Submission#: **27676**
FWA#: **FWA00001995**
Name#: **Benaroya Rsch Inst at Virginia Mason**

OMB No. 0990-0278
Approved for use through June 30, 2014

Federalwide Assurance (FWA) for the Protection of Human Subjects

Update or Renewal for FWA Number: FWA00001995

1. Institution Filing Assurance

Legal Name: **Benaroya Rsch Inst at Virginia Mason**

City: **Seattle** State/Province: **WA** Country: **USA**

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	Status
Benaroya Rsch Institute (aka)	**Seattle**	WASHINGTON	
Virginia Mason Rsch Ctr (aka)	**Seattle**	WASHINGTON	

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

The Belmont Report

4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46

5. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

6. Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
IRB00000021	Fred Hutchinson Cancer Rsch Ctr IRB #1 - Biomedical Research	E
IRB00000022	Fred Hutchinson Cancer Rsch Ctr IRB #2 - Biomed/HVTN/Inf. Disease	E
IRB00000057	Benaroya Rsch Inst at Virginia Mason IRB #1	I
IRB00000241	U of W - A	E
IRB00000242	U of Washington IRB#2 - B	E
IRB00000243	U of Washington IRB#3 - C	E
IRB00000277	Seattle Children's Hosp IRB #1	E
IRB00000533	Western IRB #1-8, #11-14, & #35	E
IRB00000668	Group Hlth Cooperative IRB #1	E
IRB00000727	U of Washington IRB#4 - D	E
IRB00000743	Swedish Med Ctr IRB #2	E
IRB00000781	National Cancer Inst Central IRB #1 (Adult)	E
IRB00002532	U of Washington IRB#5 - G	E
IRB00003226	Quorum Review Inc. IRBs 1-4	E
IRB00004442	U of Washington IRB #6 - V	E
IRB00005619	Fred Hutchinson Cancer Rsch Ctr IRB #3 - PHS & Behavioral Rsch	E
IRB00005647	U of Washington IRB #7 - J	E

7. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: **Cheryl** Middle Initial: Last Name: **Weaver**

Degrees or Suffix: **CCRC** Institutional Title: **Administrative Director, Clinical Research**

Institution: **Benaroya Research Institute at Virginia Mason**

Telephone: **206 342-6911** FAX: **206 223-7543** E-Mail: **cweaver@benaroyaresearch.org**

Address: **Benaroya Research Institute at Virginia Mason**
1201 Ninth Avenue

City: **Seattle** State/Province: **WA** Country: **USA**

8. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature: **Jack Nagan J.D.**

Date: **10/20/2011**

First Name: **Jack** Middle Initial: Last Name: **Nagan**

Degrees or Suffix: **J.D.** Institutional Title: **Executive Director (BRI) / Vice President (VMMC)**

Institution: **Benaroya Research Institute at Virginia Mason**

Telephone: **206 342-6565** FAX: **206 223-7638** E-Mail: **jnagan@benaroyaresearch.org**

Address: **1201 Ninth Avenue**
Mailstop: IN-RC

City: **Seattle** State/Province: **WA** Country: **USA**

9. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects for Institutions Within the United States submitted to HHS by the above Institution is hereby approved.

Assurance Number: Expiration Date:

HHS Approving Official: Date:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance