

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

Form #2

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SEC

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

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

RULE TYPE: Legislative 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 Alzheimers Disease Registry

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON 27 July 2007 AT 12:00 PM ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

John D. Law OR Bernard G. Schreurs, Ph.D.
State Capitol Complex, Building 3, Room 206
Charleston, West Virginia

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.



Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

2017

**TITLE 64
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

2017

**SERIES 94
WEST VIRGINIA ALZHEIMERS DISEASE REGISTRY**

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 -- West Virginia 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 with Alzheimer's disease or related disorders. These facilities include, but are not limited to, adult day care facilities, assisted living residences, behavioral health centers, nursing homes, and residential care communities.

2. Definitions.

2.1. Adult Day Care Facility - Any facility licensed as a medical adult day care center under West Virginia 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 West Virginia 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 West Virginia 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 West Virginia 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.

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 West Virginia 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 West Virginia 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 include, but are not limited to, senile dementia, presenile dementia, multi-infarct dementia, vascular dementia, alcoholic dementia, medical diagnoses with dementia.

2.14. Residential Care Community - Any facility licensed as a residential care community under West Virginia 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 of Health Sciences at West Virginia University or his 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 West Virginia 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 Services 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 or provide treatment or care for an individual with 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 <http://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 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.

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 oversight and direction of the Registry.

11. Communication.

11.1. Communication 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, 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

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: _____

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

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, Ungcr, 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.”

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: April 2, 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 _____

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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

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2 LIST OF ABBREVIATIONS AND DEFINITIONS

AD	Alzheimer's Disease
ADRD	Alzheimer's Disease and related dementias
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

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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 dementias in West Virginia.</p> <p>To obtain longitudinal data on Alzheimer's Disease and related dementias 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 dementias.</p>
Number of Registrants:	All patients with Alzheimer's Disease and related dementias are eligible for the registry. (Approximately 42,000 patients with a diagnosis of Alzheimer's Disease and related dementias 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

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- 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.

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4 INTRODUCTION

The West Virginia Alzheimer's Disease Registry (WVADR) is a population-based registry of patients with Alzheimer's disease and related dementias (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 dementias 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 dementias 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 dementias 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.

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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 dementias 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 dementia shall participate in WVADR (see Appendix 1 for classification of ADRD by ICD-9-CM codes).

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
 - Education level
- Patient contact information, including secondary contacts
- Current residential status (e.g., nursing home, community)

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- Brief Medical history
- Alzheimer's disease and related dementias 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 AD/DRD. 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 AD/DRD 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 AD/DRD 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

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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.

8.3 Changes to the Protocol

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

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8.4 External and Internal WVADR Committees

Both an external and an internal advisory committee will be established to help implement, coordinate and provide oversight of the WVADR. The Internal Advisory Committee may be comprised of, but not limited to, representatives from The Blanchette Rockefeller Neurosciences Institute, The Institute on Aging, Departments of Neurology, Community Medicine, Behavioral Medicine and Psychiatry, and the Office of the Vice President for Health Sciences.

The External Advisory Committee will consist of representatives of public and private entities and organizations and other individuals involved in Alzheimer's disease. These may include but would not be limited to the West Virginia Alzheimer's Association, West Virginia Department of Health and Human Resources, West Virginia State Medical Association, West Virginia Health Care Association, and members of the community.

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.

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Appendix One

Classification of Dementias 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.
- 290.8 Other specified senile psychotic condition.
- 290.9 Unspecified senile psychotic condition.
- 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 psychotic 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, postconcussion 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, 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.

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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"/> Senile dementia <input type="checkbox"/> Alzheimer's disease <input type="checkbox"/> Multi-infarct dementia <input type="checkbox"/> Drug induced or alcoholic dementia <input type="checkbox"/> Other organic psychotic 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"/> Senility without mention of psychosis			
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			
Has the patient been exposed to any of the following? Trauma to head: <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, Age? _____ Anemia: <input type="checkbox"/> Yes <input type="checkbox"/> No Nutritional deficiencies (vitamin B12, niacin, folic acid): <input type="checkbox"/> Yes <input type="checkbox"/> No Use of antidepressants: <input type="checkbox"/> Yes <input type="checkbox"/> No Drug abuse: <input type="checkbox"/> Yes <input type="checkbox"/> No Tobacco: <input type="checkbox"/> Yes <input type="checkbox"/> No Alcohol abuse: <input type="checkbox"/> Yes <input type="checkbox"/> No			
Prolonged exposure to contaminants and/or toxins?: <input type="checkbox"/> Yes <input type="checkbox"/> No			
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: _____@_____	