



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](mailto:SingleIRBpolicy@mail.nih.gov)***

Dear Acting Director Carr:

**We write in response to NOT-OD-15-026<sup>1</sup> 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.<sup>2</sup> 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.

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

<sup>2</sup> <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 The single IRB policy will replace the outdated, fragmented status quo that all too often has resulted in: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.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup>

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;<sup>6</sup> address the disproportionate impact on women,<sup>7</sup> African

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

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

<sup>5</sup> <http://www.alz.org/trajectory>

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

<sup>7</sup> [http://www.alz.org/downloads/facts\\_figures\\_2014.pdf](http://www.alz.org/downloads/facts_figures_2014.pdf)

Americans,<sup>8</sup> Hispanics,<sup>9</sup> and persons with intellectual disabilities;<sup>10</sup> 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.<sup>11</sup> 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)<sup>12</sup> at [ikremer@leadcoalition.org](mailto:ikremer@leadcoalition.org) or (571) 383-9916, with questions or for additional information.

Sincerely,

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<sup>8</sup> [http://www.usagainstalzhaimers.org/sites/default/files/USA2\\_AAN\\_CostsReport.pdf](http://www.usagainstalzhaimers.org/sites/default/files/USA2_AAN_CostsReport.pdf)

<sup>9</sup> <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](http://www.usagainstalzhaimers.org/sites/all/themes/alzheimers_networks/files/LatinosAgainstAlzheimers_Issue_Brief.pdf)

<sup>10</sup> [http://aadmd.org/sites/default/files/NTG\\_Thinker\\_Report.pdf](http://aadmd.org/sites/default/files/NTG_Thinker_Report.pdf)

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

<sup>12</sup> <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  
 B'nai B'rith International  
 James Brewer, M.D., Ph.D. (UC San  
 Diego and Alzheimer's Disease  
 Cooperative Study\*)  
 BrightFocus Foundation  
 Caregiver Action Network

Center for Alzheimer Research and  
 Treatment, Harvard Medical School  
 Center for BrainHealth at The  
 University of Texas at Dallas  
 Center to Advance Palliative Care  
 Sandra Bond Chapman, PhD (Center  
 for BrainHealth at The University of  
 Texas at Dallas\*)  
 ClergyAgainstAlzheimer's  
 Coalition for Imaging and  
 Bioengineering Research  
 Cognition Therapeutics  
 Suzanne Craft, PhD (Wake Forest  
 School of Medicine\*)  
 Critical Path Institute  
 Jeffrey Cummings, MD, ScD  
 (Cleveland Clinic Lou Ruvo Center  
 for Brain Health\*)  
 Cure Alzheimer's Fund  
 Darrell K. Royal Fund for Alzheimer's  
 Research  
 Department of Neurology, Washington  
 University School of Medicine  
 Rachelle S. Doody, MD, PhD (Baylor  
 College of Medicine\*)  
 Geoffrey Beene Foundation  
 Alzheimer's Initiative  
 Georgetown University Medical Center  
 Memory Disorders Program  
 Gerontological Society of America  
 Global Coalition on Aging  
 David Holtzman, MD (Washington  
 University School of Medicine,  
 Department of Neurology\*)  
 Home Instead Senior Care  
 Huntington's Disease Society of  
 America

Janssen Research & Development,  
 LLC  
 Diana R Kerwin, MD (Texas  
 Alzheimer's and Memory Disorders)  
 Walter A. Kukull, PhD (School of Public  
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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

Piramal Imaging S.A.  
 Presence Care Project  
 Peter Reed, PhD (Sanford Center for  
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 Eric Reiman, MD (Banner Alzheimer's  
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 ResearchersAgainstAlzheimer's  
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 Taos Health Systems  
 The Association for Frontotemporal  
 Degeneration  
 The Eden Alternative  
 The Evangelical Lutheran Good  
 Samaritan Society  
 THE GREEN HOUSE® Project  
 R. Scott Turner, MD, PhD  
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 Memory Disorders Program\*)  
 USAgainstAlzheimer's, LEAD Coalition  
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 Volunteers of America  
 Michael W. Weiner, MD (University of  
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 Women Against Alzheimer's

*\* Affiliations of individual researchers  
 are for identification purposes only and  
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 endorsement of the affiliated institution*