Preclinical Alzheimer Disease and the Electronic Health Record: Balancing Confidentiality and Care

Author(s):
Seth A Gale, M.D. 1; Judith Heidebrink, M.D. 2; Joshua Grill, PhD 3; Jonathan Graff-Radford, MD 4; Gregory A. Jicha, MD, PhD 5; William Menard, B.A. 6; Milap Nowrangi, M.D. 7; Susie Sami, M.A. 8; Shirley Sirivong, B.A. 9; Sarah Walter, MSc 10; Jason Karlawish, M.D. 10

Corresponding Author:
Seth A Gale, sagale@bwh.harvard.edu

Affiliation Information for All Authors: 1. Department of Neurology, Center for Brain/Mind Medicine, Brigham and Women’s Hospital, Harvard Medical School, Boston, MA; 2. Department of Neurology, The University of Michigan, Ann Arbor, MI, USA; 3. Institute for Memory Impairments and Neurological Disorders, University of California Irvine; 4. Department of Neurology, Mayo Clinic, Rochester, MN, USA; 5. Department of Neurology, Sanders-Brown Center on Aging, University of Kentucky; 6. Memory and Aging Program, Butler Hospital; 7. Division of Geriatric Psychiatry and Neuropsychiatry, Department of Psychiatry, Johns Hopkins University School of Medicine; 8. Brain Health and Memory Center, University Hospitals, Cleveland Medical Center; 9. Alzheimer’s Therapeutic Research Institute, University of Southern California; 10. University of Pennsylvania, Departments of Medicine, Medical Ethics and Health Policy, and Neurology; Penn Memory Center.

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-NoDerivatives License 4.0 (CC BY-NC-ND), which permits downloading and sharing the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

Neurology® Published Ahead of Print articles have been peer reviewed and accepted for publication. This manuscript will be published in its final form after copyediting, page composition, and review of proofs. Errors that could affect the content may be corrected during these processes.
Abstract:
As information technologies are increasingly employed to improve clinical research and care, personal health information (PHI) has wider dissemination than ever before. The 21st Century Cures Act in the U.S. now requires patient access to many components of the electronic health record (EHR). While these changes promise to enhance communication and information sharing, they also bring higher risks of unwanted disclosure, both within and outside of health systems. Having preclinical Alzheimer disease (AD), where biological markers of AD are identified before the onset of any symptoms, is sensitive PHI. Because of the melding of ideas between preclinical and “clinical” (symptomatic) AD, unwanted disclosure of preclinical AD status can lead to personal harms of stigma, discrimination, and changes to insurability. At present, preclinical AD is identified mainly in research settings, though consensus criteria for a clinical diagnosis may soon be established. There is not yet adequate legal protection for the growing number of individuals with preclinical AD. PHI generated in preclinical AD trials has clinical significance, necessitating urgent evaluations and longitudinal monitoring in care settings. AD researchers are obligated to both respect the confidentiality of participants’ sensitive PHI and facilitate providers’ access to necessary information, often requiring disclosure of preclinical AD status. The AD research community must continue to develop ethical, participant-centered practices related to confidentiality and disclosure, with attention to sensitive information in the EHR. These practices will be essential for translation into the clinic, and across health systems and society at large.

Years before the symptomatic stages of mild cognitive impairment (MCI) or dementia, the pathologic changes of Alzheimer disease (AD) -- the most common cause of these syndromes -- appear and can be detected using biological marker (biomarker) tests. Discoveries of molecular brain imaging and cerebrospinal fluid and plasma assays are revolutionizing the definition of AD. The field is moving toward an entirely biological framework, where diagnoses will likely involve determining sequential, pathologic changes of amyloid, tau, and neurodegeneration (ATN)\(^1,2\). Preclinical AD describes a stage where biomarkers indicate the diagnosis of AD in the absence of symptoms\(^3,4\). Preclinical AD could be understood as an early disease, even as health systems, patients, and society begin to embrace it as an asymptomatic stage.

Preclinical AD, while distinct from symptomatic stages, can be thought of as the start of the AD continuum. Diagnosing preclinical AD is not presently standard of care in clinical practice. Ongoing research seeks to define predictors and discover treatments to slow disease progression. At present, obtaining CSF and PET scans for evaluating AD biomarkers in cognitively normal individuals is primarily limited to the context of clinical research. AD biomarker tests have been essential in determining eligibility for secondary “prevention” trials, where results that suggest a risk of developing symptoms are used as inclusion criteria\(^5,6\).

As long as preclinical AD remains a research and not a clinical construct, researchers, providers, and patients-as-participants face a set of complex, ethically charged opportunities and challenges. Many of these relate to the recording of research results in electronic health records (EHR).

Opportunities and Risks with the Electronic Health Record (EHR) in preclinical AD trials
EHRs and Preclinical AD trials

Electronic Health Records are increasingly used to systematize the collection of patient health information in a digital format. EHRs have a similar utility in research. In conjunction with clinical trial management systems (CTMS) and other platforms in research, EHRs can facilitate scheduling, organize study visits, execute study procedures, and acquire and view study data.

The EHR is the main digital interface with the health system used by preclinical AD research teams for both observational and interventional trials. Researchers can order study tests, such as brain MRI and PET scans, through the EHR. Depending on the parameters for EHR access, these orders and test results may be viewable in the EHR. In preclinical AD drug trials, for example, the EHR may be used for the ordering and administration of the research drug. Research-equipped pharmacies and study teams rely on the EHR to place drug orders, verify order accuracy by multiple parties, and execute and document drug administration protocols. Even more routine study visits, inclusive of physical exams or interviews, may require scheduling through an EHR and uploading of a participant’s informed consent documents.

The EHR provides at least three opportunities for research. First, it creates a single platform to be the “container” of all personal health data within a health system, whether from care or research. This centralization of data allows for easy accessibility and cross-utilization between providers and researchers. For example, a subset of investigational AD drugs can cause side effects, such as amyloid-related imaging abnormalities (ARIA) detected on MRI. Since ARIA can have both immediate and longer-term implications for care, access to a research MRI could be clinically actionable in both emergent and non-emergent scenarios. Notably, observational studies may generate less clinically actionable information than interventional trials, each with potentially different needs to facilitate access to providers. Second, the use of an already-deployed clinical EHR for preclinical AD trials is often more cost-efficient and feasible for a research site than establishing a separate, research-only digital platform. Finally, integrating preclinical AD research into the EHR is an opportunity for the AD research community to be part of the larger effort toward patient-oriented clinical research and person-centered care. This is a shift that will require ongoing re-evaluation of the more traditional ways that researchers, clinicians, and patient-participants view separations between research and care activities.

OpenNotes, The 21st Century Cures Act, and AD biomarker disclosure

Recent legislation presents a challenge to using the EHR for research. In the U.S. for example, since April 2021, the 21st Century Cures Act requires patient access to 8 types of clinical notes. Efforts supported by the international OpenNotes movement have already led to ready access to personal EHR data for an estimated 50 million individuals in the U.S. and Canada. Across the world, research to better understand stakeholders’ perspectives on, and sociocultural and legal implications of, patient access to EHRs is underway, including in Scandinavia, Japan, and Chile, among other regions and countries. Allowing patients access to their health information facilitates patient autonomy but also challenges traditional communication regarding care, especially in the delivery of AD biomarker test results. Historically, disclosure of this type of information, such as a radiology result that indicates a tumor, has been clinician-mediated, providing time to ensure education and contextualized understanding of the results. With legal requirements to allow individuals immediate access to their EHR, it is a reality that AD biomarker results may sometimes be viewable without concurrent clinician counseling. When disclosure occurs without clinicians, risks for negative outcomes are likely greater. Added research will be needed to instruct opportunities to streamline disclosure processes, including opportunities to reduce or perhaps someday eliminate the role of the clinician. Relatedly, data like research MRI reports that are
viewable by patient-participants in the EHR and include findings of a drug’s adverse effects risk unblinding the participant.

While EHRs present opportunities to enhance coordination and efficiency in research and patient-centered integration of research and care, their use also poses risks to the security and privacy of health information.

**Disclosure of sensitive information**

The harms of unwanted disclosure of personal identifying information in the EHR are amplified when the health information is considered sensitive. In the US, for example, the federal Health Insurance Portability and Accountability Act (HIPAA) treats all identifiable health information as sensitive and equally deserving of protection under its Privacy Rule, although individual States and health systems have historically treated data as more sensitive when it poses high personal risks, including mental health and genetic information. These risks are not speculative, and include stigma and discrimination. Each of these risks are relevant to disclosure of AD biomarker results for preclinical AD.

Study participants with preclinical AD are generally concerned about the confidentiality of written research records and these concerns are magnified with EHRs, given the greater accessibility and therefore greater risk of unwanted disclosure. Research information revealing preclinical AD status can enter the EHR through several means. For example, biomarker status might be included in the narrative of progress notes or be written directly on a study consent form that is uploaded to the EHR. Preclinical AD trial titles often include terms like “Alzheimer disease” or “preclinical Alzheimer disease”. Despite some EHR system-based measures to minimize access to information by non-study-team users, like masking information behind a digital research “flag” (indicator), AD biomarker status might be revealed through the title of the study on the flag or through a hyperlink to the title.

**Risks of Stigma, Discrimination, and Change to Insurability**

While preclinical AD trials bring novel scientific opportunities, they also bring novel risks. The defining biomarkers for both preclinical AD and “clinical” (symptomatic) AD are the same. This heightens the risk that an AD biomarker result will be erroneously equated with clinical AD. Even if the biomarker results are inaccessible, simply disclosing through the EHR that a participant is enrolled in a study that references AD may create confusion that the individual suffers from cognitive impairment or dementia.

Biomarker results could also be misinterpreted as signifying inevitable and severe decline. This in turn may lead to stigma whereby people stereotype, patronize, or avoid individuals with preclinical AD. Personal and social consequences of stigma can include social withdrawal, interpersonal stress, depression, and threats to personal identity, such as loss of dignity. The stigma attached to AD seems mainly to be a consequence of the public’s expectation of its prognosis as terminal and as inextricably linked to profound disability. Discriminatory behavior in health care settings has included, for example, family physicians keeping “professional distance” from those with AD by avoiding treatment, resulting in poor communication about symptoms, therapeutic nihilism and feelings of helplessness.

Finally, unwanted disclosure of preclinical AD biomarkers could lead to discrimination by insurers, particularly long term care insurers, because these individuals may be more likely than persons without biomarkers to need long term care services and supports. Laws governing the privacy
and security of personal data, including health information, are different around the world, with varying regulations on data disclosure and impacts on the individuals’ rights. The European Union’s (EU) General Data Protection Regulation (GDPR) law for example, implemented in 2018, requires organizations to obtain “explicit consent” from “data subjects” for the processing of any personal health data; compliance has presented challenges for insurance carriers. The GDPR also affirms many individual rights, including the right to access one’s medical record when “data is being processed”, even while “data controllers” in the EU can limit this right in certain circumstances and access does not have to be free of charge nor provided immediately (“without delay”), as is required by the 21st Century Cures Act in the U.S. Further, the GDPR does not establish a framework to prevent discrimination resulting from the processing of personal data. Brazil’s Lei Geral de Proteção de Dados (LGPD) law and South Africa’s Protection of Personal Information Act (POPIA), both implemented in 2020, provide a similar legal framework as the GDPR and, equally do not address the mitigation of potential harms stemming from sharing of personal health information.

In the U.S., current laws also do not provide meaningful protection from discrimination by long-term care insurers based on biomarker information, even though there are protections against discrimination based on genetic information. There are legal protections in place to protect sensitive information broadly in publicly funded research but the reality of this protection is less clear. As of 2017, all participants in biomedical research that is funded even partially by the NIH are covered by a Certificate of Confidentiality (CoC). The CoC attests that disclosure of names or any information, documents, or biospecimens to anyone not connected to the research is prohibited. It does permit disclosure in certain circumstances, including when it is “necessary for the medical treatment of the individual, with consent”. Researchers can request a CoC from NIH for health-related studies that are not funded by NIH or another HHS agency. Obtaining a CoC and informing research participants about its protections reflects a person-centered approach to research. A CoC can also serve as a legal buttress to help ensure institutional support to secure protection of sensitive information within a local IT/EHR infrastructure. In sum, individuals with preclinical AD could experience various unintended harms associated with a disease they are at risk for developing but do not have.

The ethical issues involved with biomarker disclosure in preclinical AD

Researchers conducting preclinical AD trials face ethical issues related to disclosure and confidentiality. Basic principles to provide a framework for AD researchers to understand their obligations and enact practical measures include the respect for participants’ autonomy and welfare.

An overarching ethical principle to guide researchers in their responsibilities to individual participants is “respect for participants” or “respect for persons”. This principle has mostly been centered on the recognition of individuals’ autonomy regarding all aspects of study participation. Investigators should consider individual dignity, integrity, privacy, and vulnerability, of research participants. Researchers have an obligation to respect participants’ autonomy in decisions that relate directly to and stem from their study participation.

Respect for autonomy involves deferring to participants’ informed decision to not enroll in a study when the personal risks outweigh the study’s potential benefits. Informed consent by trained researchers, for example, must address any biomarker or genetic risk information that will be disclosed with enrollment. This includes a contextualized discussion of potential risks to psychological health with attainment of this knowledge as well as disease risk implications for genetic relatives. In preclinical AD clinical trials, there is rarely an option to enroll but “not to know”;
at least one ethical analysis has not supported the need for blinded enrollment. Regarding data privacy and security, researchers themselves must have detailed knowledge of the data processing and storage plan. Consented participants should be able to understand precisely how personal data will be used, where it will be stored, who it will be shared with now and in the future, and how it will be accessed. Conceivably, within the limits of an EHR’s functionality, participants could dictate what kind of users (e.g., only study team personnel; only pre-identified medical care providers) they are comfortable with having access to sensitive information. Alternatively, the research teams’ approach and the extent to which they and the institution can protect participants’ sensitive health information within the EHR should be presented through the informed consent process and documented in the consent form. Importantly, participant engagement in preferences about methods of privacy protection does not alleviate an institution from its overall responsibility to make all efforts to protect confidential information.

Respect for participants’ overall welfare and wellbeing entails beneficence by actions to avoid individual harms and to maximize benefits. Individual harms related to knowledge of preclinical AD status include potential disclosure outside of the research team. Consent forms should describe the specific, predictable study situations where care providers would be optimally served by accessing the participant’s research data. Examples include acute medical situations, particularly ones with direct neurologic care implications and when participants are emergently ill with limited capacity. Non-study clinicians such as emergency providers should have immediate access to relevant trial data (e.g., MRI images with known prior abnormalities, or the mechanism of action of investigational drugs). In this conception of welfare, the protection of a participant’s safety and allied efforts to ensure optimal medical outcomes from research over time become more important than protecting sensitive information from unwanted disclosure.

Respect for participants’ welfare and wellbeing also includes protecting an individual’s privacy by keeping sensitive information confidential. Given the risk of melding ideas about clinical AD with preclinical AD and so the potential for stigma and discrimination, steps should be taken to keep preclinical AD status confidential from everyone except providers who may need relevant information to address urgent medical concerns.

Recommendations for Preclinical AD and the EHR

EHRs differ across research institutions. Equally, there are differences in institutional policies on the management of electronic research and clinical data and protection of sensitive personal information. In multi-center trials, the risks of unwanted disclosure may be magnified, as centers’ different EHRs may be governed by dissimilar protection practices, impacting disclosure risks when data is accessed centrally. Risks also accrue if robust security measures are not in place for the data platforms themselves, including for hyperlinks within the EHR to external databases. While these factors make it difficult to offer broad, technically detailed, EHR-specific recommendations, there are general strategies to apply to local systems to enhance the protection of sensitive information. This work should consider the specific types of information in preclinical AD research (i.e., brain MRI images, AD biomarker results, study title) as these carry different levels of risk with unwanted disclosure. These differences in the risk of harm from specific data are relevant to researchers and their IT teams, as it may be necessary to prioritize which data to segment or to focus security measures on if there is limited feasibility to make technical modifications to an employed EHR. Ideally, developing a “Best Practices”, reasonable use framework for protection of sensitive research information is the goal. Such a model will, ultimately, guide how best to protect sensitive AD-related information in clinical care.
Competing interests are noted. These include protecting the privacy of research participants and sensitive health information and making clinically relevant research information available to providers who are caring for these persons. Several strategies are available to enhance protection of confidentiality and enable selective access to sensitive information outside of research. Guidelines about how to manage specific types of preclinical AD research data (i.e., prioritizing what to exclude from the EHR given associated risks of potential harms to participants) may be helpful to researchers.

**EHR strategies: Enhancing Protection of Sensitive Information**

Three, broadly presented EHR strategies can increase protection of sensitive preclinical AD research information. See Table 1 for a summary.

1. Institutions could create an EHR for research information with distinct users that is entirely separate from the clinical EHR. In this case, there should be a simple indication in the individual’s clinical EHR that: a) the person is enrolled in a study, with the study team’s contact information, but without study title or any details, and b) that should care questions arise, the study team may be contacted to provide immediate information or access.

2. Institutions could dissociate research from clinical information within the same EHR, with a focus on separating the specific, sensitive research information that carries the greatest risk with unwanted disclosure (e.g., a study title which includes “Alzheimer disease”; amyloid PET imaging results; see Table 2 below).

3. With a single clinical/research EHR, institutions could implement access control measures for predetermined, sensitive research data that dissuade or prohibit easy access for typical EHR users. These so-called “break the glass” or similar features can act as either an impenetrable firewall or an interface that requires user-input justification for tracking when accessing specific data elements. Access control systems are already used in some systems to limit and digitally track or prohibit access for certain records, such as those with mental health information or those of an institutions’ employees.

**Specific Preclinical AD data**

The likelihood and magnitude of harms from unwanted disclosure of preclinical AD research information varies depending on the kind of information (see Table 2). For example, there is generally low risk of harm should brain MRI images, that include only their date of acquisition and that they were acquired “for research”, be disclosed. On the other hand, images accompanied with radiology reports that often include the study title, and thus terms like “Alzheimer disease” or “Preclinical Alzheimer disease” carry significantly higher risk of a larger, negative impact. These disease labels are also not essential to fulfill obligations to participant welfare and safety. In emergent care scenarios, the unlabeled research data is what is relevant for treating clinicians. Additional information, like potential interpretations of MRI findings given the study drug or procedures, could be provided directly and swiftly by the study team to clinicians, outside of the EHR.

Broadly speaking, narrative description of Alzheimer pathology or any mention of “Alzheimer disease” in the EHR is more likely than raw research data, like MRI images or the numeric values of spinal fluid proteins, to divulge preclinical AD status.
To guide the implementation of privacy measures in the EHR, specific types of preclinical AD research data can be categorized into “low risk” or “significant risk” if included in the EHR. Table 2 provides a summary of these data types and categories. While a basic assumption here is the use of an all-access, combined clinical/research EHR, these recommendations are relevant to any of the 3 EHR strategies mentioned above (and in Table 1).

Beyond the EHR: The AD Continuum and Clinical Care

The biomarker revolution in defining AD holds great promise and brings new challenges. Advances in AD diagnostics and therapeutics, along with biomarker-supported, predictive models of progression through the AD continuum, will continue to erode the separation between preclinical and clinical AD even further. Indeed, as preclinical AD enters clinical practice, the term may be retired. Identifying AD biomarkers in individuals without symptoms is already occurring in clinical care, and its scale will increase over time with the arrival of blood-based AD biomarkers. Our systems of research protections must continue to adapt.

Researchers and supporting institutions who conduct studies in AD, including preclinical AD, have been charting new territory as they balance protection and disclosure of sensitive AD-related information. Inherent to this practice has been navigating the ethical obligations to patient-participants in biomarker disclosure and subsequent decision-making. Efforts to develop ethical, patient-oriented research/clinical electronic interfaces seem especially important moving forward. We know that emerging AD therapeutics will have non-trivial side effects that will require easy access to clinical data and ongoing monitoring. Similarly, we anticipate that new medications and interventions meant to delay symptomatic disease will require intervention years before symptoms develop.

In this new era of earlier AD diagnoses, potentially disease-modifying treatments, and greater numbers of individuals in clinical care at every stage in the AD continuum, interactions between providers, patients, the health system, and society will be increasingly tested. Even with challenges as the field moves forward, however, the AD research community at this moment is well-positioned to continue to improve ethical, effective practices related to confidentiality and disclosure, and to help guide the translation of experiences into the clinic and community.
### Table 1: Three EHR strategies to enhance protection of sensitive research information

<table>
<thead>
<tr>
<th>Type of research information</th>
<th>Specific component of the information</th>
<th>Inclusion/exclusion in EHR?</th>
<th>Rationale</th>
</tr>
</thead>
</table>
| Progress (narrative) notes   | A “flag” indicating research participation *with no other study-revealing information* | ✓ | • Study titles typically include the term ‘preclinical AD’ (or ‘AD’), disclosing sensitive biomarker status and/or potential for unwanted association to AD  
• The “flag” and study team contact information allow for access to study information when needed for relevant care or with participant permission |
| Informed consent form (ICF)  | Copy of the signed ICF | ✗ | • Consent forms include study titles, name of study drug/intervention, and key enrollment criteria (often AD biomarker status)  
• Verification of consent that procedures can be handled without risking inadvertent disclosure of sensitive information, e.g., through masked research documents, shared access outside of the EHR, or “hard-copy” documentation provided by study team |
| AD genetic testing           | Date genetics samples obtained      | ✗ | • Results are not immediately, clinically actionable  
• Disclosure outside of strict protocols developed to maximize participant comprehension and minimize negative consequences carries risk of negative psychological reaction and stigma.  
• Unwanted disclosure of genetic results may also have risks for biological family members. |
| Brain MRI scans              | Date MRI conducted for research     | ✓ | • Clinical EHR users should be able to view research MRI images, even if their interpretations may not reflect comprehensive knowledge of the research; scans may identify abnormalities that impact care decisions in emergent settings  
• Avoiding the terms AD or references to preclinical AD in the reports or requisitions for test is essential to protect participant confidentiality |
|                             | Viewable images                     | ✓ | |
|                             | Radiology report or clinical interpretation *with no reference to AD or preclinical AD* | ✓ | |
|                             | Stated reason for MRI other than simple statement of “research purposes” | ✗ | |
| Brain FDG-PET scans         | Date PET/CT conducted for research  | ✓ | • Disclosure of results should happen following strict protocols developed to maximize participant comprehension and minimize negative consequences  
• For individuals without symptoms, viewing images |
<p>|                             | Scan (image files)                  | ✗ | |</p>
<table>
<thead>
<tr>
<th>Type of research information</th>
<th>Specific component of the information</th>
<th>Inclusion/exclusion in EHR?</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiology report or clinical interpretation</td>
<td>Date PET conducted for research</td>
<td>✓</td>
<td>Disclosure of results should happen following strict protocols developed to maximize participant comprehension and minimize negative consequences.</td>
</tr>
<tr>
<td></td>
<td>Scan (image files)</td>
<td>✗</td>
<td>For individuals without symptoms, viewing images would not directly impact clinical care.</td>
</tr>
<tr>
<td></td>
<td>Radiology report or clinical interpretation</td>
<td>✗</td>
<td>Inclusion of scan date may have clinical relevance regarding radiation exposure for individuals with other research/clinical exposures.</td>
</tr>
<tr>
<td>Amyloid PET scans (AD biomarker)</td>
<td>Date PET conducted for research</td>
<td>✓</td>
<td>Disclosure of results should happen following strict protocols developed to maximize participant comprehension and minimize negative consequences.</td>
</tr>
<tr>
<td></td>
<td>Scan (image files)</td>
<td>✗</td>
<td>For individuals without symptoms, viewing images would not directly impact clinical care.</td>
</tr>
<tr>
<td></td>
<td>Radiology report or clinical interpretation</td>
<td>✗</td>
<td>Inclusion of scan date may have clinical relevance regarding radiation exposure for individuals with other research/clinical exposures.</td>
</tr>
<tr>
<td>Tau PET scans (AD biomarker)</td>
<td>Date PET conducted for research</td>
<td>✓</td>
<td>Disclosure of results should happen following strict protocols developed to maximize participant comprehension and minimize negative consequences.</td>
</tr>
<tr>
<td></td>
<td>Scan (image files)</td>
<td>✗</td>
<td>For individuals without cognitive symptoms, viewing images would not directly impact clinical care.</td>
</tr>
<tr>
<td></td>
<td>Radiology report or clinical interpretation</td>
<td>✗</td>
<td>Inclusion of scan date may have clinical relevance regarding radiation exposure for individuals with other research/clinical exposures.</td>
</tr>
<tr>
<td>CSF tests (AD biomarker)</td>
<td>Date lumbar puncture conducted for research</td>
<td>✓</td>
<td>Disclosure of results should only be done following strict protocols developed to maximize participant comprehension and minimize negative consequences.</td>
</tr>
<tr>
<td></td>
<td>AD protein analysis results</td>
<td>✗</td>
<td>The specific test results (levels/ratios of proteins) would not impact clinical care.</td>
</tr>
<tr>
<td></td>
<td>Dates samples collected</td>
<td>✓</td>
<td>Inclusion of collection date may have clinical relevance if other laboratory tests are completed (e.g., CSF total protein, WBC counts).</td>
</tr>
<tr>
<td>Clinical laboratory tests</td>
<td>Results</td>
<td>✓</td>
<td>Safety laboratory test results may be directly, clinically relevant.</td>
</tr>
<tr>
<td>Study Medication / Investigational Product (IP)</td>
<td>Dates medication dispensed or dates of infusion</td>
<td>✓</td>
<td>Where needed, the date of study medication/IP administration may be included.</td>
</tr>
<tr>
<td></td>
<td>Name of intervention or IP product</td>
<td>✗</td>
<td>Including name of the IP may risk loss of preclinical AD status confidentiality.</td>
</tr>
<tr>
<td></td>
<td>Unblinding information (active or placebo)</td>
<td>✗</td>
<td>Study team contact information or immediate access measures can be embedded for clinicians who need more information.</td>
</tr>
</tbody>
</table>

Table 2. Guidelines for EHR management of preclinical AD research information. ✓ = “Low risk” for inclusion in the EHR; ✗ = “Significant risk” for inclusion in the EHR. AD=Alzheimer disease, CSF=cerebrospinal fluid, WBC=White blood cell.
References:


Preclinical Alzheimer Disease and the Electronic Health Record: Balancing Confidentiality and Care

Seth A Gale, Judith Heidebrink, Joshua Grill, et al.

Neurology published online September 30, 2022
DOI 10.1212/WNL.0000000000201347

This information is current as of September 30, 2022

Updated Information & Services
including high resolution figures, can be found at:
http://n.neurology.org/content/early/2022/09/30/WNL.0000000000201347.full

Subspecialty Collections
This article, along with others on similar topics, appears in the following collection(s):
All Ethics in Neurology/Legal issues
http://n.neurology.org/cgi/collection/all_ethics_in_neurology_legal_issues
Electronic medical records
http://n.neurology.org/cgi/collection/electronic_medical_records
Health systems
http://n.neurology.org/cgi/collection/health_systems

Permissions & Licensing
Information about reproducing this article in parts (figures, tables) or in its entirety can be found online at:
http://www.neurology.org/about/about_the_journal#permissions

Reprints
Information about ordering reprints can be found online:
http://n.neurology.org/subscribers/advertise

Neurology® is the official journal of the American Academy of Neurology. Published continuously since 1951, it is now a weekly with 48 issues per year. Copyright Copyright © 2022 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the American Academy of Neurology. All rights reserved. Print ISSN: 0028-3878. Online ISSN: 1526-632X.