Informed Consent - Making Patient Data Count!

CAMD Informed Consent Working Group
Co-Chairs: Penny Dacks (Alzheimer’s Drug Discovery Foundation) and Ann Marie Hake (Eli Lilly)

Penny Dacks, PhD (Alzheimer’s Disease Discovery Foundation)
Monica Moreno (Early-Stage Initiatives, Alzheimer's Association)
# INFORMED CONSENT WORKING GROUP MEMBERS

<table>
<thead>
<tr>
<th>Member</th>
<th>Organization</th>
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<tbody>
<tr>
<td>James Hendrix</td>
<td>Alzheimer’s Association</td>
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<td>Penny Dacks</td>
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<td>Karen Friedman</td>
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<td>Mark Gordon</td>
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<td>Dagmar Theis</td>
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<td>Debra Lappin</td>
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<td>Ann Marie Hake</td>
<td>Eli Lilly &amp; Co.</td>
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<td>Karina Bienfalt</td>
<td>Merck &amp; Co.</td>
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<td>Rachel Ennis</td>
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<td>Lisa Gold</td>
<td>Merck &amp; Co.</td>
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<td>Richard Meibach</td>
<td>Novartis</td>
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<td>Elizabeth Ashford</td>
<td>Roche</td>
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<td>John Wilbanks</td>
<td>Sage Bionetworks</td>
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<td>George Vradenburg</td>
<td>USAgainstAlzheimersDisease</td>
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Sharing Clinical Trial Data
Maximizing Benefits, Minimizing Risk

Recommendations

- “provide ... templates for informed consent for participants that enable responsible data sharing;”
- “explain to participants during the informed consent process ...
  - the potential risks to privacy associated with the collection and sharing of data ... and a summary of the types of protections employed to mitigate this risk, and
  - under what conditions the trial data may be shared (with regulators, investigators, etc.) beyond the trial team; ...”
Informed-consent documents “are too long, too complicated, and filled with legal text designed more to protect institutions than participants.”
INFORMED CONSENT

Objectives

• Draft an Informed Consent template that enables access of anonymized patient-level data and samples
• Incorporate patient perspectives
• Frame the rationale and disseminate the template through editorial in an impactful journal
• Initial focus is on a US-centric statement; a secondary objective will be the global approach
• Integrate into future clinical trials (1Q2017)

January 2016

Assemble limited duration working group

March 2016

Leverage expert opinions from industry, patient advocacy groups and Sage Bionetwork’s “consent” experience

April/September 2016

Draft/Refine/Test informed consent statement for patients and caregivers

4Q 2016

Gain CAMD Coordinating Committee endorsement, share with C-Path Consortia and publish Editorial

www.c-path.org/camd
INFORMED CONSENT ENABLEMENT
FULL DOCUMENT

Overview

• The information collected in this study will be used to:
  o see if the study drug works and is safe;
  o compare the study drug to other potential or approved therapies;
  o examine the relationship of the data and samples to that of other diseases;
  o develop new tests;
  o improve the design of future studies;
  o advance the understanding of health and disease;
  o accelerate other activities (e.g., creation of clinical tools that improve the delivery of innovative treatments by advancing basic and regulatory science).

• You will not be identified in any publication from this study or in any data files shared with other researchers. Your identity will be protected as required by law.

• When the information from this study is shared outside the study site, the information that identifies you will be removed. In addition, the Sponsor, like other Sponsors, provides access to clinical data that has been further de-identified so that outside researchers can use this data. Information that could directly identify you will not be included.
INFORMED CONSENT ENABLEMENT

FULL DOCUMENT -continued

Your Rights: Data & Samples

• You have the right to decide whether to participate in the study. If you decide to participate in the study, the following are groups with whom your study team may share your data and samples to improve new treatments or the conduct of clinical trials:
  o Health authorities throughout the world (e.g., Food and Drug Administration (FDA), European Medicines Agency (EMA) and other governing bodies that review clinical trials);
  o Institutions Review Boards (IRBs) that oversee, and review the ethics of the research;
  o The study Sponsor, and those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries;
  o Other groups: Examples of which include academic, government or industry researchers, public-private partnerships, and/or external research collaborations. These entities will have oversight committees that will supervise the ethical use of the data and samples.
• At no time will the data or samples be allowed to be sold by an individual or group for profit.
• Your data and samples will be de-identified or anonymized. This means that your data or samples will not be linked with information that would allow any person or organization to determine that the data directly corresponds to you.
• The health information you contribute will be protected by U.S. federal law (the Health Information Portability and Accountability Act).
• New results obtained with your data and samples will be reported back to the sponsor, and the results made publically available.
• You have the right to withdraw your permission for us to use or share your information up until the time that your data and samples are de-identified and pooled together into a database. Your data and samples will be used and shared as described in this form.
INFORMED CONSENT ENABLEMENT

FULL DOCUMENT -continued

Potential Benefits & Risks

Benefits

Allowing your de-identified data and samples to become available to research and regulatory organizations could advance new treatments. By giving approval now for your data and samples to be shared for research purposes, your valuable contributions have the best chance to be used as effectively as possible for research not only today, but also in the future as new research questions and technologies emerge.

Risks

Your de-identified or anonymized data may be shared for research purposes. Because your data and samples are de-identified (anonymized), the potential is extremely small that a person or organization could determine that it belongs to you. However, anonymity cannot be absolutely guaranteed. Experts in re-identification may in very rare cases be able to reverse the processes used to protect your identity and confidentiality.

Withdrawal of Consent

I understand I can withdraw permission to collect data/samples at any time but data already collected and pooled into the database will continue to be used. The study doctor/staff will discuss this with you.

Consent

I give permission to use and share my data and samples as described in this document.
2. SHORT VERSION (TO EXPAND FUTURE USE OF DATA & SAMPLES)

Use of Data and Samples for Additional Research Outside of this Clinical Trial

Your Rights: Data & Samples

• You have the right to decide whether to participate in the study. If you decide to participate in the study, the following are groups with whom your study team may share your data and samples to improve new treatments or the conduct of clinical trials:
  o Health authorities throughout the world (e.g., Food and Drug Administration (FDA), European Medicines Agency (EMA) and other governing bodies that review clinical trials);
  o Institutions Review Boards (IRBs) that oversee, and review the ethics of the research;
  o The study Sponsor, and those working for or with the Sponsor, which may include affiliates of the Sponsor located in your country or other countries.
  o Other groups: Examples of which include academic, government or industry researchers, public-private partnerships, and/or external research collaborations. These entities will have oversight committees that will supervise the ethical use of the data and samples.
• Your data and samples will be de-identified or anonymized. This means that your data or samples will not be linked with information that would allow any person or organization to determine that the data directly corresponds to you.

• The health information you contribute will be protected by U.S. federal law (the Health Information Portability and Accountability Act).

• New results obtained with your data and samples will be reported back to the sponsor, and the results made publically available.

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Consent

I give permission to use and share my data and samples as described in this document.
Informed Consent: The Patient Perspective

Monica Moreno
Director, Early-Stage Initiatives
National Early-Stage Advisory Group

Advance the cause of Alzheimer’s through:
- Awareness Initiatives
- Advocacy
- Programs

Role:
- Spokesperson
- Advisor
- Presenter/Keynote speaker

Commitment:
- One year term
Raising Concern and Awareness

“A Devastating Diagnosis”

“Sandy’s Story” is an unprecedented look at the rare journey of a vibrant, once healthy man as he gradually loses his memory. Sandy Weisbach, a dentist and married assistant professor, was diagnosed with early stage Alzheimer’s disease at age 60. Instead of giving up in the face of his diagnosis, he’s fighting back. This is the first chapter of his journey.

By Stephanie Smith, CNN Photograph by John Novak, CNN

Thank you thank you very very much for EVERYTHING. Love you so much. Julie.

Julianne Moore’s text to Sandy Oltz

“It has the experience of a leader and the patience of a mother. It has lived through injustice but it lives for each moment.”

alzheimer’s association

THE BRAINS BEHIND SAVING YOURS:
National ESAG Media Placements
# ESAG Engagements

<table>
<thead>
<tr>
<th>Appointments</th>
<th>Provided Comment On</th>
<th>Presentations</th>
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<tbody>
<tr>
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<td><strong>Behavioral Risk Factor Surveillance System (BRFSS)</strong></td>
<td><strong>Social Security Administration (SSA)</strong></td>
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<td>Representative Program</td>
<td><strong>Shared Decision Making Tool (AAN)</strong></td>
<td><strong>FDA</strong> Division of Neurological &amp; Physical Medicine Devices</td>
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<td><strong>Practice Guideline on the Use of Antipsychotics to Treat Agitation &amp; Psychosis in Patients with Dementia (APA)</strong></td>
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<td><strong>Office of Minority Health</strong> Bilingual Twitter Chat: Latino’s and Alzheimer’s disease (Hispanic Heritage Month)</td>
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<td>Research, Care and</td>
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<td><strong>Society for Nuclear Medicine &amp; Neuroimaging (SNMMI)</strong></td>
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<td><strong>American Society of Neuroradiology (ASNR)</strong></td>
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<td>Engagement Advisory*</td>
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Informed consent review

• 2016 ESAG
  – Dx:
    • Alzheimer’s, Lewy Body Dementia, MCI
  – Age: 52 to 81
• Discussion held at in-person meeting in Chicago, IL
• Conference call with nine care partners
Informed consent discussion

Overall participants enthusiastically supported the development of a consent form as a necessary document to further clinical trial research through collaboration.

- “To me this is a no brainer. I am just learning now that this data was tossed out the window. I am shocked.”

- “I am getting emotional. It makes me angry to think that they could be using this [data] to find a cure.”
Informed consent discussion

Agreement among both groups that the gains for the future sharing of critical patient level information and accompanying samples outweigh any potential risks

“You always run a risk that your data or info will escape, but if it will further the cause of finding a cure/treatment, I think the benefit outweighs the risk”
Withdrawal of consent

Consensus among individuals living with dementia and care partners:

Withdrawal of consent would only be effective at the time of the request and any information from the data/samples already shared would not be eligible for withdrawal.

“Because of the nature of this disease, if I don’t remember everything I signed, yet I knew I wanted this at the time, I don’t want someone (POA) to change this decision.”
Informed consent - Primary concerns

• Ethical standards
• Protection of identity
• Protection from samples/data being sold for economic gain by individual or company
• Building trust among minority groups

“I don’t think anyone protects information better than an ethical research organization.”
Importance of engaging people living with the disease

Understanding the experience of those living with Alzheimer’s disease is paramount to:
– developing more effective treatment strategies
– offering effective care and support programs
– learning how to better enhance quality of life
– meet the needs present today
– prepare for the needs of those not yet affected
Thank you!

Monica Moreno
mmoreno@alz.org

Monica Moreno
Director, Early Stage Initiatives
INFORMED CONSENT WORKING GROUP
SUMMARY (US-Centric):

- Identification of Working group Co-Chairs (April 18, 2016 meeting)
- Have John Wilbanks frame eConsent and the work that Sage BioNetworks has initiated (March)
- Convened a focus meeting (1/2 – full day) to develop a draft informed consent document (April 18, 2016)
- Complete draft with feedback from members legal departments (June 17, 2016) & receive input from PWD and their Caregivers (August)
- Gain Coordinating Committee endorsement to integrate into future clinical trials October 5, 2016
- Frame the rationale for improving informed consent and disseminate the template through an editorial in a prominent journal
- Submit by end of 4Q16
DRAFT INFORMED CONSENT STATEMENT

Next Steps:

• Create Editorial (November).

• C-Path Consortia interested in reviewing (November):
  o CPP – Critical Path for Parkinson’s
  o MSOAC – Multiple Sclerosis Outcome Assessment Consortium
  o D-RSC – Duchenne - Regulatory Science Consortium
NEXT STEPS

Develop Ex-US version (2017)

1. (1Q17) Have Alzheimer’s Disease International provide feedback on the US-centric document to gauge potential challenges
2. If encouraging, proceed with Ex-US version
3. If not, revisit the what would provide the best return on investment of time & effort
Retrospective Reviews on Informed Consent

If participants were not informed about data-sharing, what would they assume?

- “Must respect the ‘spirit of the informed consent’ as seen through the eyes of the participant – What would a reasonable person assume?” IOM Presentation by Pearl O’Rourke, Partners HealthCare

- A patient perspective: “To me this is a no brainer. I am just learning now that this data was tossed out the window. I am shocked.”

- “There is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk.” International Committee of Medical Journal Editors (ICMJE), Taichman et al., JAMA, February 2016
Thank you!

www.c-path.org/camd