IR# 3467ext/a

Institutional Review Board (IRB) Authorization Agreement

Name of Institution Providing IRB Review:

FRED HUTCHINSON CANCER RESEARCH CENTER (FHCRC) - Federalwide Assurance (FWA) # 00001920 – IRB Registration # Com A (00000021), Com B (00000022), Com C (00005619)

Name of Institution Relying on the Designated IRB:

BRIGHAM AND WOMEN'S HOSPITAL (BWH) - Federalwide Assurance (FWA) # 00000484

Terms of Agreement

1. The Officials signing below agree that BWH, a member institution of Partners HealthCare System, Inc. (PARTNERS), may rely on the FHCRC IRB for review and continuing oversight of its human subject research described below:

   Name of Research Project: **Women's Health Initiative (WHI) Extension Study**
   Protocol #: **FHCRC IRB #3467EXT**
   Name(s) of Principal Investigator(s) at each Site: **Ross Prentice, PhD & Garnet Anderson, PhD (FHCRC)**
   Joann Manson, MD, Dr PH (BWH)
   Sponsor or Funding Source and Award # (if any): **Research Foundation of State University of New York**

2. The review and continuing oversight performed by the FHCRC IRB will meet the human subjects protection requirements of BWH's OHRP-approved FWA, a copy of which is available to the FHCRC IRB.

3. The FHCRC IRB will perform any determination required by the Health Insurance Portability and Accountability Act (HIPAA) and its regulations with respect to the research included under this Agreement, including determinations related to waivers of authorization for use and disclosure for research of subjects' Protected Health Information (PHI) as defined in the HIPAA regulations. FHCRC will provide a form of authorization for use and disclosure of PHI if such authorization is required. Determinations as to the legal sufficiency of such authorization forms under HIPAA shall be made by the entity or organization from which PHI is obtained for the research.

4. The FHCRC IRB will allow representatives of BWH to attend its meetings and will otherwise accept comments from BWH's representatives in the review of study, to the extent necessary to ensure sufficient knowledge of the local research context.

5. The FHCRC IRB, or the Women's Health Initiative CCC, will notify BWH and the responsible BWH PI in writing of its decision to approve or disapprove the study or of modifications required to secure approval of the study, as well as subsequent IRB-reviewed and approved changes in the research activity, namely, by sending copies to the BWH officials designated in this Agreement and to the BWH PI of the review notification letters it sends to investigators. Relevant minutes of FHCRC IRB meetings pertaining to the study will be made available to BWH upon written request.

6. BWH remains responsible in connection with the study for ensuring compliance with the determinations of the FHCRC IRB and with the terms of BWH's OHRP-approved FWA.

7. The FHCRC IRB will promptly notify BWH in writing of any serious or continuing non-compliance by BWH or its investigators discovered by the FHCRC IRB or FHCRC, any suspension or termination of IRB approval, and any injuries to subjects or unanticipated problems involving risks to subjects or others discovered by the FHCRC IRB or FHCRC in connection with the study. BWH will promptly report to

FHCRC any serious or continuing non-compliance by BWH or its investigators in connection with the study of which it is aware, and will make all reasonable efforts to ensure that its investigators promptly report to FHCRC any injury to subjects or unanticipated problem involving risks to subjects or others in connection with the study of which they are aware.

8. FHCRC will be responsible for any investigation of non-compliance or other such matters. If the investigative process includes the production of a report that will be made externally (e.g. OHRP), FHCRC shall provide a copy of such report made to external organizations. Nothing in this Agreement shall prevent BWH from conducting its own inquiry or investigation into any such matter pursuant to its own policies and procedures, or from making its own report to external authorities, or from taking additional, more restrictive remediation steps at its own institution, including the termination of participation by BWH investigators in the study. Each party agrees to use all reasonable efforts to cooperate with one another's inquiries or investigations, including providing access to necessary research records and related information and meeting with research representatives upon request.

9. This Agreement shall become effective on the last date signed below and shall continue until completion of the research as determined by the FHCRC IRB, provided that the parties' FWAs remain in good standing and provided that the Agreement is not earlier terminated as provided in Section 11 below.

10. Either FHCRC or BWH may terminate this Agreement (i) without cause upon 30 days prior written notice to the other or (ii) upon 14 days prior written notice to the other in the event of a breach by the other that is not cured to the reasonable satisfaction of the non-breaching party within said 14-day notice period. In the event of any termination, the parties will ensure that OHRP is notified and will work together to determine effect of such termination on the research being conducted under the Agreement at the time of termination. Sections 8, 9, 11, and 12 of this Agreement will survive any expiration or termination of the Agreement.

11. All communications, reports and notices required under this Agreement shall be delivered by hand, by facsimile, or by first-class mail, postage prepaid and addressed as follows:

If to BWH/Partners:
P. Pearl O'Rourke, M.D.
Director of Human Research Affairs
Partners HealthCare System, Inc.
Research Management
116 Huntington Ave., Suite 1002
Boston, MA 02116
Fax: (617) 424-4199

With copies to:
Elizabeth L. Hohmann, M.D.
Director and Chair
Partners Human Research Committee
116 Huntington Ave., Suite 1002
Boston, MA 02116
Fax: (617) 424-4199

and:
Maria Sundquist
Assistant Director, New Submissions
Partners Human Research Committee
116 Huntington Ave., Suite 1002
Boston, MA 02116
Fax: (617) 424-4199
Email: msundquist@partners.org

If to FHCRC:

Karen Hansen
Director, Institutional Review Office
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue N – Mailstop J6-110
Seattle, WA 98109
Fax: (206) 667-6831
Email khansen@fhcrc.org

12. Miscellaneous: This Agreement has been executed and delivered in and shall be governed by and construed and interpreted in accordance with the laws of the Commonwealth of Massachusetts. This Agreement may be amended only by a written agreement signed by the parties. If any provision of this Agreement shall be held to be invalid, illegal, or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall not be affected thereby. The failure of a party to insist upon the strict performance of any of the terms of this Agreement shall not be construed to be a waiver or relinquishment of any of the terms of the Agreement or of the whole Agreement. This Agreement is not assignable in whole or in part, and any attempt to do so shall be void.

This Agreement must be kept on file at both institutions and provided to OHRP upon request.

EXECUTED BY AUTHORIZED SIGNATORY OFFICIALS

P. Pearl O'R Date: 11/22/11

Name: P. Pearl O'Rourke, M.D.
Institutional Title: Director of Human Research Affairs
Partners HealthCare System, Inc.
Research Management
116 Huntington Ave., Suite 1002
Boston, MA 02116

Barbara E. Bierer Date: 11/18/2011

Name: Barbara E. Bierer, MD
Institutional Title: Senior Vice President, Research
Brigham and Women's Hospital
75 Francis Street -- PB-04-415
Boston, MA 02115

Karen Hansen Date: 10/14/11

Name: Karen Hansen
Institutional Title: Director, Institutional Review Office
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue N – Mailstop J6-110
Seattle, WA 98109

FRED HUTCHINSON
CANCER RESEARCH CENTER
Institutional Review Board

IRB Authorization Agreement

Institution A - Name of Institution or Organization Providing IRB Review:
Fred Hutchinson Cancer Research Center (FHCRC)
IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619), Com D (00009831)
Federalwide Assurance (FWA) #: FWA00001920

Institution B - Name of Institution Relying on the Designated IRB: **University of Buffalo**
Federalwide Assurance (FWA) #: FWA00008824

The Officials signing below agree that Institution B may rely on the Fred Hutchinson Cancer Research Center's IRB for review and continuing oversight of the human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by Institution B's FWA.

☒ This agreement is limited to the following specific protocol(s):

Title of Research Project:	Human research activities of the WHI Regional/Satellite Center relating to "Clinical Coordinating Center for the WHI 2010-2015 Extension" (FHCRC IRB #3467ext)
FHCRC Principal Investigator: Garnet Anderson, PhD	Institution B's Principal Investigator: Jean Wactawski-Wende, PhD

The review performed by the Fred Hutchinson Cancer Research Center's IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Fred Hutchinson Cancer Research Center will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This agreement will become effective upon the date of the last signature by the Institutional Officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution. Following termination of this Agreement, the Fred Hutchinson Cancer Research Center agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the relying institution's IRB. This document must be kept on file at both institutions and will be provided to OHRP upon request. Additional terms and responsibilities are outlined on the attached addendum and shall be deemed incorporated herein by reference.

Signatures:

Authorized Official of FHCRC:
(signature) 7/22/15 (date)
Name: Karen Hansen
Title: Director, Institutional Review Office

Mailing Address: 1100 Fairview Avenue N
Mailstop: J2-100
Seattle, WA 98109
Phone: (206) 667-4867 Fax: (206) 667-6831
Email: khansen@fredhutch.org

Authorized Official of (B):
(signature) 11-5-2015 (date)
Name: Kenneth M. Tramposch
Title: Associate Vice President for Research

Mailing Address: 516 Capen Hall
Buffalo, NY 14260-1631
Phone: (716) 645-3321 Fax: (716) 645-6792
Email: kmtl@buffalo.edu

Attachment to IRB Authorization Agreement:
Division of Responsibilities between FHCRC and Institution B
when FHCRC IRB is the IRB of Record

The following Division of Responsibilities is based on the premise that the FHCRC IRB is providing IRB oversight for human subjects research activity occurring at Institution B, and that Institution B's primary function is (a) to contribute local context to the FHCRC IRB review and (b) conduct oversight of local performance of these studies. As the IRB of record, the FHCRC IRB will conduct all reviews in accordance with 45 CFR 46, 21 CFR 50 and 56, 45 CFR 164, and RCW 70.02 as applicable.

The responsibilities of the FHCRC IRB are to:

- Perform initial review of new studies, discuss any issues with the Principal Investigator, require necessary modifications to the study, and make a final decision of approval or disapproval of the study;
- Conduct continuing review of the research and review study amendments;
- Conduct review of serious, unexpected, and related adverse events; serious or continuing noncompliance; and other unanticipated problems;
- Either directly, or through the appropriate FHCRC coordinating center, inform the Principal Investigator at Institution B in writing of FHCRC IRB determinations including approvals and disapproval, required modifications, determinations related to unanticipated problems and noncompliance, and any changes in the study approval status;
- Either directly, or through the appropriate FHCRC coordinating center, notify the Principal Investigator at Institution B of new materials that have been reviewed for an active study and any changes in the study approval status;
- Promptly notify the Principal Investigator at FHCRC, the Principal Investigator at Institution B, and appropriate officials at Institution B of any FHCRC IRB determinations that require reporting to institutional officials and/or regulatory agencies under 45 CFR 46.103(b)(5) and 21 CFR 56.108(b) and 56.113 . The FHCRC IRB, through the FHCRC Institutional Review Office, will submit required reports to the applicable federal department (e.g. OHRP, FDA) and/or funding agency head(s). The FHCRC Institutional Review Office will make best efforts to provide Institution B an opportunity to review and provided input on any reports prior to transmission to regulatory agencies;
- Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
- Make available to Institution B the roster of FHCRC IRB membership and the FHCRC IRB Standard Operating Procedures (SOPs);
- Ensure that FHCRC IRB members receive orientation and continuing education on topics relevant to human subjects protection;
- Ensure that the FHCRC IRB has adequate meeting space and sufficient staff to support the FHCRC IRB's review and recordkeeping duties;
- Notify Institution B immediately if there is ever a suspension or restriction of the FHCRC IRB's authorization to review a study; and
- Notify Institution B of any changes in FHCRC IRB SOPs that might affect the institution's reliance on FHCRC IRB reviews or performance of the research at the local institution.

The responsibilities of Institution B are to:

- When needed, provide a local context reviewer who has knowledge of the local research context and is able to review the informed consent form and related documents (e.g. authorizations for testing and release of medical records or donation of human specimens) to verify for the FHCRC IRBP that these documents comply with applicable federal, state or local laws, institutional requirements, or IRB policies of Institution B;
- Ensure the safe and appropriate performance of the research at Institution B. This includes, but is not limited to, conducting the research as approved by the FHCRC IRB, monitoring protocol compliance (after becoming aware of protocol deviations, unanticipated problems or noncompliance through the FHCRC IRB), managing any major protocol violations, managing any serious adverse events occurring at the institution, ensuring qualifications and training of research staff are commensurate with the research activity and providing a mechanism by which complaints about the research can be made by local study participants or others;
- Provide the names and addresses to the FHCRC Institutional Review Office of local contact persons who have the authority to correspond on behalf of Institution B (e.g. the local IRB Director);
- Maintain records of FHCRC IRB approved research at Institution B as per institution policies;
- Maintain an OHRP-approved Assurance for human subjects research;
- Promptly notify the FHCRC Institutional Review Office if Institution B becomes aware of events that may change the ability of the site to conduct the research (e.g., suspension of the institution's FWA);
- Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 50 and 56;
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects; and
- Review and monitor individual and institutional conflicts of interest per Institution B's policies and procedures.

Further Delineation by Topic

Confidentiality Laws and Regulations:

Compliance with confidentiality laws and regulations, including HIPAA and state law requirements, is considered a local institutional issue. The FHCRC IRB expects the designated local context reviewer to have knowledge of these requirements for Institution B and to be able to provide comments before or during the FHCRC IRB review process. Institution B remains responsible for how compliance with these confidentiality requirements is implemented at the institution.

Prisoners:

The FHCRC adheres to 45 CFR 46 Subpart C and needs to re-review a protocol when it becomes aware of a investigator wanting to conduct research on a prisoner. Institution B must notify the FHCRC IRB before enrolling prisoners in research overseen by FHCRC IRB. For research that is approved to include prisoners in accordance with Subpart C, the FHCRC IRB, through the FHCRC Institutional Review Office, will prepare the Prisoner Certification Letter to OHRP.

Serious Adverse Events and Other Unanticipated Problems

It is the responsibility of Institution B's Principal Investigator to identify and report Serious Adverse Events and Other Unanticipated Problems in accordance with the FHCRC IRB Policy 2.6 Unanticipated Problems Involving Risk to Subjects or Others. For events that must be reported to the FHCRC IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the event constitutes and Unanticipated Problem Involving Risk to Subjects or Others.

Noncompliance:

It is the responsibility of Institution B's Principal Investigator to identify and report Noncompliance in accordance with the FHCRC IRB Policy 1.9 Noncompliance. For events that must be reported to the FHCRC IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the event constitutes Serious or Continuing Noncompliance.

FRED HUTCHINSON CANCER RESEARCH CENTER
Institutional Review Board

IRB Authorization Agreement

Institution A - Name of Institution or Organization Providing IRB Review:
Fred Hutchinson Cancer Research Center (FHCRC)
IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619), Com D (00009831)
Federalwide Assurance (FWA) #: FWA00001920

Institution B - Name of Institution Relying on the Designated IRB: **MedStar Health Research Institute**
Federalwide Assurance (FWA) #: FWA00000504

The Officials signing below agree that Institution B may rely on the Fred Hutchinson Cancer Research Center's IRB for review and continuing oversight of the human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by Institution B's FWA.

☒ This agreement is limited to the following specific protocol(s):

Title of Research Project:	Human research activities of the WHI Regional/Satellite Center relating to "Clinical Coordinating Center for the WHI 2010-2015 Extension" (FHCRC IRB #3467EXT)
FHCRC Principal Investigator: Garnet Anderson, PhD	Institution B's Principal Investigator: Barbara Howard, PhD

The review performed by the Fred Hutchinson Cancer Research Center's IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Fred Hutchinson Cancer Research Center will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This agreement will become effective upon the date of the last signature by the Institutional Officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution. Following termination of this Agreement, the Fred Hutchinson Cancer Research Center agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the relying institution's IRB. This document must be kept on file at both institutions and will be provided to OHRP upon request. Additional terms and responsibilities are outlined on the attached addendum and shall be deemed incorporated herein by reference.

Signatures:

Authorized Official of FHCRC:
Karen Hansen 6/22/15
(signature) (date)
Name: Karen Hansen
Title: Director, Institutional Review Office

Mailing Address: 1100 Fairview Avenue N
Mailstop: J2-100
Seattle, WA 98109
Phone: (206) 667-4867 Fax: (206) 667-6831
Email: khansen@fredhutch.org

Authorized Official of (B):
(signature) 6/29/15 (date)
Name: Neil J. Weissman, MD
Title: President, MedStar Health Research Institute

Mailing Address: 6525 Belcrest Road, Suite 700
Hyattsville, MD 20782
Phone: (202) 877-0223 Fax: (301) 560-7336
Email: Neil.J. Weissman@medstar.net

Attachment to IRB Authorization Agreement:
Division of Responsibilities between FHCRC and Institution B
when FHCRC IRB is the IRB of Record

The following Division of Responsibilities is based on the premise that the FHCRC IRB is providing IRB oversight for human subjects research activity occurring at Institution B, and that Institution B's primary function is (a) to contribute local context to the FHCRC IRB review and (b) conduct oversight of local performance of these studies. As the IRB of record, the FHCRC IRB will conduct all reviews in accordance with 45 CFR 46, 21 CFR 50 and 56, 45 CFR 164, and RCW 70.02 as applicable.

The responsibilities of the FHCRC IRB are to:

- Perform initial review of new studies, discuss any issues with the Principal Investigator, require necessar modifications to the study, and make a final decision of approval or disapproval of the study;
- Conduct continuing review of the research and review study amendments;
- Conduct review of serious, unexpected, and related adverse events; serious or continuing noncompliance and other unanticipated problems;
- Either directly, or through the appropriate FHCRC coordinating center, inform the Principal Investigator at Institution B in writing of FHCRC IRB determinations including approvals and disapproval, required modifications, determinations related to unanticipated problems and noncompliance, and any changes in the study approval status;
- Either directly, or through the appropriate FHCRC coordinating center, notify the Principal Investigator a Institution B of new materials that have been reviewed for an active study and any changes in the study approval status;
- Promptly notify the Principal Investigator at FHCRC, the Principal Investigator at Institution B, and appropriate officials at Institution B of any FHCRC IRB determinations that require reporting to institutional officials and/or regulatory agencies under 45 CFR 46.103(b)(5) and 21 CFR 56.108(b) and 56.113 . The FHCRC IRB, through the FHCRC Institutional Review Office, will submit required report to the applicable federal department (e.g. OHRP, FDA) and/or funding agency head(s). The FHCRC Institutional Review Office will make best efforts to provide Institution B an opportunity to review and provided input on any reports prior to transmission to regulatory agencies;
- Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
- Make available to Institution B the roster of FHCRC IRB membership and the FHCRC IRB Standard Operating Procedures (SOPs);
- Ensure that FHCRC IRB members receive orientation and continuing education on topics relevant to human subjects protection;
- Ensure that the FHCRC IRB has adequate meeting space and sufficient staff to support the FHCRC IRB' review and recordkeeping duties;
- Notify Institution B immediately if there is ever a suspension or restriction of the FHCRC IRB's authorization to review a study; and
- Notify Institution B of any changes in FHCRC IRB SOPs that might affect the institution's reliance on FHCRC IRB reviews or performance of the research at the local institution.

The responsibilities of Institution B are to:

- When needed, provide a local context reviewer who has knowledge of the local research context and is able to review the informed consent form and related documents (e.g. authorizations for testing and

release of medical records or donation of human specimens) to verify for the FHCRC IRB that these documents comply with applicable federal, state or local laws, institutional requirements, or IRB policies of Institution B;

- Ensure the safe and appropriate performance of the research at Institution B. This includes, but is not limited to, conducting the research as approved by the FHCRC IRB, monitoring protocol compliance (after becoming aware of protocol deviations, unanticipated problems or noncompliance through the FHCRC IRB), managing any major protocol violations, managing any serious adverse events occurring a the institution, ensuring qualifications and training of research staff are commensurate with the research activity and providing a mechanism by which complaints about the research can be made by local study participants or others;
- Provide the names and addresses to the FHCRC Institutional Review Office of local contact persons who have the authority to correspond on behalf of Institution B (e.g. the local IRB Director);
- Maintain records of FHCRC IRB approved research at Institution B as per institution policies;
- Maintain an OHRP-approved Assurance for human subjects research;
- Promptly notify the FHCRC Institutional Review Office if Institution B becomes aware of events that ma change the ability of the site to conduct the research (e.g., suspension of the institution's FWA);
- Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 50 and 56;
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects; and
- Review and monitor individual and institutional conflicts of interest per Institution B's policies and procedures.

Further Delineation by Topic

Confidentiality Laws and Regulations:

Compliance with confidentiality laws and regulations, including HIPAA and state law requirements, is considered a local institutional issue. The FHCRC IRB expects the designated local context reviewer to have knowledge of these requirements for Institution B and to be able to provide comments before or during the FHCRC IRB review process. Institution B remains responsible for how compliance with these confidentiality requirements is implemented at the institution.

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Serious Adverse Events and Other Unanticipated Problems

It is the responsibility of Institution B's Principal Investigator to identify and report Serious Adverse Events and Other Unanticipated Problems in accordance with the FHCRC IRB Policy 2.6 Unanticipated Problems Involving Risk to Subjects or Others. For events that must be reported to the FHCRC IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the event constitutes and Unanticipated Problem Involving Risk to Subjects or Others.

Noncompliance:

It is the responsibility of Institution B's Principal Investigator to identify and report Noncompliance in accordance with the FHCRC IRB Policy 1.9 Noncompliance. For events that must be reported to the FHCRC IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the event constitutes Serious or Continuing Noncompliance.

FRED HUTCH
Institutional Review Office

June 15, 2015

Neil J. Weissman, MD
President
MedStar Health Research Institute
6525 Belcrest Road, Suite 700
Hyattsville, MD 20782

RE: Update to IRB Authorization Agreement between MedStar Health Research Institute and Fred Hutchinson Cancer Center (FHCRC)
IR File # 3467EXT/Protocol # 3467
Title: "Women's Health Initiative - Clinical Coordinating Center"

Dear Dr. Weissman,

FHCRC recently added a 4th IRB to our system and we are updating all IRB Authorization Agreements to reflect the addition of FHCRC IRB Committee D (IRB00009821).

All authorization agreements are also being updated with more detail on the delineation of duties to reflect Association for Accreditation of Human Research Protection Programs (AAHRPP) standards and to more clearly document each of our institution's responsibilities.

Attached is an updated IRB Authorization Agreement for the above referenced activity. A copy of our existing agreement is attached for reference. Please sign the updated agreement and return to:

James Riddle, MCSE, CIP, CPIA
Assistant Director, Institutional Review Office
1100 Fairview Ave N.
Seattle WA 98109

Or via e-mail to jriddle@fredhutch.org

Thank you for your continued partnership with FHCRC IRB. Feel free to contact me with any questions and/or concerns.

Sincerely,

Karen Hansen
Director, Institutional Review Office
Tel: 206-667-4867
khansen@fredhutch.org

KH:MR

enc: Copy of IRB Authorization Agreement

cc: Garnet Anderson; M3-A410
Doris Nodtvedt, Doris; M3-A410
IR File #3467EXT/ Protocol # 3467

FRED HUTCHINSON
CANCER RESEARCH CENTER
Institutional Review Board

IRB Authorization Agreement

Institution A - Name of Institution or Organization Providing IRB Review:
Fred Hutchinson Cancer Research Center (FHCRC)
IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619), Com D (00009831)
Federalwide Assurance (FWA) #: FWA00001920

Institution B - Name of Institution Relying on the Designated IRB: **University of Pittsburgh**
Federalwide Assurance (FWA) #: FWA00006790

The Officials signing below agree that Institution B may rely on the Fred Hutchinson Cancer Research Center's IRB for review and continuing oversight of the human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by Institution B's FWA.

☒ This agreement is limited to the following specific protocol(s):

Title of Research Project:	Human research activities of the WHI Regional/Satellite Center relating to "Clinical Coordinating Center for the WHI 2010-2015 Extension" (FHCRC IRB #3467ext)

FHCRC Principal Investigator:	Institution B's Principal Investigator:
Garnet Anderson, PhD	Lewis Kuller, MD

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Signatures:

Authorized Official of FHCRC:
Karen Hansen 6/16/15
(signature) (date)
Name: Karen Hansen
Title: Director, Institutional Review Office

Mailing Address: 1100 Fairview Avenue N
Mailstop: J2-100
Seattle, WA 98109
Phone: (206) 667-4867 Fax: (206) 667-6831
Email: khansen@fredhutch.org

Authorized Official of (B):
(signature) 9/25/15 (date)
Name: George A. Huber, JD, MSIE, MSSM
Title: Interim Vice Provost for Research Conduct and Compliance

Mailing Address: 132 Cathedral of Learning
4200 Fifth Avenue
Pittsburgh, PA 15260
Phone:(412)624-2202 Fax: (412) 624-6903
Email: ghuber@pitt.edu

Attachment to IRB Authorization Agreement:
Division of Responsibilities between FHCRC and Institution B
when FHCRC IRB is the IRB of Record

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- Conduct review of serious, unexpected, and related adverse events; serious or continuing noncompliand and other unanticipated problems;
- Either directly, or through the appropriate FHCRC coordinating center, inform the Principal Investigat at Institution B in writing of FHCRC IRB determinations including approvals and disapproval, require modifications, determinations related to unanticipated problems and noncompliance, and any changes i the study approval status;
- Either directly, or through the appropriate FHCRC coordinating center, notify the Principal Investigato Institution B of new materials that have been reviewed for an active study and any changes in the study approval status;
- Promptly notify the Principal Investigator at FHCRC, the Principal Investigator at Institution B, and appropriate officials at Institution B of any FHCRC IRB determinations that require reporting to institutional officials and/or regulatory agencies under 45 CFR 46.103(b)(5) and 21 CFR 56.108(b) and 56.113 . The FHCRC IRB, through the FHCRC Institutional Review Office, will submit required repo to the applicable federal department (e.g. OHRP, FDA) and/or funding agency head(s). The FHCRC Institutional Review Office will make best efforts to provide Institution B an opportunity to review and provided input on any reports prior to transmission to regulatory agencies;
- Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provide special expertise as needed to adequately assess all aspects of each study;
- Make available to Institution B the roster of FHCRC IRB membership and the FHCRC IRB Standard Operating Procedures (SOPs);
- Ensure that FHCRC IRB members receive orientation and continuing education on topics relevant to human subjects protection;
- Ensure that the FHCRC IRB has adequate meeting space and sufficient staff to support the FHCRC IR review and recordkeeping duties;
- Notify Institution B immediately if there is ever a suspension or restriction of the FHCRC IRB's authorization to review a study; and
- Notify Institution B of any changes in FHCRC IRB SOPs that might affect the institution's reliance on FHCRC IRB reviews or performance of the research at the local institution.

The responsibilities of Institution B are to:

- When needed, provide a local context reviewer who has knowledge of the local research context and is able to review the informed consent form and related documents (e.g. authorizations for testing and

release of medical records or donation of human specimens) to verify for the FHCRC IRB that these documents comply with applicable federal, state or local laws, institutional requirements, or IRB polic of Institution B;

- Ensure the safe and appropriate performance of the research at Institution B. This includes, but is not limited to, conducting the research as approved by the FHCRC IRB, monitoring protocol compliance (after becoming aware of protocol deviations, unanticipated problems or noncompliance through the FHCRC IRB), managing any major protocol violations, managing any serious adverse events occurrir the institution, ensuring qualifications and training of research staff are commensurate with the resear activity and providing a mechanism by which complaints about the research can be made by local stu participants or others;
- Provide the names and addresses to the FHCRC Institutional Review Office of local contact persons v have the authority to correspond on behalf of Institution B (e.g. the local IRB Director);
- Maintain records of FHCRC IRB approved research at Institution B as per institution policies;
- Maintain an OHRP-approved Assurance for human subjects research;
- Promptly notify the FHCRC Institutional Review Office if Institution B becomes aware of events that change the ability of the site to conduct the research (e.g., suspension of the institution's FWA);
- Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 50 and 56;
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects; and
- Review and monitor individual and institutional conflicts of interest per Institution B's policies and procedures.

Further Delineation by Topic

Confidentiality Laws and Regulations:

Compliance with confidentiality laws and regulations, including HIPAA and state law requirements, i considered a local institutional issue. The FHCRC IRB expects the designated local context reviewer have knowledge of these requirements for Institution B and to be able to provide comments before or during the FHCRC IRB review process. Institution B remains responsible for how compliance with th confidentiality requirements is implemented at the institution.

Prisoners:

The FHCRC adheres to 45 CFR 46 Subpart C and needs to re-review a protocol when it becomes awa a investigator wanting to conduct research on a prisoner. Institution B must notify the FHCRC IRB be enrolling prisoners in research overseen by FHCRC IRB. For research that is approved to include prisoners in accordance with Subpart C, the FHCRC IRB, through the FHCRC Institutional Review Office, will prepare the Prisoner Certification Letter to OHRP.

Serious Adverse Events and Other Unanticipated Problems

It is the responsibility of Institution B's Principal Investigator to identify and report Serious Adverse Events and Other Unanticipated Problems in accordance with the FHCRC IRB Policy 2.6 Unanticipa Problems Involving Risk to Subjects or Others. For events that must be reported to the FHCRC IRB, Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the event constitutes and Unanticipated Problem Involving Risk to Subjects or Others.

Noncompliance:

It is the responsibility of Institution B's Principal Investigator to identify and report Noncompliance in accordance with the FHCRC IRB Policy 1.9 Noncompliance. For events that must be reported to the FHCRC IRB, the Principal Investigator at Institution B will be responsible for providing the appropri documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure repor to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the eve constitutes Serious or Continuing Noncompliance.

June 15, 2015

Ann M. Arvin, MD
Vice Provost and Dean of Research
Leland Stanford Junior University
Office of the Dean of Research
Building 10, Main Quad
Stanford, CA 94305-2061

RE: Update to IRB Authorization Agreement between Leland Stanford Junior University and Fred Hutchinson Cancer Center (FHCRC)
IR File # 3467EXT/Protocol # 3467
Title: "Women's Health Initiative - Clinical Coordinating Center"

Dear Dr. Arvin,

FHCRC recently added a 4th IRB to our system and we are updating all IRB Authorization Agreements to reflect the addition of FHCRC IRB Committee D (IRB00009821).

All authorization agreements are also being updated with more detail on the delineation of duties to reflect Association for Accreditation of Human Research Protection Programs (AAHRPP) standards and to more clearly document each of our institution's responsibilities.

Attached is an updated IRB Authorization Agreement for the above referenced activity. A copy of our existing agreement is attached for reference. Please sign the updated agreement and return to:

James Riddle, MCSE, CIP, CPIA
Assistant Director, Institutional Review Office
1100 Fairview Ave N.
Seattle WA 98109

Or via e-mail to jriddle@fredhutch.org

Thank you for your continued partnership with FHCRC IRB. Feel free to contact me with any questions and/or concerns.

Sincerely,

Karen Hansen
Director, Institutional Review Office
Tel: 206-667-4867
khansen@fredhutch.org

KH:MR

enc: Copy of IRB Authorization Agreement

cc: Garnet Anderson, PhD; M3-A410
Doris Nodtvedt; M3-A410
IR File #3467EXT/ Protocol #3467

FRED HUTCHINSON CANCER RESEARCH CENTER
Institutional Review Board

IRB Authorization Agreement

Institution A - Name of Institution or Organization Providing IRB Review:
Fred Hutchinson Cancer Research Center (FHCRC)
IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619), Com D (00009831)
Federalwide Assurance (FWA) #: FWA00001920

Institution B - Name of Institution Relying on the Designated IRB: **Leland Stanford Junior University**
Federalwide Assurance (FWA) #: FWA00000935

The Officials signing below agree that Institution B may rely on the Fred Hutchinson Cancer Research Center's IRB for review and continuing oversight of the human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by Institution B's FWA.

☒ This agreement is limited to the following specific protocol(s):

Title of Research Project:	Human research activities of the WHI Regional Satellite Center relating to "Clinical Coordinating Center for the WHI 2010-2015 Extension" (FHCRC IRB #3467ext)
FHCRC Principal Investigator: Garnet Anderson, PhD	Institution B's Principal Investigator: Marcia Stefanick, PhD

The review performed by the Fred Hutchinson Cancer Research Center's IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Fred Hutchinson Cancer Research Center will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This agreement will become effective upon the date of the last signature by the Institutional Officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution. Following termination of this Agreement, the Fred Hutchinson Cancer Research Center agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the relying institution's IRB. This document must be kept on file at both institutions and will be provided to OHRP upon request. Additional terms and responsibilities are outlined on the attached addendum and shall be deemed incorporated herein by reference.

Signatures:

Authorized Official of FHCRC:
Karen Hansen 6/16/15
(signature) (date)
Name: Karen Hansen
Title: Director, Institutional Review Office

Mailing Address: 1100 Fairview Avenue N
Mailstop: J2-100
Seattle, WA 98109
Phone: (206) 667-4867 Fax: (206) 667-6831
Email: khansen@fredhutch.org

Authorized Official of (B):
(signature) 6/23/15 (date)
Name: Ann M. Arvin, MD
Title: Vice Provost and Dean of Research

Mailing Address: Office of the Dean of Research
Building 10, Main Quad
Stanford, CA 94305-2061
Phone: (650) 725-4421 Fax: (650) 725-1653
Email: aarvin@stanford.edu

Attachment to IRB Authorization Agreement:
Division of Responsibilities between FHCRC and Institution B
when FHCRC IRB is the IRB of Record

The following Division of Responsibilities is based on the premise that the FHCRC IRB is providing IRB oversight for human subjects research activity occurring at Institution B, and that Institution B's primary function is (a) to contribute local context to the FHCRC IRB review and (b) conduct oversight of local performance of these studies. As the IRB of record, the FHCRC IRB will conduct all reviews in accordance with 45 CFR 46, 21 CFR 50 and 56, 45 CFR 164, and RCW 70.02 as applicable.

The responsibilities of the FHCRC IRB are to:

- Perform initial review of new studies, discuss any issues with the Principal Investigator, require necessar modifications to the study, and make a final decision of approval or disapproval of the study;
- Conduct continuing review of the research and review study amendments;
- Conduct review of serious, unexpected, and related adverse events; serious or continuing noncompliance and other unanticipated problems;
- Either directly, or through the appropriate FHCRC coordinating center, inform the Principal Investigator at Institution B in writing of FHCRC IRB determinations including approvals and disapproval, required modifications, determinations related to unanticipated problems and noncompliance, and any changes in the study approval status;
- Either directly, or through the appropriate FHCRC coordinating center, notify the Principal Investigator a Institution B of new materials that have been reviewed for an active study and any changes in the study approval status;
- Promptly notify the Principal Investigator at FHCRC, the Principal Investigator at Institution B, and appropriate officials at Institution B of any FHCRC IRB determinations that require reporting to institutional officials and/or regulatory agencies under 45 CFR 46.103(b)(5) and 21 CFR 56.108(b) and 56.113 . The FHCRC IRB, through the FHCRC Institutional Review Office, will submit required report to the applicable federal department (e.g. OHRP, FDA) and/or funding agency head(s). The FHCRC Institutional Review Office will make best efforts to provide Institution B an opportunity to review and provided input on any reports prior to transmission to regulatory agencies;
- Maintain an IRB membership that satisfies the requirements of 45 CFR 46 and 21 CFR 56 and provides special expertise as needed to adequately assess all aspects of each study;
- Make available to Institution B the roster of FHCRC IRB membership and the FHCRC IRB Standard Operating Procedures (SOPs);
- Ensure that FHCRC IRB members receive orientation and continuing education on topics relevant to human subjects protection;
- Ensure that the FHCRC IRB has adequate meeting space and sufficient staff to support the FHCRC IRB' review and recordkeeping duties;
- Notify Institution B immediately if there is ever a suspension or restriction of the FHCRC IRB's authorization to review a study; and
- Notify Institution B of any changes in FHCRC IRB SOPs that might affect the institution's reliance on FHCRC IRB reviews or performance of the research at the local institution.

The responsibilities of Institution B are to:

- When needed, provide a local context reviewer who has knowledge of the local research context and is able to review the informed consent form and related documents (e.g. authorizations for testing and

release of medical records or donation of human specimens) to verify for the FHCRC IRB that these documents comply with applicable federal, state or local laws, institutional requirements, or IRB policies of Institution B;

- Ensure the safe and appropriate performance of the research at Institution B. This includes, but is not limited to, conducting the research as approved by the FHCRC IRB, monitoring protocol compliance (after becoming aware of protocol deviations, unanticipated problems or noncompliance through the FHCRC IRB), managing any major protocol violations, managing any serious adverse events occurring a the institution, ensuring qualifications and training of research staff are commensurate with the research activity and providing a mechanism by which complaints about the research can be made by local study participants or others;
- Provide the names and addresses to the FHCRC Institutional Review Office of local contact persons who have the authority to correspond on behalf of Institution B (e.g. the local IRB Director);
- Maintain records of FHCRC IRB approved research at Institution B as per institution policies;
- Maintain an OHRP-approved Assurance for human subjects research;
- Promptly notify the FHCRC Institutional Review Office if Institution B becomes aware of events that ma change the ability of the site to conduct the research (e.g., suspension of the institution's FWA);
- Maintain a human subjects protection program compliant with 45 CFR 46 and 21 CFR 50 and 56;
- Maintain compliance with state, local, or institutional requirements related to the protection of human subjects; and
- Review and monitor individual and institutional conflicts of interest per Institution B's policies and procedures.

Further Delineation by Topic

Confidentiality Laws and Regulations:

Compliance with confidentiality laws and regulations, including HIPAA and state law requirements, is considered a local institutional issue. The FHCRC IRB expects the designated local context reviewer to have knowledge of these requirements for Institution B and to be able to provide comments before or during the FHCRC IRB review process. Institution B remains responsible for how compliance with these confidentiality requirements is implemented at the institution.

Prisoners:

The FHCRC adheres to 45 CFR 46 Subpart C and needs to re-review a protocol when it becomes aware a investigator wanting to conduct research on a prisoner. Institution B must notify the FHCRC IRB befor enrolling prisoners in research overseen by FHCRC IRB. For research that is approved to include prisoners in accordance with Subpart C, the FHCRC IRB, through the FHCRC Institutional Review Office, will prepare the Prisoner Certification Letter to OHRP.

Serious Adverse Events and Other Unanticipated Problems

It is the responsibility of Institution B's Principal Investigator to identify and report Serious Adverse Events and Other Unanticipated Problems in accordance with the FHCRC IRB Policy 2.6 Unanticipated Problems Involving Risk to Subjects or Others. For events that must be reported to the FHCRC IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the event constitutes and Unanticipated Problem Involving Risk to Subjects or Others.

Noncompliance:

It is the responsibility of Institution B's Principal Investigator to identify and report Noncompliance in accordance with the FHCRC IRB Policy 1.9 Noncompliance. For events that must be reported to the FHCRC IRB, the Principal Investigator at Institution B will be responsible for providing the appropriate documentation directly to the FHCRC IRB, or to the appropriate coordinating center at FHCRC which will report the event it to the FHCRC IRB. The FHCRC IRB accepts the responsibility to ensure reporting to the appropriate regulatory agencies (i.e. OHRP and/or FDA) if the FHCRC IRB determines the event constitutes Serious or Continuing Noncompliance.

FRED HUTCHINSON CANCER RESEARCH CENTER

Institutional Review Board

IRB Authorization Agreement

Institution A - Name of Institution or Organization Providing IRB Review:
Fred Hutchinson Cancer Research Center (FHCRC)

IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619)
Federalwide Assurance (FWA) #: FWA00001920

Institution B - Name of Institution Relying on the Designated IRB:
Leland Stanford Junior U

Federalwide Assurance (FWA) #: FWA00000935

The Officials signing below agree that **Leland Stanford Junior U** may rely on the designated IRB for review and continuing oversight of its human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by Fred Hutchinson Cancer Research Center's FWA.

☒ This agreement is limited to the following specific protocol(s):

Title of Research Project:	Human research activities of the WHI Regional/Satellite Center relating to "Clinical Coordinating Center for the WHI 2010-2015 Extension (FHCRC IRB #3467ext)"

FHCRC's Principal Investigator:	Institution B's Principal Investigator:
Ross Prentice, PhD Garnet Anderson, PhD	Marcia Stefanick, Ph.D.

The review performed by the designated IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. The term of this Agreement shall be for a period of 5 (5) years, which term shall renew automatically for additional one-year periods unless terminated by either party upon thirty (30) days' advance written notice. This document must be kept on file at both institutions and provided to OHRP upon request.

Signatures:

Authorized Official of (A):

Karen Hansen 1/5/11

(signature) (date)

Name: Karen Hansen
Title: Director, Institutional Review Office

Mailing Address: 1100 Fairview Avenue N
Mailstop: J6-110
Seattle, WA 98109

Authorized Official of Institution (B) – Regional Center:

12/17/10

(signature) (date)

Name: Ann M. Arvin, M.D.
Title: Vice Provost and Dean of Research

Mailing Address: Office of the Dean of Research
Building 10, Main Quad
Stanford, CA 94305-2061

Phone: (206) 667-4867 Fax: (206) 667-6831
Email: khansen@fhcrc.org

Phone: (650) 725-4421 Fax: (650) 725-1653
Email: aarvin@stanford.edu

FRED HUTCHINSON CANCER RESEARCH CENTER

Institutional Review Board

IRB Authorization Agreement

Institution A - Name of Institution or Organization Providing IRB Review:
Fred Hutchinson Cancer Research Center (FHCRC)
IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619), Com D (00009831)
Federalwide Assurance (FWA) #: FWA00001920

Institution B - Name of Institution Relying on the Designated IRB: **University of Florida, Gainesville**
Federalwide Assurance (FWA) #: FWA00005790

The Officials signing below agree that Institution B may rely on the Fred Hutchinson Cancer Research Center's IRB for review and continuing oversight of the human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by Institution B's FWA.

☒ This agreement is limited to the following specific protocol(s):

Title of Research Project:	Human research activities of the WHI Regional/Satellite Center relating to "Clinical Coordinating Center for the WHI 2010-2015 Extension" (FHCRC IRB #3467ext)

FHCRC Principal Investigator: Garnet Anderson, PhD	Institution B's Principal Investigator: Marian Limacher, MD

The review performed by the Fred Hutchinson Cancer Research Center's IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Fred Hutchinson Cancer Research Center will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This agreement will become effective upon the date of the last signature by the Institutional Officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution. Following termination of this Agreement, the Fred Hutchinson Cancer Research Center agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the relying institution's IRB. This document must be kept on file at both institutions and will be provided to OHRP upon request. Additional terms and responsibilities are outlined on the attached addendum and shall be deemed incorporated herein by reference.

Signatures:

Authorized Official of FHCRC:

Karen Hansen 7/17/15
(signature) (date)

Name: Karen Hansen
Title: Director, Institutional Review Office

Mailing Address: 1100 Fairview Avenue N
Mailstop: J2-100
Seattle, WA 98109
Phone: (206) 667-4867 Fax: (206) 667-6831
Email: khansen@fredhutch.org

Authorized Official of (B):

(signature) 7/22/15 (date)

Name: David Norton, PhD
Title: Vice President for Research

Mailing Address: PO Box 115500
Gainesville, FL 32611

Phone: (352) 392-9271 Fax: (352)846-0491
Email:

FRED HUTCHINSON CANCER RESEARCH CENTER
Institutional Review Board

IRB Authorization Agreement

Institution A - Name of Institution or Organization Providing IRB Review:
Fred Hutchinson Cancer Research Center (FHCRC)
IRB Registration #: Com A (00000021), Com B (00000022), Com C (00005619), Com D (00009831)
Federalwide Assurance (FWA) #: FWA00001920

Institution B - Name of Institution Relying on the Designated IRB: **Wake Forest University Health Sciences, Medical Center Boulevard, Winston-Salem, NC 27157-1023**
Federalwide Assurance (FWA) #: FWA00001435

The Officials signing below agree that Institution B may rely on the Fred Hutchinson Cancer Research Center's IRB for review and continuing oversight of the human subject research described below: (*check one*)

☐ This agreement applies to all human subject research covered by Institution B's FWA.

☒ This agreement is limited to the following specific protocol(s):

Title of Research Project:	Human research activities of the WHI Regional/Satellite Center relating to "Clinical Coordinating Center for the WHI 2010-2015 Extension" (FHCRC IRB #3467ext)

FHCRC Principal Investigator:	Institution B's Principal Investigator:
Garnet Anderson, PhD	Sally A Shumaker, PhD

The review performed by the Fred Hutchinson Cancer Research Center's IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Fred Hutchinson Cancer Research Center will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This agreement will become effective upon the date of the last signature by the Institutional Officials below and will remain in effect until such time that either institution provides 30 days written notice of termination to the other institution. Following termination of this Agreement, the Fred Hutchinson Cancer Research Center agrees to provide continued IRB oversight of ongoing research for the reasonable time necessary to appropriately transfer oversight of the protocol(s) to the relying institution's IRB. This document must be kept on file at both institutions and will be provided to OHRP upon request. Additional terms and responsibilities are outlined on the attached addendum and shall be deemed incorporated herein by reference.

Signatures:

Authorized Official of FHCRC:
Ken Hansen 6/12/15
(signature) (date)
Name: Karen Hansen
Title: Director, Institutional Review Office

Mailing Address: 1100 Fairview Avenue N
Mailstop: J2-100
Seattle, WA 98109
Phone: (206) 667-4867 Fax: (206) 667-6831
Email: khansen@fredhutch.org

Authorized Official of (B):
Joseph E. Andrews 6/30/15
(signature) (date)
Name: Joseph Andrews, PhD
Title: Director, Institutional Review Board

Mailing Address: Office of Research
Medical Center Blvd.
Winston-Salem, NC 27157
Phone: (336) 716-4542 Fax: (336) 716-4480
Email: jandrews@wfubmc.edu