

RECEIVED
Do Not Mark In This Box

2007 JUL 27 PM 4:13

SECRETARY OF STATE
STATE OF WEST VIRGINIA

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #3

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: West Virginia Department of Health and Human Resources (WVU) TITLE NUMBER: 64

CITE AUTHORITY: 16-5R-7

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 94

TITLE OF RULE BEING PROPOSED: West Virginia Alzheimer's Disease Registry

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Martha Yeager Walker
Authorized Signature

Summary of the West Virginia Alzheimer's Disease Registry

West Virginia Code §16-5R-7 established an Alzheimer's Disease Registry within West Virginia University to act as a central information database for policy and planning relative to Alzheimer's disease and related dementias. §16-5R-7 stipulated that the West Virginia University Board of Governors propose rules pursuant to the provisions of article three, chapter twenty-nine-a of the West Virginia code to implement the West Virginia Alzheimer's Disease Registry.

Preamble

It is estimated that 42,000 people in West Virginia had Alzheimer's Disease (AD) in 2005 and that by 2025 there will be an estimated 25% increase in AD in the state. West Virginia is particularly vulnerable to an increased incidence of AD because it has one of the oldest populations in the country and the risk factors for AD such as heart disease, diabetes, high cholesterol, smoking and high blood pressure are all higher in WV than the national average. This is borne out by the state hospitalization rates for patients with AD which was 68% higher than national average in 2001 and the rate of dementia mortality was 38% higher than the national average. However, many of these statistics are only estimates and are often outdated. **There is a strong need for a more accurate and timely assessment of the incidence and prevalence of AD and related dementias in WV.** This need becomes even clearer when the estimated financial burden of the disease is taken into account. For example, Medicare beneficiaries with AD increased by 250% in 1990s and Medicare costs for AD are three times higher than for all other beneficiaries. The national per patient lifetime cost for AD care is currently estimated at \$175,000. With approximately 42,000 West Virginians thought to have AD, the cost over the lifetime of the disease is in excess of \$7 billion. If estimations are accurate, the cost by 2025 will be in excess of \$9 billion.

One proven way to collect information about the number of people in WV with AD and related dementias is with a population-based disease registry.

History

Based on a model developed in South Carolina, faculty of the West Virginia University School of Medicine together with representatives of the WV Alzheimer's Association, the Department of Health and Human Resources, the Blanchette Rockefeller Neurosciences Institute, and the South Carolina Alzheimer's Disease and Related Dementias Registry formulated and proposed legislation that would establish a registry of people with AD and related dementias. This legislation was introduced January 11th, 2006 as Senate Bill 112 by Senator Roman Prezioso, Chair of the Senate Health and Human Resources Committee and sponsored by all the members of that committee (Senators Prezioso, Sharpe, Hunter, Foster, Unger, Jenkins, Plymale, Helmick, Dempsey, White, Fanning, Sprouse, Deem, Yoder, Facemyer, Love, Bowman and Minard). SB 112 passed on March 11th, 2006 and became law on June 11th, 2006.

Legislation

“(a) To the extent funds are available, **the Governing Board of the West Virginia University** shall establish an Alzheimer's Disease Registry to collect information concerning Alzheimer's disease and related disorders. The purpose of the registry shall be to provide a central database of information to assist in the development of public policy and planning. The information collected by the registry shall be analyzed to prepare reports and perform studies as necessary when such data identifies information useful in developing policy.”

“(d) The governing board shall propose rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to implement this section. The rules shall include, but not be limited to:

- (1) The content and design of all forms and reports required by this section;
- (2) the type of information to be collected and maintained;
- (3) the procedures for disclosure of non-identifying data to other appropriate research entities;
- (4) the manner in which reporting entities or individuals, including families, may be contacted by the registry for additional relevant information; and
- (5) any other matter necessary to the administration of this section.”

Statement of Circumstances of the West Virginia Alzheimer's Disease Registry

West Virginia Code §16-5R-7 established an Alzheimer's Disease Registry within West Virginia University to act as a central information database for policy and planning relative to Alzheimer's disease and related dementias. §16-5R-7 stipulated that the West Virginia University Board of Governors propose rules pursuant to the provisions of article three, chapter twenty-nine-a of the West Virginia code to implement the West Virginia Alzheimer's Disease Registry.

Legislation

“(a) To the extent funds are available, **the Governing Board of the West Virginia University** shall establish an Alzheimer's Disease Registry to collect information concerning Alzheimer's disease and related disorders. The purpose of the registry shall be to provide a central database of information to assist in the development of public policy and planning. The information collected by the registry shall be analyzed to prepare reports and perform studies as necessary when such data identifies information useful in developing policy.”

“(d) The governing board shall propose rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to implement this section. The rules shall include, but not be limited to:

- (1) The content and design of all forms and reports required by this section;
- (2) the type of information to be collected and maintained;
- (3) the procedures for disclosure of non-identifying data to other appropriate research entities;
- (4) the manner in which reporting entities or individuals, including families, may be contacted by the registry for additional relevant information; and
- (5) any other matter necessary to the administration of this section.”

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: 27 July 2007

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: *(Agency Name, Address & Phone No.)* John D. Law or Bernard G. Schreurs, Ph.D.
State Capitol Complex
Building 3, Room 206
Charleston, West Virginia 25305

LEGISLATIVE RULE TITLE: West Virginia Alzheimers Disease Registry

1. Authorizing statute(s) citation W.Va Code 16-5R-7

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:
27 June 2007

b. What other notice, including advertising, did you give of the hearing?
Notified all other interested parties of the proposed rule.

c. Date of Public Hearing(s) *or* Public Comment Period ended:
27 July 2007

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.
Attached 3 persons No comments received _____

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

27 July 2007

- f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

John D. Law or Bernard G. Schreurs, Ph.D.

State Capitol Complex

Building 3, Room 206

Charleston, West Virginia 25305

- g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

d. Attach findings and determinations and reasons:

Attached

Comments Received

1. Jesse W. Samples, West Virginia Health Care Association
2. Jane Marks, Alzheimers Association, West Virginia Chapter
3. Amy N. Tolliver, West Virginia State Medical Association

FISCAL NOTE FOR PROPOSED RULES

Rule Title: West Virginia Alzheimer's Disease Registry

Type of Rule: Legislative Interpretive Procedural

Agency: _____

Address: West Virginia University
PO Box 6201
Morgantown, WV 26506

Phone Number: 304-2935531 Email: general.counsel@mail.wvu.edu

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

The proposed rule provides procedures for the West Virginia Alzheimer's Disease Registry and will have no impact on costs or revenues

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: West Virginia Alzheimer's Disease Registry

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

Estimates are based on the fact that there will be no impact on costs or revenues

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

Date: _____

Signature of Agency Head or Authorized Representative

Martha Yague Walker

This document contains the comments and responses on Proposed Rule Title 64 Series 94 - West Virginia Alzheimer's Disease Registry.

Mindful that the Proposed Rule Title 64 Series 94 - West Virginia Alzheimer's Disease Registry (WVADR) needs to be in line with the authorizing language (WV Code §16-5R-7), the following replies to comments and resultant changes have been made to the Proposed Rule.

**Comments from Jesse W. Samples, Chief Executive Officer,
West Virginia Health Care Association:**

Comment:

“First, the registry is not voluntary. Any gathering of medical information should be at the discretion of the patient, and the mandate of such data to be gathered by the provider community regardless of the will of the patient is a violation of the patient's privacy. The rule specifically outlines what information is to be included for each person on the registry and includes a medical history and history of the Alzheimer's disease and related disorders. Furthermore, absent a public health threat, I see little need for such a registry to be mandatory.”

Response:

The authorizing legislation (WV Code §16-5R-7) states that “(b) All reporting sources, including hospitals, physicians, facilities, clinics or other similar units diagnosing or providing treatment or care for Alzheimer's disease and related disorders, shall provide a report of each case to the Alzheimer's Disease Registry in the format specified.” The use of the words “shall provide a report” indicates the mandatory intent of the legislation.

Comment:

“Second, the rule requires “related disorders” to be part of the WVADR and defines related disorders using the language “includes, but are not limited to.” This type of reporting is extremely broad and likely not workable in a practical application. I would think the definition in the proposed rule would apply to everyone in a long term care facility. As you already know, nursing home data is already gathered as part of the required minimum data set (MDS) from Centers for Medicare and Medicaid (CMS).”

Response:

The language in the Rule has been clarified and narrowed to identify specific related disorders and the expression “includes, but are not limited to” has been removed. The Rule now states:

2.13. Related Disorders - Dementias associated with vascular disease, mixed dementia and other medical conditions such as Parkinson's disease and Huntington's disease. These dementias also include senile dementia, presenile dementia, multi-infarct dementia, vascular dementia, and alcoholic dementia, dementia with Lewy bodies, Creutzfeldt-Jakob disease, frontotemporal dementia, and medical diagnoses with dementia.

Comment:

“Third, the rule requires that staff of the facility report disease information on patients while at the same time they have no ability to diagnose any of the reportable diseases.”

Response:

The Rule has been modified (1.5 and 8.1) so that diagnosis of Alzheimer's disease or with a related disorder is made by a physician.

1.5. Applicability. -- This rule shall apply to all hospitals, physicians, health care providers, health care facilities, Alzheimer's disease/dementia special care units and programs, clinics or other similar units diagnosing or providing treatment or care for individuals who are diagnosed by a physician to have Alzheimer's disease or a related disorder. These facilities include, but are not limited to, adult day care facilities, assisted living residences, behavioral health centers, nursing homes, and residential care communities.

8.1. Health care Providers and Facilities. All health care providers and facilities, as defined herein, that diagnose or provide treatment or care for an individual who is diagnosed by a physician to have Alzheimer's disease or a related disorder shall provide a report of each case of the disease or condition as required by this rule.

Comment:

“And finally, there will be an enormous cost to the operators and the residents of facilities that are required to comply with this rule. The rule is overly broad and requires substantial information gathering that will mandate more “man hours” on the part of long term care facilities. This will translate into significant additional Medicaid dollars. Additionally, it will, yet again, place another burden upon the time of nursing home staff, which in turn, will take more time away from resident care.”

Response:

As noted above, the definition of related disorders has been narrowed. The data collection form (included as an appendix) is a single page, should not take long to complete and need only be done once for each patient.

**Comments from Jane Marks, Executive Director,
Alzheimer's Association, WV Chapter:**

Comment:

1. According to the United States Department of Health and Human Services document titled “User's Guide” for patient registries, that may be accessed on the US DHHS website at <http://effectivehealthcare.ahrq.gov>, a registry and rule for such, should be developed by a team and advisors based on expertise and experience. This rule was not developed by a comprehensive team of major stakeholders or experts.

Response:

WV Code §16-5R-7 required that an Alzheimer's Disease and related disorders registry be established by the West Virginia University Board of Governors. Experts from West

Virginia University including Dr. Richard Ham, a recognized geriatrician and expert on Alzheimer's disease, Dr. John Brick, a board-certified neurologist, Dr. Alan Ducatman, Chair of Community Medicine, Dr. James Stevenson, Chair of Behavioral Medicine and Psychiatry and a psychiatrist, and Dr. Ian Rockett, an epidemiologist in the Department of Community Medicine were engaged from the outset in the formulation of the WVADR. In addition, experts and consultants were engaged in the development of the WVADR including Carol Corman, Director of the South Carolina Alzheimer's Disease and Related Disorders Registry who consulted extensively on the WVADR, and Mr. Dan Christy of the West Virginia Department of Health and Human Resources.

Input and feedback on the subject matter of the rule was obtained before and during the comment period from the experts and consultants listed above as well as the West Virginia chapter of the Alzheimer's Association, the West Virginia State Medical Association and the West Virginia Health Care Association.

The content of the proposed Rule was guided and constrained by the authorizing Legislation (§16-5R-7). The Rule, protocol, and data collection form were approved by the West Virginia Institutional Review Board. The form and content of the Rule were modeled after existing West Virginia Legislative Rules including the Reportable Diseases Rule (64CSR7).

Comment:

2. The rule as written states that the purpose is for "policy and planning". The USDHHS user's guide for registries states that "a registry should have a defined purpose and should be either focused on analytical questions or a research question". Thus we recommend a clearly stated purpose and function for the registry in much greater detail. This purpose and function should be in the rule itself, not in the protocols.

Response:

The following section has been added to the Rule:

1.6. Purpose. -- The West Virginia Alzheimer's Disease Registry will provide a database to evaluate the incidence and prevalence of Alzheimer's disease and related disorders in West Virginia, provide information for policy planning purposes and provide non-identifying data to support research on Alzheimer's disease and related disorders.

Comment:

3. The USDHHS guide recommends use of an advisory committee in overseeing and monitoring the function of the Registry and that the advisory committee should be comprehensive and include a large variety of experts. We strongly recommend the advisory group be detailed in the rule itself, again, NOT in the protocol and that required members to include representatives from the following : The Alzheimer's Association, AARP, WV BOSS, representatives from the HealthCare Association, Assisted Living Association, day care facilities, social workers, WV Medical Society, WV Primary Care Assn , WV DHHR, WV Hospital Association, a caregiver of an individual with Alzheimer's disease and an individual with Alzheimer's disease. Early stage individuals are still very capable and their input would be invaluable.

We realize this is a far reaching suggestion however, in the spirit of assisting the state of WV in tracking prevalence etc, it would be sensible to include representation from the other two medical schools as they both have clinics that see a lot of Alzheimer' patients, (i.e. the Hanshaw Geriatric Center at Marshall, etc.). The advisory committee function should be exactly as the South Carolina rule states.

We strongly recommend there be only ONE advisory committee. Having two, an internal and an external, gives the impression that the internal is private and is the real "oversight" group and that the external one is merely to placate. In addition, two oversight or advisory committees would over complicate an already complicated process as well as dilute the authority of the oversight group.

We suggest the language say "shall include" not "may include".

Response:

The relevant section of the Rule has been modified so that there is ONE advisory committee and membership includes the wording "shall be comprised":

13.1.2. The Advisory Board shall be comprised of, but not limited to, representatives from The Blanchette Rockefeller Neurosciences Institute, The Institute on Aging, West Virginia University, Marshall University, West Virginia Department of Health and Human Resources, and representatives of public and private entities and organizations and other individuals involved in Alzheimer's disease and related disorders. These shall include, but not be limited to, the West Virginia Alzheimer's Association, West Virginia State Medical Association, West Virginia Health Care Association, West Virginia AARP, West Virginia NASW and members of the community including a caregiver of a person with Alzheimer's disease.

We have received enthusiastic support and commendations from the West Virginia State Medical Association and the West Virginia chapter of the National Association of Social Workers and both organizations look forward to having a representative serve on the Advisory Board.

Comment:

4. The current draft rule states that any healthcare provider would be required to submit names for the registry. Only a physician is qualified to make the determination of Alzheimer's or a related dementia. That diagnostic procedure is lengthy and comprehensive. In item 6.3 of protocol 001 the statement should probably be amended to add "rendered by a qualified physician" after the phrase "a diagnosis of probable".

In addition, this document lists day care facilities as healthcare providers. The only daycare facilities currently operating in WV are social model daycares that do not provide healthcare, they provide ADL assistance. This is true for assisted living facilities as well. Therefore, we recommend that the registry information only come from diagnostic records, or data sources including inpatient hospitalizations that include a dementia diagnosis by a qualified physician, mental health records that

include a dementia diagnosis, Medicaid records, and long term care evaluations as is the case in South Carolina.

Response:

The Rule has been modified to include that the diagnosis be made by a physician:

1.5. Applicability. -- This rule shall apply to all hospitals, physicians, health care providers, health care facilities, Alzheimer's disease/dementia special care units and programs, clinics or other similar units diagnosing or providing treatment or care for individuals who are diagnosed by a physician to have Alzheimer's disease or a related disorder. These facilities include, but are not limited to, adult day care facilities, assisted living residences, behavioral health centers, nursing homes, and residential care communities.

8.1. Health care Providers and Facilities. All health care providers and facilities, as defined herein, that diagnose or provide treatment or care for an individual who is diagnosed by a physician to have Alzheimer's disease or a related disorder shall provide a report of each case of the disease or condition as required by this rule.

Item 6.3 of the Protocol (attached as an appendix) has been modified as suggested:

6.3 Enrollment

All patients who have a probable diagnosis of AD or a related disorder diagnosed by a physician shall participate in WVADR.

The rule does NOT list day care facilities as health care providers. The Rule states "This rule shall apply to all hospitals, physicians, health care providers, health care facilities, Alzheimer's disease/dementia special care units and programs, clinics or other similar units diagnosing or providing treatment or care for individuals who (are diagnosed by a physician to) have Alzheimer's disease or a related disorder. "

The authorizing language (§16-5R-7b) states that "reporting sources including hospitals, physicians, facilities, clinics or other similar units diagnosing or providing treatment or care for Alzheimer's disease and related disorders, shall provide a report . . .". Thus, the rule applies to day care facilities.

**Amy N. Tolliver, Government Relations Specialist
West Virginia State Medical Association**

Comment:

The statute, §16-5R-7(c), makes specific reference to HIPAA for reports that include the individual's identity. The WVSMA notes that confidentiality is discussed in the rule at paragraph number 10, "Confidential Information, Utilization of Information and Permitted Disclosures of Information." Some of the language in this paragraph seems to track HIPAA disclosure rules. However, nowhere in the rule are the patient's HIPAA rights addressed. Such rights include: the right to agree or object to certain uses and disclosures; the right to request restriction of uses and disclosures; the right to access and the right to amend protected health information (PHI). Patients also have a right to request an accounting of disclosures, and perhaps most importantly the right to file a privacy complaint. WVSMA is very concerned about this on behalf of

the patients for whom our member physicians provide care and thus recommends that this rule be reviewed by the State Privacy Officer prior to a final rule being filed with the Legislative Rule Making Review Committee.

Response:

We accept the comment and are researching the issue.

Comment:

Additionally, the WVSMA is concerned with the process and content of reporting. As to the process, there needs to be a system delineated for the coordination of reporting. As drafted, the rule requires reporting of Alzheimer's disease and related disorders by the physicians, hospitals nursing homes and residential facilities. All of which may be reporting on the same patient. We suggest that a better process be developed to reduce the redundant reporting that is inevitable under the current draft. In cases of patients of nursing homes, we suggest that there be no reporting of physicians and hospitals when the individual resides under their care. Additionally, we are concerned that residential care communities which may in some cases not be entitled to the PHI are now being asked to determine whether the resident has Alzheimer's disease and related disorders and report such. We ask that this be further clarified.

Response:

There will be some redundancy in reporting. However, reports will go to a central computerized database either electronically or via paper record that will be keyed into the database. The database will be designed to detect multiple reports on the same person and will be programmed to reconcile the entries into a single report.

All cases of Alzheimer's disease or a related disorder are those that are diagnosed by a physician. Residential care communities are not asked to make that determination.

Comment:

In regard to the process and content of reporting, the WVSMA has a concern about the ability for the provider to provide accurate answers to the questionnaire. By way of example the form asks for the answer to the question "Prolonged exposure to contaminants and/or toxins." A patient with dementia will not be a reliable source as to this answer and the health care community will have no way of knowing the answer to the question. Additionally, many of the questions are missing the category "unknown."

Response:

Some of the questions may not be answerable. The questionnaire has been modified to include the category "Unknown" as an answer to all of the patient exposure questions.

1. General.

1.1. Scope -- This legislative rule sets forth and establishes procedures governing the West Virginia Alzheimer's Disease Registry as a central information database for policy and planning relative to Alzheimer's disease and related disorders, pursuant to the provisions of the West Virginia Administrative Procedures Act, 29A-3-1 et.seq.

1.2. Authority -- WV Code §16-5R-7

1.3. Filing Date--

1.4. Effective Date--

1.5. Applicability. -- This rule shall apply to all hospitals, physicians, health care providers, health care facilities, Alzheimer's disease/dementia special care units and programs, clinics or other similar units diagnosing or providing treatment or care for individuals who are diagnosed by a physician to have Alzheimer's disease or a related disorder. These facilities include, but are not limited to, adult day care facilities, assisted living residences, behavioral health centers, nursing homes, and residential care communities.

1.6. Purpose. -- The West Virginia Alzheimer's Disease Registry will provide a database to evaluate the incidence and prevalence of Alzheimer's disease and related disorders in West Virginia. It will provide information for policy planning purposes and provide non-identifying data to support research on Alzheimer's disease and related disorders.

2. Definitions.

2.1. Adult Day Care Facility - Any facility licensed as a medical adult day care center under WV Division of Health Legislative Rule, Medical Adult Day Care Center licensure, 64 CSR 2 or any day care program maintained and operated by a nursing home, hospital or other licensed health care facility.

2.2. Alzheimer's Disease - A progressive, neurodegenerative disease leading to loss of mental functions such as memory and learning characterized by a loss of function and death of nerve cells in several areas of the brain. This disease is considered to be one of the most common forms of dementia.

2.3. Alzheimer's Disease/Dementia Special Care Units and Programs - Any facility licensed as an Alzheimer's Disease/Dementia special care unit or program under WV Division of Health Legislative Rule, Medical Adult Day Care Center licensure, 64 CSR 85 or any Alzheimer's Disease/Dementia special care unit or program maintained and operated by a nursing home, hospital or other licensed health care facility.

2.4. Assisted Living Residence - Any facility licensed as an assisted living residence under WV Division of Health Legislative Rule, Assisted Living Residence licensure, 64 CSR 14.

2.5. Behavioral Health Centers - Any facility licensed as a behavioral health center under WV Division of Health Legislative Rule, Behavioral Health Center licensure, 64 CSR 11.

2.6. Dementia - A deterioration of intellectual function and other cognitive skills, leading to a decline in the ability to perform activities of daily living.

RECEIVED

2007 JUL 27 PM 4:14
SECRETARY OF STATE
STATE OF WEST VIRGINIA

2.7. Director – The Director of the West Virginia Alzheimer’s Disease Registry or his or her designee.

2.8. Health care facility - Any hospital, nursing home, clinic, behavioral health center, adult medical day care facility, or other facility that provides health care or diagnostic services to individuals whether public or private.

2.9. Health care provider - Any physician, nurse, or other individual who provides medical, psychiatric, nursing, or other health care services of any kind to individuals.

2.10. Hospital - A facility licensed as a hospital under WV Division of Health Legislative Rule, Hospital Licensure, 64 CSR 12.

2.11. Medical Information - Data or other information regarding the history, examination, radiological or laboratory findings, diagnosis, treatment, or other clinical care for a person examined or treated for a suspected or actual illness.

2.12. Nursing Home - Any facility licensed as a nursing home under WV Legislative Rule, Nursing Home Licensure, 64 CSR 13, or any extended care facility operated in conjunction with a hospital.

2.13. Related Disorders - Dementias associated with vascular disease, mixed dementia and other medical conditions such as Parkinson’s disease and Huntington’s disease. These dementias also include senile dementia, presenile dementia, multi-infarct dementia, vascular dementia, alcoholic dementia, dementia with Lewy bodies, Creutzfeldt-Jakob disease, frontotemporal dementia, and medical diagnoses with dementia.

2.14. Residential Care Community - Any facility licensed as a residential care community under WV Division of Health Legislative Rule, Residential Care Community licensure, 64 CSR 75.

2.15. WVADR - West Virginia Alzheimer’s Disease Registry is a central information database concerning Alzheimer’s disease and related disorders maintained by West Virginia University.

2.16. WVU BOG – West Virginia University Board of Governors.

3. Required Reporting of Alzheimer’s disease and related disorders.

3.1. The WVU BOG shall establish the WVADR and delegate to the Vice-President for Health Sciences at West Virginia University or their designee the responsibility for developing specific protocols for the reporting of Alzheimer’s disease and related disorders to the WVADR. The protocols shall include any information to be reported under this rule and any additional relevant information determined to be necessary for adequate reporting. All protocols must be approved by the West Virginia University Institutional Review Board.

3.2. The reports required by this rule shall be reported electronically or in paper format on forms available from or provided by the WVADR.

4. Registry contents.

4.1. Information to be reported. Reports from health care providers and facilities, as defined herein, shall include:

- 4.1.a. Last name, first name and middle initial of individual;
- 4.1.b. Birth date;
- 4.1.c. Gender;

4.1.d. Last four digits of the Social security number;
4.1.e. Maiden name(if female);
4.1.f. Race/ethnicity;
4.1.g. Address, including street, city, county, and zip code;
4.1.h. Contact information including secondary contacts;
4.1.i. Brief medical history;
4.1.j. History of Alzheimer's disease and related disorders;
4.1.k. Physician's name;
4.1.l. Physician's contact information including address, phone, fax numbers, or email
4.1.m. Other information deemed relevant for policy and planning relative to Alzheimer's disease and related disorders.

4.2. Content and design of forms. Content and design of all forms for the WVADR shall be consistent with the minimum information necessary to maintain the registry, pursuant to the provisions of WV Code 16-5R-7(a).

4.3. Content and design of reports. Content and design of all reports for the WVADR shall provide the most relevant and complete summary statistics and information required to advise policy development, pursuant to the provisions of WV Code 16-5R-7(c).

5. Standard operating procedures.

5.1. All aspects of data collection, management, and maintenance shall be governed by written standard operating procedures developed by WVADR.

6. Data management.

6.1. WVADR data shall be managed in compliance with standard data management procedures.

7. Regulatory compliance.

7.1. The WVADR shall comply with all applicable Department of Health and Human Resources requirements and regulations.

8. Persons and Facilities, Required to Report.

8.1. Health care Providers and Facilities. All health care providers and facilities, as defined herein, that diagnose Alzheimer's disease or a related disorder or provide treatment or care for an individual who is diagnosed by a physician to have Alzheimer's disease or a related disorder shall provide a report of each case of the disease or condition as required by this rule.

9. Distribution of Rule.

9.1. The WVADR shall distribute this rule to licensed health care providers or facilities, as defined herein, which have a duty to report pursuant to the provisions of this rule. Local health departments may copy and distribute this rule to local health care providers or facilities, as defined herein, at no cost. The rule shall also be available online from the WVADR at www.WVADR.hsc.wvu.edu.

10. Confidential Information, Utilization of Information, and Permitted Disclosures of Information.

10.1. Confidential Information: Any information collected and maintained pursuant to this rule by the WVADR which identifies an individual as having Alzheimer's disease or a related disorder is

“confidential information” and exempt from disclosure to third parties, pursuant to the provisions of all applicable state and federal laws, unless such disclosure is permitted pursuant to the provisions of Section 10.3.

10.2. Utilization of non-identifying information:

10.2.1. The WVADR may disclose non-identifying information for research purposes only.

10.3. Permitted Disclosures of Confidential Information:

10.3.1. WVADR may release “confidential information” to the following:

10.3.1.a. The individual diagnosed with Alzheimer’s disease or related disorder;

10.3.1.b. The individual’s representative, who shall have the legal authority to access the individual’s confidential information by virtue of a lawful written authorization or legal instrument or by virtue of an order from a court of competent jurisdiction;

10.3.1.c. A physician or other health care provider, if the request for confidential information is for the purpose of medical evaluation or treatment of the individual;

10.3.1.d. Any individual or entity which shall provide WVADR with a lawful written authorization for the disclosure of confidential information from the individual diagnosed with Alzheimer’s disease or related disorder or that individual’s representative.

10.3.1.e. Any individual or entity which shall provide WVADR with an order from a court of competent jurisdiction ordering the disclosure of confidential information.

10.4. In order to ensure patient confidentiality, patients will be assigned a unique identifying number. All patient information will be stored as identified and de-identified information in two linked datasets on a secure, encrypted, password-protected database server. The Director of the WVADR and a designee will have the only means of linking the identified and de-identified information.

11. Communication.

11.1. Communication by the WVADR with individuals, individual’s representatives, and health care providers or facilities, as defined herein, shall be made directly via U.S. mail, telephone, or e-mail to notify individuals and individual’s representatives about inclusion in the WVADR and, if requested, to advise about research opportunities and to convey disease-related information.

12. WVADR Director.

12.1. The WVU BOG shall delegate to the President of West Virginia University or his/her designee the responsibility for appointment of the Director of the WVADR.

13. WVADR Advisory Board.

13.1. The WVU BOG shall delegate to the President of West Virginia University or his/her designee the responsibility for the appointment of an Advisory Board to the WVADR.

13.1.1. The Advisory Board shall make recommendations to the Director about the implementation, coordination and oversight of the Registry.

13.1.2. The Advisory Board shall be comprised of, but not limited to, representatives from The Blanchette Rockefeller Neurosciences Institute, The Institute on Aging, West Virginia University, Marshall University, West Virginia Department of Health and Human Resources, and representatives of public and private entities and organizations and other individuals involved in Alzheimer's disease and related disorders. These shall include, but not be limited to, the West Virginia Alzheimer's Association, West Virginia State Medical Association, West Virginia Health Care Association, West Virginia AARP, West Virginia NASW and other stakeholders as well as members of the community including a caregiver of a person with Alzheimer's disease or a related disorder.

West Virginia University
Morgantown, WV, 26506
TEL: 304 293-0497
FAX: 304 293-4855

PROTOCOL NUMBER: 0001

PROTOCOL TITLE: West Virginia Alzheimer's Disease Registry

DATE: July 27, 2007
Version 1.0

I approve this document in accordance with West Virginia University's current policies and procedures.

<authorizing representative name>, <title>,
West Virginia University

Date

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

TABLE OF CONTENTS

1	CONTACT LIST	3
1.1	Coordinating Center	3
2	LIST OF ABBREVIATIONS AND DEFINITIONS	4
3	SYNOPSIS.....	5
4	INTRODUCTION	7
4.1	Rationale for WVADR	7
5	PRIMARY OBJECTIVES.....	7
6	PROGRAM DESIGN FOR WEST VIRGINIA ALZHEIMER'S DISEASE REGISTRY	8
6.1	Overview of WVADR	8
6.2	Registry Awareness	8
6.3	Enrollment.....	8
6.4	Information Collected at Enrollment	8
6.5	Follow-Up	9
6.6	Completeness of Patient Identification	9
6.7	Sponsor Discontinuation of WVADR	9
7	STATISTICAL CONSIDERATIONS.....	9
7.1	Sample Size.....	9
7.2	Statistical Methods.....	9
7.3	Reporting Period	10
8	ETHICAL, REGULATORY, AND ADMINISTRATIVE REQUIREMENTS.....	10
8.1	Confidentiality	10
8.2	Institutional Review Board	10
8.3	Changes to the Protocol	11
8.4	External and Internal WVADR Committees	11
8.4.1	Coordinating Center.....	11
8.5	Record Retention	11
8.6	Completion of WVADR	11

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of
West Virginia University

1 CONTACT LIST

1.1 Coordinating Center

West Virginia Alzheimer's Disease Registry
West Virginia University
PO Box 9302
Morgantown, WV 26505
Phone: 304 293-0497
Fax: 304 293 4855
E-mail: bschreurs@hsc.wvu.edu

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of
West Virginia University

2 LIST OF ABBREVIATIONS AND DEFINITIONS

AD	Alzheimer's Disease
ADRD	Alzheimer's Disease and related disorders
IRB	Institutional Review Board
PHI	Protected health information
PIPA	Personal information protection approval
US	United States
WVADR	West Virginia Alzheimer's Disease Registry
WVU	West Virginia University
Incidence	Number of patients newly diagnosed with AD in the population
Prevalence	Number of existing patients with AD in the population

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of
West Virginia University

3 SYNOPSIS

Protocol Number:	001
Version Number:	1
Protocol Title:	West Virginia Alzheimer's Disease Registry
Program Objectives:	<p>To estimate the incidence and prevalence of Alzheimer's Disease and related disorders in West Virginia.</p> <p>To obtain longitudinal data on Alzheimer's Disease and related disorders within West Virginia for future public health policy decision making</p> <p>To provide de-identified data to support research on Alzheimer's Disease and related disorders.</p>
Number of Registrants:	All patients with Alzheimer's Disease and related disorders are eligible for the registry. (Approximately 42,000 patients with a diagnosis of Alzheimer's Disease and related disorders are thought to be resident in West Virginia)
Enrollment:	Registration in the WVADR can be initiated at any time during the patient's course of disease. Registration can occur either (1) when the patient is seen by his/her physician at or by a health care provider any time after diagnosis, or (2) when the decision to initiate treatment with a cognitive enhancer is made.
Information Collection:	<p>Patients may be enrolled into the Registry by any health care provider. The reporter will send the requested information to the WVADR using a standardized data collection form which may be obtained from the Internet or by contacting WVADR Coordinating Center. This information may be sent by electronic or paper means.</p> <p>West Virginia death certificates will be reviewed to identify additional cases of ADRD and to confirm vital status of patients enrolled in the WVADR.</p>
Assessments:	<p>The following information will be collected at the time the patient is enrolled into the Registry:</p> <ul style="list-style-type: none"> • Patient name

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

- Address
- Last four digits of Social Security number
- Patient demographic information
- Caregiver name
- Caregiver contact information
- Name of health care professional enrolling the patient
- Address of health care professional enrolling the patient
- Brief general medical history
- Specific Alzheimer's Disease history

Statistical Analysis:

Patient information will be summarized using descriptive statistics. Incidence and prevalence of ADRD will be calculated, using the current population census estimates available for West Virginia as the denominator. Comparisons will be made with ADRD estimates from other data sources such as hospital discharge records, insurance claims, vital statistics and other governmental databases.

Summary reports will be prepared on an annual basis, within 90 days of the close of the reporting year.

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

4 INTRODUCTION

The West Virginia Alzheimer's Disease Registry (WVADR) is a population-based registry of patients with Alzheimer's disease and related disorders (ADRD). WVADR will estimate the incidence rate and prevalence of ADRD in West Virginia using all available information sources, including primary care and consulting physicians, other health care providers, nursing homes, government agencies, public and private insurance agencies, and DHHR vital statistics and other databases.

4.1 Rationale for WVADR

It is estimated that 42,000 people in West Virginia had AD in 2005 (WV Alzheimer's Association) and that by 2025 there will be an estimated 25% increase in AD in the State. West Virginia is particularly vulnerable to an increased incidence of AD because it has one of the oldest populations in the country and risk factors for AD including high cholesterol, high blood pressure, smoking and diabetes are all higher in WV than the national average. This is borne out by the state hospitalization rate for patients with AD which was 68% higher than national average in 2001; the rate of dementia mortality was 38% higher than the national average (WV DHHR, 2005). However, these statistics are crude estimates and are often dated. **There is a strong need for a more accurate and timely assessment of the incidence and prevalence of AD and related disorders in WV.** This need becomes even clearer when the estimated financial burden of the disease is considered. For example, Medicare beneficiaries with AD increased by 250% in 1990s and Medicare costs for AD are three times higher than for all other beneficiaries. The national per patient lifetime cost for AD care is currently estimated at \$175,000. With approximately 42,000 West Virginians with AD, the cost over the lifetime of the disease is in excess of \$7 billion. If estimations are accurate, the cost by 2025 will be in excess of \$9 billion.

5 PRIMARY OBJECTIVES

The primary objectives of the WVADR are:

- To estimate the incidence rate and prevalence of Alzheimer's Disease and related disorders in West Virginia.
- To use the Registry data to provide guidance to the State of West Virginia, its counties and local communities in the development of public policy and facilities, infrastructure and financial planning .
- To obtain longitudinal data on Alzheimer's Disease and related disorders within West Virginia for future public health policy decision making.
- To provide de-identified data to support research on Alzheimer's Disease and related disorders.

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

6 PROGRAM DESIGN FOR WEST VIRGINIA ALZHEIMER'S DISEASE REGISTRY

6.1 Overview of WVADR

WVADR is a population-based registry of patients with Alzheimer's Disease and related disorders in West Virginia.

6.2 Registry Awareness

The WVADR will use some or all of the following options currently being drafted to make health care providers and patients aware of the WVADR:

- Notification to all primary care providers, neurologists, psychiatrists and other practitioners
 - Letters to West Virginia health care entities and organizations
 - Mailing to all members of health care-related entities and organizations
 - Mailing to all WV nursing homes and other care facilities
- Notification of ADRD education and support groups
- Registry brochure provided to health care providers
- Public service announcements and media articles
- WVADR web site

All communication regarding the WVADR will be submitted to the WVU IRB for approval prior to dissemination.

6.3 Enrollment

All patients who have a probable diagnosis of AD or a related disorder diagnosed by a physician shall participate in WVADR. These include disorders associated with vascular disease, mixed dementia and other medical conditions such as Parkinson's disease and Huntington's disease. These disorders also include senile dementia, presenile dementia, multi-infarct dementia, vascular dementia, and alcoholic dementia, dementia with Lewy bodies, Creutzfeldt - Jakob disease, frontotemporal dementia, and medical diagnoses with dementia. Registration into WVADR can be initiated by a health care provider when the patient is diagnosed or, in preexisting cases, as soon as practicable.

6.4 Information Collected at Enrollment

The WVADR will collect information routinely documented in the patient medical record, with no protocol-required interventions or procedures to be conducted. Using standard data collection tools, the registering health care provider will collect the following information to initiate Registration into the WVADR:

- Patient demographic characteristics
 - Date of birth
 - Gender
 - Race and ethnicity
 - Place of birth

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

- Education level
- Patient contact information, including secondary contacts
- Current residential status (e.g., nursing home, community)
- Brief Medical history
- Alzheimer's disease and related disorders history
 - Date of diagnosis
 - Method(s) of diagnosis
 - Current medications
 - Previous AD medications

Information will also be collected on the reporter:

- Name
- Contact information
- Medical specialty

6.5 Follow-Up

The only active data collection in the WVADR is at the time of patient enrollment. There is no active follow-up of patients in the registry at this time. All follow-up for information on patient vital status will be obtained through passive surveillance. That is, information on enrolled patients will be matched against the National Death Index (NDI) and against West Virginia Vital Statistics to determine vital status. The NDI match process will occur annually beginning in the second year of WVADR operation, or as soon as data from the NDI are available to cover the time period of WVADR Registration.

6.6 Completeness of Patient Identification

Death certificates of West Virginia residents will be reviewed annually for any residents with a cause of death attributed to ADRD. These individuals will be matched against the patients enrolled in to the WVADR. Any residents identified from death certificates who do not match an enrollee in the WVADR will be included in the registry, and assigned a status of "death certificate only".

6.7 Sponsor Discontinuation of WVADR

West Virginia University may terminate WVADR at any time.

7 STATISTICAL CONSIDERATIONS

7.1 Sample Size

The WVADR will attempt to identify and enroll all patients with ADRD in West Virginia.

7.2 Statistical Methods

Patient data will be summarized using descriptive statistics, such as frequency distribution and other basic summary statistics. Incidence rates and prevalence of ADRD

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

will be calculated using the current population census estimates available for West Virginia as the denominator. Incidence and prevalence estimates will be made on a geographic basis within West Virginia, using three digit zip code or other relevant geographic classifications (while ensuring that no individual patient can be identified). Comparisons will be made with ADRD estimates from other data sources such as hospital discharge records, insurance claims, vital statistics and other governmental databases.

Prior to data analysis, statistical methods will be detailed in a separate Statistical Analysis Plan.

7.3 Reporting Period

Summary WVADR reports will be prepared on an annual basis, within 90 days of the close of the reporting year.

8 ETHICAL, REGULATORY, AND ADMINISTRATIVE REQUIREMENTS

The sponsor, West Virginia University, agrees to comply with this protocol and to conduct WVADR according to applicable local, state and federal law and regulations.

8.1 Confidentiality

In order to ensure patient confidentiality, patients will be assigned a unique identifying number.

Upon Registration, patients will be required to provide their name and contact information, and a secondary contact. They will also be asked to provide the last four digits of their Social Security number. Patients who decline to provide the last four digits of their Social Security number may still enroll in WVADR. Patient identifying information will be used to establish a unique identity within the WVADR (e.g., to be sure no duplicate entries exist for the same patient) and as a basis for calculating ADRD incidence and prevalence by geographic region of West Virginia. The patient's information will be used for matching against vital statistics records such as West Virginia death certificates and the NDI. Information on the patient's secondary contact will be used should additional research opportunities exist within the registry and there is a need to alert the patient and legal guardian to such new research opportunities.

In any presentations or in publications of the results of WVADR, the patients' identities will remain anonymous and confidential. West Virginia University, its designee(s), and various government health agencies may inspect the records of WVADR. Every effort will be made to keep the patients' personal medical data confidential.

8.2 Institutional Review Board

Approval of this protocol and the patient informed consent form will be obtained from the West Virginia University Institutional Review Board (WVU IRB) prior to the start of the WVADR.

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

8.3 Changes to the Protocol

The WVU IRB will be contacted about and will need to approve changes to the protocol.

8.4 WVADR Advisory Board

An advisory board will be established to help implement, coordinate and provide oversight of the WVADR. The Advisory Board shall be comprised of, but not limited to, representatives from The Blanchette Rockefeller Neurosciences Institute, The Institute on Aging, West Virginia University, Marshall University, West Virginia Department of Health and Human Resources, and representatives of public and private entities and organizations and other individuals involved in Alzheimer's disease and related disorders. These shall include, but not be limited to, the West Virginia Alzheimer's Association, West Virginia State Medical Association, West Virginia Health Care Association, West Virginia AARP, West Virginia NASW and members of the community including a caregiver of a person with Alzheimer's disease.

8.4.1 Coordinating Center

West Virginia University is the Coordinating Center for the WVADR. WVU will be responsible for the collection and management of data generated in WVADR.

8.5 Record Retention

West Virginia University will follow its applicable standard operating procedures regarding retention of records.

8.6 Completion of WVADR

The WVU IRB must be notified of completion or termination of WVADR.

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of West Virginia University

Appendix One

Classification of Disorders by ICD-9-CM codes**Alzheimer's disease**

- 290.0 Senile dementia.
 290.1-290.13 Presenile dementia.
 290.2-290.21 Senile dementia with delusional/depressive features.
 290.3 Senile dementia with delirium.
 331.0 Alzheimer's disease.

Multi-infarct dementia

- 290.4-290.43 Arteriosclerotic dementia.

Alcoholic dementia

- 291.2 Other alcoholic dementia.
 292.82 Drug-induced dementia.

Medical diagnoses with dementia

- 294.0-294.9 Other organic conditions (chronic). Includes: amnesic syndrome, dementia in conditions classified elsewhere, other specified organic brain syndromes.
 310.0-310.9 Specific nonpsychotic mental disorders due to organic brain damage. Includes: frontal lobe syndrome, organic personality syndrome, post concussion syndrome, other specified nonpsychotic mental disorder following organic brain damage, unspecified nonpsychotic mental disorder following organic brain damage.
 331.1-331.9 Other cerebral degenerations. Includes: Pick's disease, senile degeneration of the brain, communicating hydrocephalus, obstructive hydrocephalus, and cerebral degenerations in diseases classified elsewhere, other cerebral degenerations.
 332.0-332.1 Parkinson's disease.
 333.4 Huntington's disease.
 797 Senility without mention of psychosis.

Classification of Disorders by ICD-10-CM codes**A81 Creutzfeldt-Jakob disease****F01 Vascular dementia**

- F01.0 Vascular dementia of acute onset
 F01.1 Multi-infarct dementia
 F01.2 Subcortical vascular dementia
 F01.3 Mixed cortical and subcortical vascular dementia
 F01.8 Other vascular dementia
 F01.9 Vascular dementia, unspecified

G10 Huntington's disease**G20 Parkinson's disease****G30 Alzheimer's disease**

- G30.0 Alzheimer's disease with early onset (onset usually before the age of 65)
 G30.1 Alzheimer's disease with late onset (onset usually after the age of 65)

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of
 West Virginia University

- G30.8 Other Alzheimer's disease
- G30.9 Alzheimer's disease, unspecified

- G31 Other degenerative diseases of the nervous system, not elsewhere classified**
- G31.0 Circumscribed brain atrophy
 - Pick's disease
- G31.1 Senile degeneration of brain, not elsewhere classified
- G31.2 Degeneration of nervous system due to alcohol
 - Wernicke-Korsakoff syndrome
- G31.8 Other specified degenerative disease of nervous system
 - Grey-matter degeneration
 - Lewy body disease
- G31.9 Degenerative disease of nervous system, unspecified

CONFIDENTIAL

The information contained herein may not be used, disclosed, or published without the written consent of
West Virginia University

West Virginia Alzheimer's Disease Registry

Patient Information & Medical History of Alzheimer's Disease or Related Dementia (ADRD)

Today's Date: _____			
First Name: _____	Middle Initial: _____	Last Name: _____	Maiden Name: _____
Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female	Last Four Digits of Social Security Number: XXXX - XXX - _____		
Place of Birth: City: _____ State: _____ Country: _____		Date of Birth: _____ (Month / Day / Year)	
Patient's Current Address			
Street: _____		City: _____	State: _____ Zip: _____
With whom does the patient live? <input type="checkbox"/> Alone <input type="checkbox"/> Assisted living <input type="checkbox"/> Nursing home <input type="checkbox"/> State Facility <input type="checkbox"/> Veterans Administration facility <input type="checkbox"/> Other <input type="checkbox"/> Private residence with caregiver			
Is the caregiver: <input type="checkbox"/> Spouse <input type="checkbox"/> Other family member <input type="checkbox"/> Paid assistant <input type="checkbox"/> Adult day care center?			
Race: <input type="checkbox"/> White <input type="checkbox"/> African American <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Asian/Pacific Islander <input type="checkbox"/> Multi-racial			
Ethnicity: <input type="checkbox"/> Non-Hispanic/Non-Latino <input type="checkbox"/> Hispanic			
At what age did the ADRD symptoms begin? _____		At what age was the ADRD diagnosed? _____	
Please classify the patient's dementia (check all that apply):			
<input type="checkbox"/> Multi-infarct dementia <input type="checkbox"/> Drug induced or alcoholic dementia <input type="checkbox"/> Other organic conditions (chronic) <input type="checkbox"/> Specific non-psychotic mental disorders due to organic brain damage <input type="checkbox"/> Other cerebral degenerations <input type="checkbox"/> Parkinson's disease <input type="checkbox"/> Huntington's disease <input type="checkbox"/> Dementia with Lewy Bodies			
Stage of ADRD at Diagnosis: <input type="checkbox"/> Early (Mild) <input type="checkbox"/> Middle (Moderate) <input type="checkbox"/> Late (Severe) Current stage of ADRD: <input type="checkbox"/> Early (Mild) <input type="checkbox"/> Middle (Moderate) <input type="checkbox"/> Late (Severe)			
Studies undertaken regarding ADRD. Check all that apply. <input type="checkbox"/> Medical History <input type="checkbox"/> Angiography <input type="checkbox"/> CT Scan <input type="checkbox"/> Cisternography <input type="checkbox"/> EEG <input type="checkbox"/> EEG Quantitative <input type="checkbox"/> Cerebral Blood Flow <input type="checkbox"/> Mini Mental <input type="checkbox"/> MRI <input type="checkbox"/> SPECT <input type="checkbox"/> Lumbar Puncture <input type="checkbox"/> Others (specify): _____			
Is the patient receiving prescription medication(s) for ADRD? <input type="checkbox"/> Yes <input type="checkbox"/> No			
Does the patient have any of the following health conditions? <input type="checkbox"/> Obesity <input type="checkbox"/> Diabetes <input type="checkbox"/> Hypertension <input type="checkbox"/> Elevated cholesterol <input type="checkbox"/> Cardiovascular disease <input type="checkbox"/> Cerebrovascular disease <input type="checkbox"/> Neurological disease <input type="checkbox"/> Other (specify): _____			
Does the patient have blood relatives that have or had ADRD? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
Has the patient been exposed to any of the following? Trauma to head: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, Age? _____ Anemia: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Nutritional deficiency (e.g., B12, niacin): <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Antidepressants: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Drug abuse: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Tobacco: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Alcohol abuse: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
Prolonged exposure to contaminants and/or toxins?: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
If yes, please describe: _____			

West Virginia Alzheimer's Disease Registry

West Virginia Alzheimer's Disease Registry Physician Participation Form

West Virginia Medical License Number:	First Name:	Middle Initial:	Last Name:	
Medical Specialty: <input type="checkbox"/> Neurology <input type="checkbox"/> Psychiatry <input type="checkbox"/> Geriatrics <input type="checkbox"/> Family / General Practice <input type="checkbox"/> Internal Medicine <input type="checkbox"/> Other				
Physician's Preferred Contact Address				
Street:		City:	State:	Zip:
Telephone:	Fax:		Email: _____@_____	