SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **10/29/2021**
Revised Date:

Application Number: **1 K99 AG076809-01**

Principal Investigator

VON HOLLE, ANN

Applicant Organization: U.S. NATIONAL INST OF ENVIRON HLTH SCIS

Review Group: **AGCD-1**
Career Development Facilitating The Transition to Independence Study Section
NIA-AGCD-1

Meeting Date: **10/14/2021**
Council: **JAN 2022**
Requested Start: **04/01/2022**

RFA/PA: **PA20-188**
PCC: **2CDEMAK**
Dual IC(s): **ES, CA**

Project Title: **Lifestyle change over time and postmenopausal risk of breast cancer**

SRG Action: **++**
Next Steps: **Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects: **X4-Human subjects involved - Exemption #4 designated**
Animal Subjects: **10-No live vertebrate animals involved for competing appl.**

Project Year	Direct Costs Requested
1	100,000
2	100,000
3	150,000
4	150,000
5	150,000
TOTAL	650,000

++NOTE TO APPLICANT: Members of the Scientific Review Group (SRG) were asked to identify those applications with the highest scientific merit, generally the top half. Written comments, criterion scores, and preliminary impact scores were submitted by the assigned reviewers prior to the SRG meeting. At the meeting, the more meritorious applications were discussed and given final impact scores; by concurrence of the full SRG, the remaining applications, including this application, were not discussed or scored. The reviewers' comments (largely unedited by NIH staff) and criterion scores for this application are provided below. Because applications deemed by the SRG to have the highest scientific merit generally are considered for funding first, it is highly unlikely that an application with an ND recommendation will be funded. Each applicant should read the written critiques carefully and, if there are questions about the review or future options for the project, discuss them with the Program Contact listed above.

DESCRIPTION (provided by applicant): Modifiable lifestyle characteristics are among the leading causes of mortality and health outcomes such as breast cancer. Women in the United States have a one in eight chance of being diagnosed with breast cancer in their lifetime, and one out of five postmenopausal breast cancer cases could be eliminated following lifestyle modification. Furthermore, lifestyle characteristics tend to co-occur in individuals. Despite the importance of these characteristics in health prevention research, few studies examine more than one of these measures at a time. Compounding this research gap is the lack of longitudinal evidence for these factors for an aging population, which can inform prevention studies targeting modifiable lifestyle characteristics. In this proposal, I will examine multiple modifiable lifestyle characteristics, including body fatness, alcohol use, exercise, and smoking as they relate to postmenopausal breast cancer outcomes and all-cause mortality. Unlike prior studies, I will examine them simultaneously and longitudinally in a contemporary prospective cohort of 50,884 women sampled throughout the United States with a median age of 56 years at study entry. This rich data resource, along with the novel application of methods to epidemiological research aims, allows me to capture a comprehensive, dynamic, and granular picture of the relationship between lifestyle change with risk of breast cancer and all-cause mortality. First, I will first characterize a group of correlated lifestyle characteristics using factor analysis and assess the composite lifestyle factor change over a decade (Aim 1, K99). To complement this first aim, I will use this opportunity to obtain additional training in areas such as physical activity and obesity epidemiology, aging, and methods development. This training will enhance my knowledge of lifestyle- related exposures and inform the development of all three of my research aims. After characterizing a composite lifestyle factor, I will capture tandem associations between lifestyle factor changes over time with risk of breast cancer and all-cause mortality using newly developed joint analysis models (Aim 2, R00). In the third aim, I will determine to what extent people carrying the highest burden of adverse lifestyle characteristics have greater genetic risk of breast cancer compared to groups with the lowest adverse lifestyle burden (Aim 3, R00). In completing these novel research aims, I will develop a more comprehensive picture of the association between lifestyle change over time with the risk of breast cancer and all-cause mortality. By applying these concepts to a large sample of postmenopausal women, this knowledge has the potential to inform widely applicable areas of public health interventions to improve the health of an aging population.

PUBLIC HEALTH RELEVANCE: Modifiable lifestyle characteristics number among the top ten attributable causes of all-cause mortality and also offer some of the greatest potential to reduce cancer incidence. Current research lacks large-scale evidence for lifestyle change over time and its association with disease specific to women following menopause. Determining how lifestyle characteristics form a correlated measure, change over time, and are related to risk of breast cancer and all-cause mortality could inform intervention policies targeted at postmenopausal women.

CRITIQUE 1:

Candidate: 6
Career Development Plan/Career Goals/Plan to Provide Mentoring: 7
Research Plan: 5
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 6
Environment and Commitment to the Candidate: 3

Overall Impact:
This is a new application from a candidate with training in biostatistics and epidemiology, who is currently a post-doctoral fellow at the National Institute of Environmental Health Sciences (NIEHS) in North Carolina. She has expertise in longitudinal modeling of biomarkers to predict adverse health

outcomes, and her post-doctoral research has focused on breast cancer. With this career development award, she seeks additional training in measurement of lifestyle factors in large-scale epidemiological studies of breast cancer, and statistical modeling of inter-related lifestyle factors in predicting breast cancer incidence and mortality. The candidate clearly has strong quantitative skills that could be leveraged to this important area of research and rich Sister Study dataset, and her post-doctoral mentors and institution are strong and committed. Concerns include feasibility of building independence in a new research area within the mentored phase of the award, and whether the primary mentoring team has the necessary expertise in measurement of lifestyle factors for the candidate to build independence in this realm.

1. Candidate:

Strengths

- Strong training and experience as a biostatistician for epidemiological studies and the letters attest to her strong quantitative skills.
- The candidate has contributed to a wide array of papers in her role as a biostatistician.
- The candidate has recently published two papers in 2021 in the area of the proposed research.

Weaknesses

- The candidate's research trajectory has not had a central theme building towards the proposed research focusing on lifestyle predictors of breast cancer outcomes. The path towards this focus and commitment for a long-term research program could be more developed.
- There is no link to the candidate's full list of publications, making it difficult to evaluate the breadth of contributions to published epidemiological research.
- The fit for the candidate for a K99/R00 when taking on a new research direction in regard to both predictors and outcome could be better addressed by the candidate and letter writers.

2. Career Development Plan/Career Goals & Objectives:

Strengths

- The candidate has strong quantitative skills and recent momentum relevant to the proposed training and research.
- Time is dedicated publishing the results from research aims.
- Leadership and management training is planned.

Weaknesses

- The primary mentors do not have expertise in measurement of lifestyle factors in epidemiological studies.
- The proposed training is heavy on courses and readings, and it is not clear the training will support scientific independence.
- It is not entirely clear in the training plan what the scope of "lifestyle factors in the aging population" is? More description of the scope for intended focus is needed for developing independence within a 2-yr K99 training period.
- Key aspects of the candidate's long-term goals are not represented clearly in the proposed training, including current methods for estimating polygenic risk scores for cancer outcomes and effects of lifestyle changes on breast cancer outcomes.

3. Research Plan:

Strengths

- Highly significant research program and potential to identify core modifiable lifestyle factors increasing risk for breast cancer incidence.
- Rich longitudinal dataset will be leveraged for analyses.
- Preliminary data and power analyses are presented to demonstrate feasibility and formalized statistical models.

Weaknesses

- The innovation section could be better contextualized within the latest findings and perspectives of the field, with citations.
- It is not clear how well the proposed research is a strong vehicle for training towards independence, since there is no study design, data collection, or data cleaning involved.
- There is a concern that the consideration of lifestyle to be quantified by a single index is over-simplified and the proposed training doesn't increase nuance to this thinking.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Dr. Weinberg is a strong primary mentor with necessary expertise with the Sister study to be utilized for analyses, and a strong track record in mentoring and commitment to the candidate.
- Dr. Dale Sandler brings complementary expertise and additional mentorship in epidemiology of breast cancer and professional development.
- Advisor, Dr. Terry, brings expertise in lifestyle factors associated with cancer risk, genetics, epigenetics, and biomarkers of cancer risk with a focus on breast cancer.
- Dr. Zhao will advise on statistical modeling of inter-related lifestyle factors and Dr. Gottfredson will advise on applying latent variable models in this context.

Weaknesses

- There is not a primary mentor with expertise in assessment of lifestyle factors associated with cancer risk in longitudinal epidemiology studies.
- There is a concern that the mentoring team overall is too heavy in expertise and skills that the candidate is already strong in.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Clear access to data and resources needed to complete the proposed training and research.

Weaknesses

- Letter of institutional commitment did not specify commitment for amount of protected time, though it is stated that she will not have teaching or clinical duties.
- The path to independence for the candidate's trajectory could be better described.

Protections for Human Subjects:

- Secondary data analysis of de-identified data.

Inclusion Plans:

- Sex/Gender: Distribution not justified scientifically.
- Race/Ethnicity: Distribution not justified scientifically.
- Inclusion/Exclusion Based on Age: Distribution not justified scientifically.
    - No information is given to justify the nature of the sample with respect to sex/gender and race/ethnicity relative to the scientific goals of the proposed research.

Training in the Responsible Conduct of Research:

Acceptable.

Budget and Period of Support:

Recommend as Requested.

- It is unclear why the full available amount for the R00 is not budgeted.

CRITIQUE 2:

Candidate: 5
Career Development Plan/Career Goals/Plan to Provide Mentoring: 4
Research Plan: 5
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2
Environment and Commitment to the Candidate: 1

Overall Impact:
This is a new application by Dr. Ann Von Holle who is seeking to become an independent investigator after completing her training by her present mentor. The candidate will work on examining the relationship of changes of lifestyle with the death from breast cancer. There are several lifestyles that can affect the outcome such as smoking, change in bodyfat during aging, alcohol use, and exercise. Several studies have been performed under these parameters and their risk in the development of breast cancer and survival of the patients, especially after menopause, have been well defined. Initially, the candidate will receive training in the understanding of various factors such as the relationship between lifestyle changes on the risk of breast cancer and all causes of mortality. She will study the effect of each style for a decade before coming up with a conclusive relationship. After characterizing each parameter/activity, she will include all the three lifestyles and perform their relationship as a group with breast cancer and mortality using newly developed joint analysis models. Further, she aims to find out the major factor(s) that really is important in breast cancer and mortality. Based on the data obtained from a large group of patients she will come up with a conclusion that fits better and is applicable in the areas of public health interventions to improve the health of an aging population. The approach appears to be interesting but is not novel. Several studies have been performed in the past and a dearth of information is available.

1. Candidate:
Strengths

- The candidate, Dr. Ann Von Holle, obtained a MS in Biostatistics from the University of North Carolina in 2003, a MA in Demography from University of Pennsylvania, and a PhD in Epidemiology from University of North Carolina in 2018. Since then, she is working as a post-doctoral fellow at NIEHS. She has been working in finding the biomarkers which could be important in the diagnosis of breast cancer. In the K99 project she will be entering in new phase of studies focused on chronic diseases such as breast cancer and find out the risk factors and lifestyle that could provide some lead in the development of breast cancer and its outcome.
- She published research papers in different areas of epidemiology such as eating disorders, association of serum iron biomarkers and breast cancer, predictors of early postnatal growth, effect of weight in breast cancer, pattern of remission, continuation, and incidence of broadly defined eating disorders.

Weaknesses

- Overall Dr. Von Holle’s research is not focused in one area. Her research is diffuse and spread out in different area of public health.
- She has published few research papers in very moderate impact factor scientific journals.
- No compelling evidence is provided to become an independent investigator.

2. Career Development Plan/Career Goals & Objectives:
Strengths

- Dr. Von Holle’s objective and CDP are well thought out and well written, however lacks compelling information to become independent investigator.

Weaknesses

- Dr. Von Holle does not have a well-defined path to become an independent investigator. She needs to focus on a specific novel area in public health and publish in high impact journals. Her approach is weak and diffuse.

3. Research Plan:

Strengths

- In Aim 1 of the K99, the candidate will follow the Sister Study between years 2017 to 2019 that was planned and executed by her mentor. She will study the lifestyles of the people enrolled and their outcome and relationship with different parameters to come up with a conclusion based on statistical analysis which parameter is better correlated with breast cancer.
- In Aim 2 which is also part of the K99, Dr. Von Holle will assess changes in lifestyle in tandem with risk of breast cancer. Following the implementation of Aim 1, she will simultaneously evaluate the association between longitudinal change in the lifestyle factors, considered the exposure, and breast cancer risk with time to event data. She will develop a joint data model in the context of associations between lifestyles and breast cancer risk and its application.
- In Aim 3 which is part of the R00 phase, Dr. Von Holle will use a novel definition of risk associated with lifestyle groups to evaluate modification by established genetic underpinning of breast cancer risk. In this Aim, she will include all the risk factors such as BMI (body weight, obesity), smoking, alcohol use, and physical activity, and will define the relationship of all the risk factors with breast cancer and mortality. She will use large number of samples that make the outcome statistically significant.
- The approach is well described and in sufficient detail.

Weaknesses

- The candidate has limited experience in proposed studies described, therefore she needs additional training to focus primarily on the risk factors in relation to breast cancer.
- She is not well trained in the area of the proposed study, and she lacks good publications.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Dr. Clarice Weinberg will serve as a mentor during the K99 phase and will provide close supervision and advise to the candidate to get the required training to become an independent investigator in risk factors and their relationship with breast cancer. Dr. Weinberg obtained her Ph.D. in Biomathematics from the University of Washington, Seattle in 1980. At present she is working as Chief of Biostatistics and Computational Biology Branch at NIEHS, Research Triangle Park, NC. She also serves as a member of the committee to study Mortality of Military Personnel at Atmospheric tests of nuclear weapons, under the Institute of Medicine, National Academy of Sciences. She is a well-established scientist capable to provide the needed mentorship.
- Dr. Dale Sandler from NIEHS also will serve as a co-mentor.
- Dr. Shanshan Zhao will serve as an advisor. Dr. Zhao is an adjunct assistant professor at the University of North Carolina. Additional members of the advisory committee include Drs. Nisha Gottfredson (University of North Carolina) and Mary Beth Terry (Columbia University).

Weaknesses

- Not provided.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- Environment at NIEHS is excellent.

Weaknesses

- None noted.

Protections for Human Subjects:
Acceptable Risks and Adequate Protections.

Inclusion Plans:
- Only women will be enrolled in the study.

Select Agents:
Acceptable.

Resource Sharing Plans:
Acceptable.

Authentication of Key Biological and/or Chemical Resources:
Acceptable.

Budget and Period of Support:
Recommend as Requested.

CRITIQUE 3:

Candidate: 2
Career Development Plan/Career Goals/Plan to Provide Mentoring: 2
Research Plan: 3
Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s): 2
Environment and Commitment to the Candidate: 1

Overall Impact:
This project will develop a comprehensive picture of the association between lifestyle change over time with the risk of breast cancer and all-cause mortality in a large population of post-menopausal women. The candidate's goals are to apply her knowledge in methodological and epidemiological research areas to the study of lifestyle exposures and their relationship with cancer and all-cause mortality in post-menopausal women. The candidate seeks further training in aging research, lifestyle exposures, and joint analysis models to combine both longitudinal exposures and time to event models. Overall, this is a very well thought out application from a strong candidate. Even though the application is dealing more with midlife than late-life, it could be strengthened with the addition of more aging mentoring or coursework. For example, the concepts of heterogeneity of health status or survival bias are not mentioned. As written, this application may be a better fit with NCI as it seems little light on aging. Further, little information is provided on the measures themselves or the potential for measurement error. Lifestyle factors are notoriously hard to accurately quantify and some information on how this will be handled would be helpful. Finally, disentangling the risk factors associated with aging and cancer should be addressed, since many overlap.

1. Candidate:
Strengths
- Outstanding experience as a biostatistician and research analyst.
- History of obtaining external funding for her dissertation research from American Heart Association (AHA).

- Experience with the Sister Study has led to the current project and informed her interest in life course epidemiology.

Weaknesses

- A varied research background with no natural progression between topics. A better link to the current aging related focus is needed.

2. Career Development Plan/Career Goals & Objectives:

Strengths

- Figure 1 nicely outlines prior research training, proposed K99 training and transition to independent investigator.
- Trainee timeline is feasible and well thought-out. The percentages give a good reference for time allocation.

Weaknesses

- The only structured aging training is a summer short course. Would be advantageous to see an aging journal club or a course on the epidemiology of aging.

3. Research Plan:

Strengths

- Proposes to define risk inequality measures involving modifiable behaviors to improve targets for breast cancer prevention.
- The creation of a lifestyle construct could benefit many studies examining breast cancer risk.
- Proposes to study lifestyle change to help characterize common risk factors and change across the life course, and these changes can modify genetic association with breast cancer, a novel approach.
- Longitudinal data in a large cohort of women with elevated risk.
- Joint modeling is a new and innovative approach.

Weaknesses

- Many of the risk factors for cancer and aging overlap. How with this be handled? Specifically, what is the plan to address what the excess risk associated with cancer beyond that or “normal” aging (attributable risk).
- Aim 2 assumes a sufficient number of people will change their behaviors to make this research feasible.
- There is little information on the data collection tool other than a “questionnaire.” This should be addressed b/c of the potential for reporting biases such as “social desirability bias” as well as error in calculating “body fatness,” which cannot truly be done without a DEXA or CT scan.

4. Mentor(s), Co-Mentor(s), Consultant(s), Collaborator(s):

Strengths

- Dr. Weinberg is very accomplished but does not adequately highlight her cancer research in her biosketch.
- Dr. Sandler brings strong cancer and epidemiological expertise.
- Dr. Terry brings outstanding cancer expertise from an external institution.

Weaknesses

- Would be helpful to have an aging expert on the team, given one of the career goals is to obtain aging expertise.

5. Environment and Institutional Commitment to the Candidate:

Strengths

- As a current postdoctoral IRTA, Dr. Von Holle has access to the vast resources of the NIH. The NIEHS is commitment to helping Dr. Von Holle attains her goals.

Weaknesses
- None noted.

Protections for Human Subjects:
Acceptable Risks and Adequate Protections.

Inclusion Plans:
- Sex/Gender: Distribution justified scientifically.
- Race/Ethnicity: Distribution justified scientifically.
- Inclusion/Exclusion Based on Age: Distribution justified scientifically.
    - Good use of existing data.

Training in the Responsible Conduct of Research:
Acceptable.
Comments on Format:
- Intramural training, required on a regular basis.

Budget and Period of Support:
Recommend as Requested.

Footnotes for 1 K99 AG076809-01; PI Name: Von Holle, Ann

NIH has modified its policy regarding the receipt of resubmissions (amended applications).See Guide Notice NOT-OD-18-197 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-197.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Career Development Facilitating The Transition to Independence Study Section
National Institute on Aging Initial Review Group
NATIONAL INSTITUTE ON AGING
NIA-AGCD-1

AGCD-1
10/14/2021 - 10/15/2021

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html, NOT-OD-15-106 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html, and NOT-OD-18-115 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-115.html, including removal of the application from immediate review.

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* Temporary Member. For grant applications, temporary members may participate in the entire meeting or may review only selected applications as needed.

Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.