World Trade Center

Health Program

Children's Research Recommendations

Scientific and Technical Advisory Committee

June 2, 2016

Summary of WTCHP Children's Research Activities

Funding Success Rate (2012 - Present)

Funded 33 of the 101 (33%) research project applications submitted/reviewed for all categories.

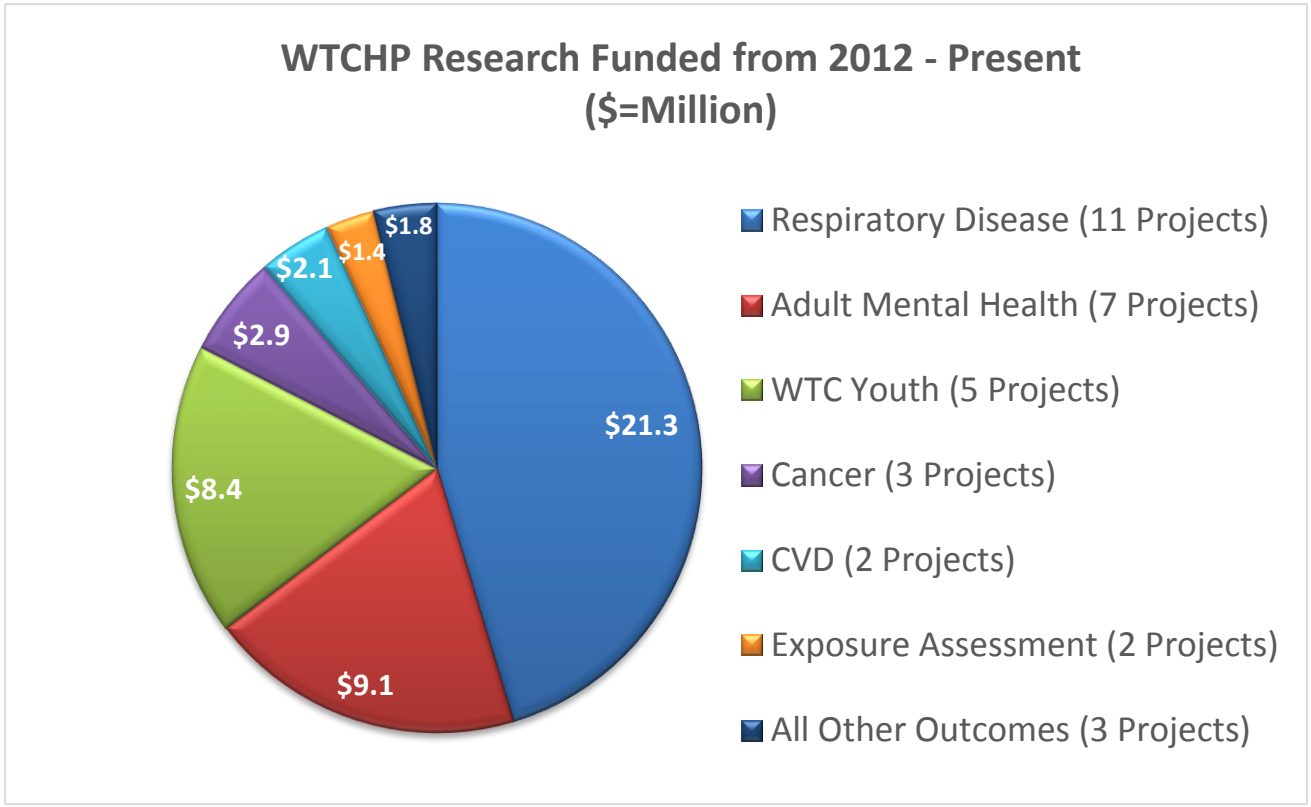
Funded 5 of the 14 (36%) youth category project applications submitted/reviewed.

Continuation of funding for 9/11 Health Registry – multiple projects within single funding award.

Total Funding for WTCHP Youth Cooperative Agreements (2012 - Present)

The 5 Youth projects cost $8.4 million, which is 3rd highest category funded – more than projects on Cancer, Cardiovascular Disease, Exposure Assessment and "All Other Outcomes Combined" (Autoimmune Disease, Cognitive Functioning, and Assessment of the Impact of Epidemiological Biases on WTC Research).

Only exceeded by Respiratory Disease (11 projects, $21.3 million) and Adult Mental Health (7 projects, $9.1 million) – see pie chart below.



Recruitment of Children

- Sub-cohort of Children Enrolled in the WTC Health Registry

Extensive outreach led to enrollment of 3,068 children under 18 years of age on 9/11/2001; but 556 were over 18 when the first survey was conducted (2003-2004). 2,499 (81%) of the original cohort are now at least 18 years of age – with only 1,027 consenting to continue to participate (as adults) despite aggressive outreach.

There was a small subset of enrolled women (approximately 500) who were pregnant on 9/11/2001.

- New York City Board of Education

Had agreed to contact the area public schools (through a contractor) to recruit for initial study participation. At the time, 6 of the 15 schools in the most affected area refused to participate. Subsequently, the Board chose not to facilitate further outreach for study recruitment.

Current WTCHP Youth Studies

The five current WTCHP youth studies are listed below. Each of these studies have recruited subjects from the WTC Health Registry cohort of children. While interim findings have been discussed in WTCHP Research Grantee Meetings, no findings have been published from these studies as yet.

1. The Impact of 9/11 on Youth: Mental Health, Substance Use & Other Risk Behaviors
   Principal Investigator: Christina Hoven (2012)
   Project Duration: 4 years, in progress

2. Early Identification of World Trade Center Conditions in Adolescents
   Principal Investigator: Leonardo Trasande (2013)
   Project Duration: 3 years, in progress

3. Service Need and Use among Youth Exposed to the WTC Attack
   Principal Investigator: Christina Hoven—took over for Peng-Wu (2012)
   Project Duration: 2 years – closed and no publications to date

4. Childhood Exposures to Persistent Organic Pollutants in the World Trade Center Disaster and Cardiovascular Consequences
   Principal Investigator: Leonardo Trasande (2015)
   Project Duration: 1 year, in progress

5. Context and Ethnic Diversity: Children's Responses to 9/11
   Principal Investigator: Christina Hoven (2015)
   Project Duration: 1 year, in progress

Please Note:
Seven additional youth studies have been proposed in response to the FY 16 WTCHP research solicitation. These proposed studies include a range of physical and mental health outcomes.

WTCHP Youth Research Publications

The WTC Health Registry published the following four peer reviewed articles focusing on WTC Youth during 2008 - 2014:

1. Thomas PA, Brackbill R, Thalji L, DiGrande L, Campolucci S, Thorpe L, Henning K. Respiratory and other health effects reported in children exposed to the World Trade Center disaster of 11 September 2001. *Environ Health Perspect* 2008;116:1383-1390.

2. Lipkind HS, Curry AE, Huynh M, Thorpe LE, Matte T. Birth outcomes among offspring of women exposed to the September 11, 2001, terrorist attacks. *Obstet Gynecol* 2010;116:917-925.

3. Stellman SD, Thomas PA, Osahan S, Brackbill RM, Farfel MR. Respiratory health of 985 children exposed to the World Trade Center disaster: Report on World Trade Center Health Registry Wave 2 follow-up, 2007-2008. *J Asthma* 2013; 50:354-363.

4. Mann M, Li J, Farfel MR, Maslow CB, Osahan S, Stellman SD. Adolescent behavior and PTSD 6-7 years after the World Trade Center Disaster in New York City. *Disaster Health* 2014; 2:3-4, 1-9.

In 2009, the New York City Department of Health and Mental Hygiene published "Clinical Guidelines for Children and Adolescents Exposed to the World Trade Center Disaster." Advisors included researchers, pediatric researchers, and parents representing the affected community. These guidelines are available at: http://www.nyc.gov/html/doh/downloads/pdf/chi/chi28-4.pdf.

Anticipated in 2016

The following five articles about WTC Health Registry studies of youth are currently undergoing journal peer review.

1. *Substance Use in Adolescents 10 Years after the World Trade Center Attacks in New York City*
2. *Asthma Control in Adolescents 10 to 11 Years after Exposure to the World Trade Center Disaster*
3. *Unmet Healthcare Needs and School Functioning of New York City Adolescents Following the World Trade Center Attacks of September 11, 2001*
4. *Impact of Parent Physical and Mental Health co-morbidity on Adolescent Behavior*
5. *Reproductive Outcomes Following Prenatal Exposure to Effects of September 11th, 2001 at the World Trade Center in New York City*

The 2016 STAC Recommendations for Children's Research:

WTC Health Program Actions

STAC Recommendation # 1 **WTCHP Action: Agree**

Children and adolescent survivors enrolled in the WTC Health Registry are an extremely important resource for understanding the health effects of WTC exposures. Recommend that the WTCHP:

- Make substantial efforts to sustain and renew participation in surveys and special studies.
- Consider a highly collaborative approach that could examine a broad range of mental and physical health outcomes in the Registry population.
- Develop a funding mechanism that would encourage collaboration between the Registry and a consortium of investigators with diverse expertise.
- Conduct an analysis of the feasibility and usefulness of a standardized health assessment approach, similar to NHANES, which could examine a broad range of mental and physical health outcomes in the Registry population prospectively.

WTCHP Comment

Current WTC Health Registry practices and the WTCHP Research Solicitation (PAR-16-098) address the first 3 bullets. The WTCHP is discussing the last bulleted recommendation with the WTC Health Registry staff. We are exploring the experience of the NYC HANES (Health and Nutrition Examination Survey) in terms of recruitment and statistical power.

STAC Recommendation # 2 **WTCHP Action: Agree**

Recommend that the WTCHP include the general area of childhood and adolescent physical and mental health in their requests for proposals and make this a priority for funding.

WTCHP Comment

Funding investments have demonstrated that this is a priority for funding. Current and past NIOSH/OEP WTCHP research solicitations have included childhood and adolescent research.

- Since 2012, 101 research projects have been reviewed and 33 (33%) have been funded
  - Since 2012, 14 WTC youth projects were received and 5 (36%) were funded
- Total funding for the 5 WTC Youth cooperative agreements is $8.4M (18% of total funding), # 3 in investment size, behind only Adult Mental Health (19% of total funding) and Respiratory Disease (45% of total funding)
  - Youth investment has more total funding than Cancer, CVD, Exposure Assessments, and the next 3 research outcomes combined (Autoimmune Disease, Cognitive Functioning, and Assessment of the Impact of Epidemiological Biases on WTC Research)

STAC Recommendation # 3a **WTCHP Action: Under Review**

Recommend that the WTCHP create a distinct pediatric study section under the Zadroga research funding mantle so that pediatric proposals can be reviewed by experts with appropriate expertise in environmental health of children and not compete in the review process, explicitly or implicitly, with responder proposals.

WTC Health Program Comment

Youth study proposals have been reviewed by pediatric experts since 2013, resulting in a 36% funding rate – higher than the funding rate of any other study topic. Expert peer review assesses the technical merit of the proposed methodology and whether recruitment strategies are realistic. We are looking at the review process, score differentials and the impact of multiple reviewer disciplines.

STAC Recommendation # 3b **WTCHP Action: Agree**

If a distinct pediatric study section is not created, at a minimum, we recommend that the primary and secondary reviewers in the NIOSH review process be pediatricians or other relevant health professionals with research emphasis in childhood environmental health.

WTC Health Program Comment

Pediatricians have been included in all WTCHP research scientific reviews since 2013.

STAC Recommendation # 4 **WTCHP Action: Agree**

Recommend that the WTCHP prioritize funding of pediatric research that examines a range of WTC physical health effects including respiratory illness, cardio-metabolic (including blood pressure), endocrine, neurologic, autoimmune and cancer impacts.

WTC Health Program Comment

Current WTC Health Registry practice addresses this recommendation.

All WTC Health Registry published research studies, including those focusing on cancer, overall mortality, PTSD among individuals hospitalized with cardiovascular disease, and autoimmune disease include children and children who have aged into young adults.

Please see the summary of published, current, and proposed WTC youth studies projects on pages 2 and 3.

STAC Recommendation # 5 **WTCHP Action: Agree**

Recommend that the WTCHP prioritize, to the extent possible, longitudinal studies of physical and mental health of affected pediatric populations.

WTC Health Program Comment

Please see the summary of published, current and proposed WTC youth studies projects on pages 2 and 3.

STAC Recommendation # 6 **WTCHP Action: Under Review**

Recommend that the WTCHP incentivize the creation of consortia for collaborative pediatric research.

WTC Health Program Comment

We do encourage and support researcher collaboration, as does the WTC Health Registry. The WTC Health Registry utilizes an equitable and efficient process to recruit for participants from the registrants. We also facilitate cross-fertilization among the interested researchers by doing bi-annual grantee meetings. There may be a way to utilize this platform to further incentivize collaborative efforts.

STAC Recommendation # 7 **WTCHP Action: Under Review**

Recommend that the WTCHP expedite the development of a funding opportunity for limited short-term projects that attempt cohort identification, location, and willingness to participate in studies to answer outstanding questions about whether unexamined opportunities to learn more about childhood effects of 9/11 can be addressed 15 years after the event.

WTC Health Program Comment

We are evaluating the outreach conducted by the WTC Health Registry and whether additional or different outreach strategy would be more fruitful to retain participation from registrants exposed to 9/11 as children. We are exploring the willingness of the NYC Board of Education to release information or facilitate an exploratory effort for study recruitment from 2001 rosters of school attendees in the affected area. We are also exploring whether national surveys administered by CDC might be helpful with potential recruitment options (e.g., National Health and Nutrition Examination Survey).

STAC Recommendation # 8 **WTCHP Action: Agree**

Recommend that the WTCHP encourage the use of appropriate incentives to the WTC children cohort to enhance their ongoing participation. Recommend that WTCHP require researchers provide individual study results, where appropriate, and overall study results back to study participants.

WTC Health Program Comment

Current WTCHP youth research projects do utilize incentives to increase recruitment and retention of study subjects. IRB approval is required for all proposed incentives.

All WTCHP research projects are required to disseminate study results to the public. Principal Investigators can and do provide participants with individual test results.

STAC Recommendation # 9 **WTCHP Action: Agree**

Recommend that the WTCHP support collection, bio-banking, and preservation of biological samples from WTC-exposed children using state-of-the-art methods so that biological markers of exposure, effects, and long-lasting toxins can be studied now and in the future.

WTC Health Program Comment

The WTC Health Registry has access to statewide infant blood spots that are being utilized to address this recommendation. Use of these samples is included in proposed FY 16 prenatal studies. We are exploring the experience of the NYC HANES (Health and Nutrition Examination Survey) in terms of successful recruitment and statistical power.

STAC Recommendation 10 **WTCHP Action: Agree**

Encourage the WTCHP to inform researchers about the WTCHP treatment programs and covered conditions and provide this information to study participants.

WTC Health Program Comment

The WTCHP communication staff is providing this information using a variety of unique and innovative methods.

STAC Recommendation 11 **WTCHP Action: Under Review**

Recommend that the WTCHP communicate to the health care community up-to-date WTC research findings and their implications for practice, such as through updated WTC pediatric care and treatment guidelines.

WTC Health Program Comment

We are looking into the numbers of children at-risk and whether current scientific evidence and program experience supports changes to the existing guidance issued by the NYC Department of Health and Mental Hygiene.

STAC Recommendation 12 **WTCHP Action: Under Review**

Recommend that the WTCHP conduct a formal study of missed opportunities for childhood study from 9/11, including a roadmap for the post-disaster setting about how to identify and enlist exposed childhood subsets; how to approach exposure measurement; and the nature, range, and tools to use to study health effects.

WTC Health Program Comment

We are exploring available mechanisms and authority to propose such a roadmap to guide future studies of childhood exposure in the post-disaster setting.