipients are required to:

a. submit a report of Federally-owned property.
b. provide a listing of equipment items, with an acquisition cost of $5,000 or more, when the awarding agency has reserved the right to transfer title to the equipment to the Federal Government or a third party.
c. compensate the awarding agency for residual unused supplies with a total aggregate fair market value greater than $5,000 that are not needed for any other Federally sponsored programs or projects.

Federal Grant or Other Identifying Number Assigned by Federal Agency. Enter the Federal grant, cooperative agreement or other Federal financial assistance award instrument number or other identifying number assigned to the Federal financial assistance award.

1. **Report.** Check applicable lines a-c to indicate the type of property that is being reported. Note: Federally-owned property includes items provided by the awarding agency, regardless of dollar value. Check line d to indicate no property to report, if the awarding agency requires a negative report.

2. Complete the relevant sections to correspond with the property reported in Block 1.

2a. **Federally-owned Property.**

(i) To request transfer of the property for use on a specific Federal award.
(ii) To request Federal agency disposition instructions for unneeded Federally-owned property.
(iii) To request a disposition other than (i) or (ii). For example, requests for transfer of title under authority of the Stevenson-Wydler Act.

2b. **Acquired Equipment with acquisition cost of $5,000 or more for which the awarding agency has reserved the right to transfer title.**

(i) When statutory authority exists, the Federal awarding agency has the option to vest title to equipment. acquired with award funds in the recipient with no further obligation to the Federal government and under conditions the Federal awarding agency considers appropriate.
(ii) To request Federal agency disposition instructions for equipment acquired with award funds.

2c. **Reportable Residual Unused Supplies.** Indicate whether the supplies have been sold or if they will be retained for use solely on non Federally-funded projects.

(i) Enter the total amount of sales proceeds or an estimate of the current fair market value if the supplies will be retained. Note: Fair market value means the best estimate of the gross sales proceeds if the property were to be sold in a public sale.
(ii) Enter the percentage of Federal Government participation in the award under which the supplies were acquired.
(iii) Enter the dollar amount of sales proceeds (or estimate of current fair market value) multiplied by the percentage of Federal Government participation listed in (ii).
(iv) If the supplies were sold, enter the amount of selling and handling expenses. Enter zero if the supplies will be retained for use on non Federally funded projects.
(v) Enter the amount of the Federal share in (iii) less the selling and handling expense listed in (iv). Indicate in Block 3 how the funds are being returned to the government (e.g., attached check made out to the Awarding Agency/U.S. Treasury or electronic remission).

3. **Comments.** Provide any explanations or additional information in this block. Attach additional sheets if necessary.

Agency use only. This section is reserved for Federal agency use only.