



January 28, 2015

Sarah Carr, Acting Director
Office of Clinical Research and Bioethics Policy
Office of Science Policy
National Institutes of Health
6705 Rockledge Drive
Suite 750
Bethesda, MD 20892

via electronic delivery to SingleIRBpolicy@mail.nih.gov

Dear Acting Director Carr:

We write in response to NOT-OD-15-026¹ and offer our strong support for the NIH draft policy to promote the use of a single Institutional Review Board (single IRB) of record for domestic sites of multi-site studies funded by the National Institutes of Health (NIH).

The LEAD Coalition is committed to accelerating the science needed to achieve the National Plan to Address Alzheimer's Disease goal number one of preventing and effectively treating Alzheimer's disease and related dementias by 2025.² We have supported increasing federal research resources, modernizing the regulatory environment, and implementing more efficient research practices and trial recruitment methods. In each area, measurable progress is being achieved through strategic collaborations, catalytic innovation, and the broadly embraced recognition that business as usual is as scientifically unacceptable as it is ethically indefensible. While not a silver bullet, we believe the single IRB policy is an important next step toward accelerated trials without compromising trial quality, ethical standards or – most important – research participant safety.

¹ <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-026.html>

² <http://aspe.hhs.gov/daltcp/napa/NatlPlan.pdf>

IRBs are essential to the clinical trial process. Assuring more consistent standards will provide greater study integrity, efficient use of finite public and private resources, and thorough protection of research participants. The single IRB policy will replace the outdated, fragmented status quo that all too often has resulted in:

- costly bureaucratic delays in study approval and start up;
- underutilization of academic research sites; and
- the unintended and counter-intuitive exclusion of people living with Alzheimer's disease and related dementias, informal caregivers and dementia research experts from local IRBs.

The single IRB policy will help enhance and accelerate research vital to addressing the current and projected health and financial threats posed by Alzheimer's disease and related dementias. Today our nation is spending more than \$150 billion annually in Medicare and Medicaid costs to care for people living with ADRD.³ Alzheimer's disease alone contributes to the deaths of approximately 500,000 Americans each year, making it the third leading cause of death in the United States.⁴ These figures will explode over the coming decades as our population ages, but a modernized and more robust research enterprise can help us prevent this future and move us closer to achieving our 2025 goal.⁵

Congress, the President and NIH Director Dr. Francis Collins have overcome enormous obstacles to increase funding and prioritization of Alzheimer's disease and related dementias research over the past several years while the Food and Drug Administration (FDA) has worked tirelessly and effectively to encourage new avenues of research with substantially clarified paths to regulatory approval. The National Institute on Aging (NIA) and other NIH institutes -- such as the National Institute of Neurological Disorders and Stroke, the National Institute of Biomedical Imaging and Bioengineering, the National Institute of Mental Health and the National Institute of Child Health and Human Development -- are supporting a number of promising research projects to: understand the genetic risk factors;⁶ address the disproportionate impact on women,⁷ African

³ <http://www.nejm.org/doi/pdf/10.1056/NEJMsa1204629>

⁴ <http://www.neurology.org/content/early/2014/03/05/WNL.0000000000000240>

⁵ <http://www.alz.org/trajectory>

⁶ <http://www.nia.nih.gov/alzheimers/publication/2012-2013-alzheimers-disease-progress-report/genetics-alzheimers-disease>

⁷ http://www.alz.org/downloads/facts_figures_2014.pdf

Americans,⁸ Hispanics,⁹ and persons with intellectual disabilities;¹⁰ and pursue cutting-edge but costly and time consuming trials aimed at preventing or substantially slowing disease progression by administering treatments much earlier in the disease process.¹¹ These resources of time, talent and treasure are precious. We owe it to the taxpayers, to the research community and – most of all – to people living with, or at risk of, Alzheimer’s disease and related disorders to apply those resources in the most efficient and ethically consistent manner possible.

The single IRB policy is an indispensable step in this direction, particularly as an increasing number of Alzheimer’s disease and related disorders trials involve multiple sites, including groundbreaking “prevention” trials that seek to determine if treatments administered when the disease is in earliest stages can slow, delay or amend its progression. Given this potential, we again offer our **strong support for the NIH draft policy to promote the use of a single Institutional Review Board of record for domestic sites of multi-site studies funded by the National Institutes of Health.**

Thank you for considering our views and for your commitment to overcoming Alzheimer’s disease and related disorders. Please contact Ian Kremer from Leaders Engaged on Alzheimer's Disease (the LEAD Coalition)¹² at ikremer@leadcoalition.org or (571) 383-9916, with questions or for additional information.

Sincerely,

⁸ http://www.usagainstalzhaimers.org/sites/default/files/USA2_AAN_CostsReport.pdf

⁹ <http://www.nhcoa.org/wp-content/uploads/2013/05/NHCOA-Alzheimers-Executive-Summary.pdf> and http://www.usagainstalzhaimers.org/sites/all/themes/alzheimers_networks/files/LatinosAgainstAlzheimers_Issue_Brief.pdf

¹⁰ http://aadmd.org/sites/default/files/NTG_Thinker_Report.pdf

¹¹ <http://www.nia.nih.gov/alzheimers/publication/2012-2013-alzheimers-disease-progress-report/advancing-discovery-alzheimers#priorities>

¹² <http://www.leadcoalition.org> Leaders Engaged on Alzheimer’s Disease (the LEAD Coalition) is a diverse national coalition of member organizations including patient advocacy and voluntary health non-profits, philanthropies and foundations, trade and professional associations, academic research and clinical institutions, and homecare, biotechnology and pharmaceutical companies. The LEAD Coalition works collaboratively to focus the nation’s strategic attention on Alzheimer’s disease and related dementias -- including vascular, Lewy body or frontotemporal dementia -- and to accelerate transformational progress in detection and diagnosis, care and support, and research leading to prevention, effective treatment and eventual cure. One or more participants may have a financial interest in the subjects addressed.

Academy of Radiology Research
ActivistsAgainstAlzheimer's
African American Network Against
Alzheimer's
Alliance for Aging Research
Alzheimer's & Dementia Alliance of
Wisconsin
Alzheimer's Drug Discovery
Foundation
Alzheimer's Foundation of America,
LEAD Coalition co-convenor
Alzheimer's Tennessee
American Academy of Neurology
American Association for Long Term
Care Nursing
American Federation for Aging
Research (AFAR)
American Geriatrics Society
American Society of Nephrology
Assisted Living Federation of America
Laura D. Baker, PhD (Wake Forest
School of Medicine*)
Banner Alzheimer's Institute
Beating Alzheimer's by Embracing
Science
Biogen Idec
Biotechnology Industry Organization
Blanchette Rockefeller Neurosciences
Institute
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BrightFocus Foundation
Caregiver Action Network

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Coalition for Imaging and
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Cure Alzheimer's Fund
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Alzheimer's Initiative
Georgetown University Medical Center
Memory Disorders Program
Gerontological Society of America
Global Coalition on Aging
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Home Instead Senior Care
Huntington's Disease Society of
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LatinosAgainstAlzheimer's
Latino Alzheimer's and Memory
Disorders Alliance
LeadingAge
Lewy Body Dementia Association
LinkedSenior
LuMind Foundation (formerly Down
Syndrome Research and Treatment
Foundation)
Mary Mittelman, DrPH (New York
University Medical Center*)
David G. Morgan, PhD (Byrd
Alzheimer's Institute, University of
South Florida*)
National Alliance for Caregiving
National Association of States United
for Aging and Disabilities
National Certification Council for
Activity Professionals
National Consumer Voice for Quality
Long-Term Care
National Down Syndrome Society
National Task Group on Intellectual
Disabilities and Dementia Practices
Neurocern
Neurotechnology Industry Organization
New York Academy of Sciences
NYU Alzheimer's Disease Center
OWL-The Voice of Women 40+
Pioneer Network

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Presence Care Project
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School*)
Taos Health Systems
The Association for Frontotemporal
Degeneration
The Eden Alternative
The Evangelical Lutheran Good
Samaritan Society
THE GREEN HOUSE® Project
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Memory Disorders Program*)
USAgainstAlzheimer's, LEAD Coalition
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Volunteers of America
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Women Against Alzheimer's

** Affiliations of individual researchers
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endorsement of the affiliated institution*