AWARD NUMBER: W81XWH-16-1-0254

TITLE: Grandparental Exposures and Risk of Autism in the Third Generation

PRINCIPAL INVESTIGATOR: Dr. Barbara A. Cohn

CONTRACTING ORGANIZATION: Public Health Institute, Oakland, CA 94607

REPORT DATE: August 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
~~XX/XX/2017~~ August 2017	Annual	15 July 2016 - 14 July 2017

4. TITLE AND SUBTITLE
Grandparental Exposures and Risk of Autism in the Third Generation

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-16-1-0254

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Public Health Institute
555 12th Street, Ste 1050
Oakland CA 94607-4046

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
In the first year, we have successfully completed the first milestones of this project: getting institutional, state and federal IRB approval for this study and acquiring California Birth Records (1975-2014) for linkage to the Child Health and Development Studies (CHDS). We are developing and refining a matching procedure to optimize the identification of the third generation (F2) of CHDS births. To test our matching criteria and protocols, we ran a pilot match using 1994, which was one of the birth years predicted to include a maximum of CHDS births. The results of the pilot show that we identified approximately 800 matches for our F1 females, which reflect our initial prediction. Because the birth record variables available for matching change by year, each year will potentially require its own matching criteria. We are continuing to refine the matching protocol for other years and for our F1 males. This will be the first study of its kind in the United States, linking three generations from the 1960's through the 2010's and will establish a platform for studying germline exposures and risk of autism.

15. SUBJECT TERMS
Autism, Prospective Study, Germline Exposures, Multi-generation Cohort, Grand-parental Risk Factors

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	20	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This study will test the hypothesis that Grandparental exposures during peri-conception and pregnancy predict increased risk of autism in the grandchildren. This study will identify cases of autism spectrum disorder (ASD) and unaffected controls in the grandchildren of The Child Health and Development Studies (CHDS) multigenerational cohort. We will use a prospective matched nested case-control sample of an estimated 72 autism cases and 216 year-of-birth matched controls in CHDS grandchildren to explore the effect of grandparental exposures. The CHDS study population is a 50+ year follow-up of 20,000 pregnancies that occurred in the 1960's. Significantly, the 1960's was a period when maternal pregnancy exposures to a wide variety of endocrine active compounds were high, including prescription drugs, cigarette smoking, alcohol and coffee. Our team will identify CHDS grandchildren with autism via linkages to California birth records and California Department of Developmental Services (CA-DDS) files. For each ASD case, three controls will be randomly selected. Controls will be matched to its case on year of case birth and gender. We will have a large enough control pool to match on year of case birth. Risk factors include grandmaternal and grandpaternal age, smoking, alcohol, coffee, and grandmaternal prescription drugs (tranquilizers, sedatives, amphetamines, diuretics, antihistamines hormones) during pregnancy.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Autism, Prospective Study, Germline Exposures, Multi-generation Cohort, Grand-parental Risk Factors

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

1. Submit for Local IRB (PHI) & CPHS approval. COMPLETED
2. Submit for DDS and Vital Records approval. COMPLETED
3. Submit for HRPO approvals. COMPLETED
4. Perform CHDS linkage to California Vital Statistics Birth Records to identify CHDS grandchild births. IN PROGRESS
5. Link CHDS grandchild birth records to the Department of Developmental Services records to identify cases of autism in grandchildren. IN PROGRESS
6. Link archive CHDS data on grandparents and parents to data generated on grandchildren. BEGIN INYEAR 2
7. Analysis of grandparental peri-conceptual and prenatal risk factors for grandchild autism. BEGIN INYEAR 2
8. Investigate relation of grandparental risk factors for autism to growth and development in the parent. BEGIN INYEAR 2

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1. We have submitted and received approval from both Local IRB (Public Health Institute) & California Committee of Human Subjects (CPHS) approval.
2. We have submitted and received approval from the California Department of Health Information and Research Section to receive access to birth files from 1975 to 2014.
3. We have submitted and received approval from HRPO.
4. We have received the physical files containing the birth records from 1975 to 2014.
    a. We have begun to match our cohort members (F1) to the California birth records and this process is ongoing.
    b. We have run a pilot match for 1994 to develop and refine our matching protocol and achieved the predicted numbers for the F1 mothers (approximately 800 matches). We are in the process of developing and optimizing the matching protocol for F1 fathers.
5. We have identified DDS variables we would like to match on and are applying for DDS approval.
6. This will start in Year 2.
7. This will start in Year 2.
8. This will start in Year 2.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

"Nothing to Report."

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

In March, 2016 at our quarterly Participant Advisory Council (PAC) meeting, we announced receiving this funding to study "*Grandparental Exposures and Risk of Autism in the Third Generation*". Our PAC is a diverse group of CHDS mothers, sons and daughters who have partnered with us to help guide our research. They have expressed interest in studying Autism on multiple occasions and are eager to hear updates on our progress and findings in this study.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

4. Continue to match the cohort (F1) to the birth files to acquire F2
5. Continue to match to DDS files:
    a. Receive approval from DDS to link data.
    b. Matching state record numbers (F2) to Department of Developmental Services to identify Autism cases.
6. Link archive CHDS data on grandparents (F0) and parents (F1) to data generated on grandchildren (F2).
7. Conduct analysis of grandparental peri-conceptual and prenatal risk factors for grandchild autism.
8. Investigate relation of grandparental risk factors for autism to growth and development in the parent.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Applying for and being granted IRB approval and linkage approval at Institutional, State and Federal levels, for linkage to public records sets a precedent for future linkages. This is an expansion of the permissions and linkages the CHDS already routinely conducts (DMV, CA death and CA cancer). Proving the feasibility and process of linking grand-parental health to grandchild health information should impact multigenerational and transgenerational research possibilities.

We are creating a matching procedure that CHDS and other researchers can use in conducting data linkages, especially for matching to California Vital Statistics data.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

"Nothing to Report."

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

"Nothing to Report."

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

"Nothing to Report."

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

"Nothing to Report."

Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

We are on track with our project timeline as stated in the SOW.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

"Nothing to Report."

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

"Nothing to Report."

Significant changes in use or care of vertebrate animals.

"Nothing to Report."

Significant changes in use of biohazards and/or select agents

"Nothing to Report."

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

- **Journal publications.** *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

"Nothing to Report."

- **Books or other non-periodical, one-time publications.** *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: Author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

"Nothing to Report."

- **Other publications, conference papers, and presentations**. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

"Nothing to Report."

- **Website(s) or other Internet site(s)** *List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.*

"Nothing to Report."

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

"Nothing to Report."

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

"Nothing to Report."

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment, and/or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *biospecimen collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

"Nothing to Report."

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*

Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award).*

Name:	*Barbar A. Cohn*
Project Role:	*PI*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Cohn contributed to the design and is overlooking the project. She has overseen the IRB and linkage approvals.*
Name:	*Piera Cirillo*
Project Role:	*Project Director*
Nearest person month worked:	*1*
Contribution to Project:	*Ms. Cirillo contributed to the design and is overlooking the project. She has written and overseen the IRB and linkage approvals.*
Name:	*Lauren Zimmermann*
Project Role:	*Researcher*
Nearest person month worked:	*1*
Contribution to Project:	*Ms. Zimmermann assisted with writing the IRB and linkage approvals. She also is assisting with conducting the Birth Record File matching.*
Name:	*Nickilou Krigbaum*
Project Role:	*Researcher*
Nearest person month worked:	*3*
Contribution to Project:	*Ms. Krigbaum is conducting the Birth Record File matches and assisted with the IRB and linkage approvals.*
Name:	*Gayle Windham*
Project Role:	*Co-Investigator*
Nearest person month worked:	*1*
Contribution to Project:	*Dr. Gayle Windham contributed to the design of this project and consulted on California IRB and linkage protocol. She responsible for acquiring permission to link CHDS data to DDS data.*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

"Nothing to Report."

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Escher Fund for Autism Los Angeles, CA Collaboration: Jill Escher initiated the partnership for this project and provided background expertise for writing the proposal.

8. **SPECIAL REPORTING REQUIREMENTS**
   COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

   QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

PUBLIC HEALTH INSTITUTE

Institutional Review Board
Human Subjects Review Committee

June 9, 2017

Barbara Cohn, Ph.D.
Child Health and Development Studies
1683 Shattuck Avenue, Suite B
Berkeley, CA 94709

Re: Continuing Approval of *Grandparental Exposures and Risk of Autism in the Third Generation*
IRB# I16-025

Dear Dr. Cohn:

This is to advise you that the above referenced Study has been presented to the Institutional Review Board on 6/8/17. The proposal was approved.

This approval is valid for one year, and will expire on 6/7/18. Prior to that date, we will send you a continuation/renewal request form. At that time we would appreciate your completing the form and returning it to the Committee.

If this project is modified in any way, it must be submitted to the IRB for approval. In addition, the Board must be promptly notified of unanticipated problems involving risks to human subjects or any complications which may occur during any experimental procedure.

Sincerely,

Debora Pinkas

Debora Pinkas
IRB Administrator

STATE OF CALIFORNIA - HEALTH AND HUMAN SERVICES AGENCY EDMUND G. BROWN JR., *Governor*

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
400 R Street, Suite 359
Sacramento, California 95811-6213
(916) 326-3660 FAX (916) 322-2512

05/22/2017

Cohn, Barbara
Public Health Institute
1683 Shattuck Ave
Berkeley, CA 94709

Project Title: Grandparental Exposures and Risk of Autism in the Third Generation
Project Number: 16-09-2718

Dear Dr. Cohn,

The Committee for the Protection of Human Subjects (CPHS) has reviewed and approved the above new project. Included with the approval are the following item(s) beginning with project type:

Common Rule, Minimal Risk, HIPAA Waiver

This approval is issued under the California Health and Human Services Agency#s Federalwide Assurance #00000681.

Pursuant to 45 CFR 46.109(e), CPHS cannot approve a project for more than one year at a time. Therefore, a project must be renewed yearly. To continue your research or data analysis, submit a Continuing Review request by your project's deadline date, **January 5, 2018.** If your project is not approved again (renewed), it will expire on February 2, 2018. Once a project is expired, all research, including data analysis, must cease (unless discontinuance will have an adverse impact on research subjects).

You will receive courtesy email reminders from CPHS to renew your project. It is the Principal Investigator's responsibility to submit their Continuing Review request on time and to notify CPHS of any changes in contact information.

If a project has been completed or is no longer active, it must be submitted to CPHS for completion approval or withdrawal approval. Instructions for these processes can be found in our Instructions for Researchers located on the CPHS Homepage.

Any unanticipated problems, adverse events, protocol deviations, and breaches in data security must

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
400 R Street, Suite 359
Sacramento, California 95811-6213
(916) 326-3660 FAX (916) 322-2512

be reported to CPHS via a Report Form within 48 hours of the event. File a report by logging into CalProtects and clicking on the protocol's "Protocol ID" number. A pop-up window will appear, select the "Start Report Form" option. Upon completion of the form, click the "Submit Form" button on the left side of the screen. You must call CPHS staff at (916)326-3660 to notify them of the report submission.

If you have any questions, you may call our office at (916) 326-3660 or email us at cphs-mail@oshpd.ca.gov.

Sincerely,

Lucila Martinez
CPHS Administrator
(916) 326-3661
lucila.martinez@oshpd.ca.gov

State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
Director and State Health Officer

EDMUND G. BROWN JR.
Governor

May 17, 2017

Dr. Barbara Cohn
Public Health Institute
1683 Shattuck Avenue, Suite B
Berkeley, CA 94709

Project Number: 16-09-2718

Project Title: Grandparental Exposures and Risk of Autism in the Third Generation

Dear Dr. Cohn:

The California Department of Public Health's (CDPH) State Registrar has approved the release of custom data files of the 1975-2014 (select variables) Birth Files for the above named research project.

Based on the documentation CDPH has on file, CDPH requires that you submit a more current Committee for the Protection of Human Subjects (CPHS) approval letter. A copy of each new CPHS approval and/or all extension letters must be provided to CDPH. If at any time during this project there are any changes, either in the scope of the study or in Principal Investigator, you are required to notify both CPHS and CDPH. Upon CPHS approval, the revised project must then be reviewed by Vital Statistics Advisory Committee before implementing any changes.

Upon completion of your project, you are required to return the vital statistics data to CDPH or confidentially destruct said data.

Finally, if you will be publishing any articles or manuscripts, CDPH would appreciate obtaining a copy of these documents. You can email the documents to HIRS@cdph.ca.gov or you can mail them to the mailing address listed below.

CDPH Center for Health Statistics and Informatics, MS 5000 • P.O. Box 997410 •
Sacramento, CA 95899-7410
(916) 440-7350 • (916) 440-7357 FAX
Internet Address: www.cdph.ca.gov

California Department of Public Health
Health Information and Research Section
Attn: Data Request Desk
1616 Capitol Avenue, MS 5101
P.O. Box 997410
Sacramento, CA 95899-7410

If you have any questions, please contact the Health Information and Research Section at HIRS@cdph.ca.gov.

Sincerely,

Tony Agurto

Tony Agurto, MPA
Deputy State Registrar
Assistant Deputy Director
Center for Health Statistics and Informatics

From:	Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (US)
To:	Barbara Cohn
Cc:	Lauren Zimmermann; Bennett, Jodi H CIV USARMY MEDCOM USAMRMC (US); Rosario, Sandra CIV USARMY MEDCOM USAMRAA (US); Niu, Shui-Lin CIV USARMY MEDCOM CDMRP (US); Tamar Dorfman; Brosch, Laura R CIV USARMY MEDCOM USAMRMC (US); Odam, Kimberly L CIV USARMY MEDCOM USAMRMC (US); Bowden, Derek T CTR USARMY MEDCOM USAMRMC (US)
Subject:	A-19528, HRPO Concurrence Memorandum (Proposal Log Number AR150104, Award Number W81XWH-16-1-0254) (UNCLASSIFIED)
Date:	Monday, September 12, 2016 1:07:07 PM

Classification: UNCLASSIFIED
Caveats: NONE

SUBJECT: HRPO Concurrence With the Exempt Determination for the Proposal, "Grandparental Exposures and Risk of Autism in the Third Generation," Submitted by Barbara A. Cohn, PhD, Public Health Institute, Berkeley, California, Proposal Log Number AR150104, Award Number W81XWH-16-1-0254, HRPO Log Number A-19528

1. The subject protocol and supporting documents received on 14 July 2016 in the US Army Medical Research and Materiel Command, Office of Research Protections (ORP), Human Research Protection Office (HRPO) have been reviewed for applicability of human subjects protection regulations.

2. The research involves the analysis of de-identified birth records from the California Department of Public Health to link second and third generation births with the California autism surveillance program database to identify relationships between risk factors in grandparents and autism in grandchildren.

3. The Public Health Institute Institutional Review Board (IRB) Office determined that the protocol is exempt as it is research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

4. As required by DOD Instruction 3216.02, encl 3, paragraph 4.c(1), the ORP HRPO concurs with the exempt determination made by the Public Health Institute IRB Office. The project may proceed with no further requirement for review by the HRPO. The HRPO protocol file will be closed.

5. In the event that there is a change to the subject research or statement of work (SOW), the Principal Investigator must notify the Grant Officer's Representative (GOR) and send a description of the change to the HRPO at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil referencing both the proposal log number and the HRPO log number listed in the "SUBJECT" line above. The HRPO will re-open the protocol file if necessary.

Any changes to the SOW that the GOR determines could affect the exemption status

of the project must be reviewed by the HRPO prior to approval by the Contracting Officer/Grants Officer.

6. Do not construe this correspondence as approval for any contract funding. Only the Contracting Officer/Grants Officer can authorize expenditure of funds. It is recommended that you contact the appropriate contract specialist or contracting officer regarding the expenditure of funds for your project.

7. Further information regarding this review may be obtained by contacting Derek Bowden, Human Subjects Protection Scientist, at 301-619-1667.

KIMBERLY L. ODAM, MS, CIP
Human Subjects Protection Scientist
Human Research Protection Office
Office of Research Protections
US Army Medical Research and Materiel Command

Note: The official copy of this memo is housed with the protocol file at the Office of Research Protections, Human Research Protection Office, 810 Schreider Street, Fort Detrick, MD 21702-5000. Signed copies will be provided upon request.

Classification: UNCLASSIFIED
Caveats: NONE