

**SUMMARY STATEMENT**

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( Privileged Communication )

*Release Date:* 04/27/2017  
*Revised Date:*

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*Application Number:* 1 R01 CA209781-01A1

Principal Investigator

GERSTEIN, MARK BENDER

Applicant Organization: YALE UNIVERSITY

*Review Group:* ZRG1 OBT-B (55)  
Center for Scientific Review Special Emphasis Panel  
PAR Panel: Basic Research in Cancer Health Disparities/Diversity

*Meeting Date:* 03/30/2017                      *RFA/PA:* PAR15-093  
*Council:* MAY 2017                              *PCC:* J3SB  
*Requested Start:* 07/01/2017

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*Project Title:* The Genomic Basis of Racial Disparities in Kidney Cancer

*SRG Action:* ++  
*Next Steps:* Visit [https://grants.nih.gov/grants/next\\_steps.htm](https://grants.nih.gov/grants/next_steps.htm)  
*Human Subjects:* 44-Human subjects involved - SRG concerns  
*Animal Subjects:* 10-No live vertebrate animals involved for competing appl.

Project Year	Direct Costs Requested
1	250,000
2	250,000
3	250,000
4	250,000
5	250,000
<b>TOTAL</b>	<b>1,250,000</b>

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**++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.

**1R01CA209781-01A1 Gerstein, Mark**

**SCIENTIFIC REVIEW OFFICER'S NOTES**

**DESCRIPTION (provided by applicant):** Recent studies have shown significant racial disparities in kidney cancer including early disease onset for African-Americans, different histologic distribution, and worst disease outcome, even when controlling for treatment. No study has evaluated a biologic or cause of racial disparities in kidney cancer. In our study, we intend to investigate whether these disparities are due to recurrent coding or non-coding germline and somatic alterations and whether these alterations are more common in African-American or Caucasian individuals with clear cell and papillary kidney cancer. For this purpose, we have developed four specific aims. In our first aim, we intend to perform whole genome sequencing of 15 African-Americans in order to increase the number of African-Americans currently existing in TCGA with kidney cancer. For these individuals, we intend to perform high-quality mutation calls for structural and genomic variation including SNPs, indels, inversions and copy number variations for both coding and non-coding regions. Our second aim is to assemble a comprehensive list of somatic & germline mutations associated with cancer and prioritize regions with greatest impact. To complete our aim, we will use our novel and already developed tools including i) FunSeq, a sophisticated algorithm that prioritizes high impact variants, ii) LARVA, a burden test algorithm that identifies significant mutation enrichment in non coding elements, iii) an extension of FunSeq to construct connected genetic modules based on molecular and protein interactions and iv) an extension of LARVA to include additional covariates such as mutation rate, replication time etc. In our third aim, we will test a list of prioritized regions and modules obtained from aim 2 to identify racial genomic differences. More specifically, we intend to test for disparities across i) germline mutations in coding regions using WES data, ii) genomic regions with higher mutational burdens, iii) germline mutations in non-coding prioritized regions using WGS data and iv) somatic mutations in prioritized regions. Finally, in our fourth objective, we intend to validate racial disparities from a list of 550 prioritized regions using a Yale Validation Cohort, a cohort consisting of total 384 individuals; an equal number of 96 Caucasian and African-American clear cell and papillary tumors. To validate for racial disparity, we will use the MassArray system, a highly accurate technology for rapid detection of known or suspected somatic or germline alterations.

**PUBLIC HEALTH RELEVANCE:** Narrative We investigate the genomic cause of racial disparities in renal cell carcinoma. We will evaluate clear cell and papillary renal tumors from African American and Caucasians to identify and prioritize both common and rare, germline and somatic variants, in coding and non-coding regions. Utilizing a range of cancer genome data and novel bioinformatics tools, our goal is to prioritize variants contributing to racial disparity.

**CRITIQUES:** The written critiques of individual reviewers are provided in essentially unedited form below. These critiques were prepared prior to the meeting and may not have been revised afterwards.

**CRITIQUE 1**

Significance: 3  
Investigator(s): 2  
Innovation: 3  
Approach: 5  
Environment: 1

**Overall Impact:** Renal cell carcinoma (RCC) is the urological malignancy with the highest mortality. RCC incidence has been increasing in most populations, with the highest increase reported in African Americans (AA). The reasons for such incidence rate increase remain unknown. This application proposes to investigate whether genomic differences between AA and non-Hispanic Whites (NHW) can account for existing racial disparities in incidence. Specifically, these investigators propose to carry out

whole genome sequencing (WGS) of RCCs from AA (Aim 1), to identify germline and somatic RCC associated variants (Aim 2), to identify risk variants that differ between AA and NHW RCCs (Aim 3) and to perform a validation of variants likely associated with racial disparities in an independent cohort. The score driving elements include the focus on the genomic study of a malignancy that was not well characterized by the TCGA study and the tremendous expertise on cancer genomics of the PI. The study however has a number of weaknesses. It lacks a well-defined guiding hypothesis and its Aims are inter-dependent. The germline analyses could have been more rigorous: they have limited power to detect risk variants and the use of publicly available controls may not be fully appropriate. The lack of studies on the mechanistic/functional aspects of RCC in AA is also another limitation of the study. Overall, the weaknesses of the study outweigh its strengths and the proposal, as presented, is likely to have a low to moderate impact.

### **1. Significance:**

#### **Strengths**

- RCC incidence has been rising during the last four decades and genomic analyses can provide some clues associated with such increase.
- The study will fill an existing gap on the genomics of RCC in AAs.
- The study has a moderate scientific premise.

#### **Weaknesses**

- The racial disparity in RCC has changed over time (starting in the 90's, based on Figure 1), which suggests a role of a changing environment rather than biology in the observed disparity.
- A higher incidence of pRCC in AA is not well supported by the data. Extreme care should be exercised when using subtype prevalence information from TCGA, as such study was not designed as either a clinic-based or a population-based epidemiological study.

### **2. Investigator(s):**

#### **Strengths**

- Dr. Gerstein is a world leading expert in cancer genomics and has expertise in cancer genome characterization projects such as the one proposed here.
- Dr. Adeniran will provide expertise in RCC clinical and translational research.

#### **Weaknesses**

- Limited experience of these researches in disparities research

### **3. Innovation:**

#### **Strengths**

- The use of a new population in a genome sequencing study is mildly innovative.

#### **Weaknesses**

- None noted

### **4. Approach:**

#### **Strengths**

- The proposal will be carried out by a highly-qualified team.
- The focus on genomics of an understudied cancer in an understudied minority population is a strength.
- Most analyses, particularly those involving somatic mutation analyses, are rigorously described and consider relevant biological variables.

#### **Weaknesses**

- There seems to be a lack of guiding hypothesis and the proposal reads more like a large sequencing study with little mechanistic insights.
- The aims are interdependent.
- The germline analyses have limited power and potential issues with stratification.

**5. Environment:**

**Strengths**

- The scientific environment and resources at Yale are excellent for the proposed studies.

**Weaknesses**

- None noted

**Protections for Human Subjects:**

Unacceptable Risks and/or Inadequate Protections

- This section is missing in the application.

**Inclusion of Women, Minorities and Children:**

- Sex/Gender: Distribution not justified scientifically
- Race/Ethnicity: Distribution not justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; not justified scientifically
- Sections on inclusion of women, minorities and children are missing in the application

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Resubmission:**

- The application addresses some of the concerns raised in the previous review.

**Resource Sharing Plans:**

Acceptable

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**CRITIQUE 2**

Significance: 3

Investigator(s): 1

Innovation: 3

Approach: 5

Environment: 1

**Overall Impact:** This is a revised R01 grant application from an outstanding PI to study the genomic cause of racial disparity in kidney cancer. There are racial disparities in kidney cancer among African American versus Caucasian Americans. The proposed work will evaluate clear cell and papillary renal tumors from African American and Caucasians to identify germline and somatic variants in coding and non-coding regions. The proposal is supported by some preliminary data; and it can partly address the genetic causes of cancer health disparities in kidney cancer. The investigators are highly qualified to conduct the proposed study. The research environment and the facilities at the Yale University is

excellent. In this revised application, some concerns brought by previous reviewers are nicely addressed. Some new preliminary data have been included to demonstrate that genes required for the development and progression of kidney cancer are racially burdened with deleterious mutations. Some of the missing controls have been added. However, it is still not clear how the variants will be segregated. How the genetic difference between clear cell versus papillary RCC will be addressed? The feasibility of Aim-3 is totally dependent on the success of Aim-2. Although the proposal is based on a strong scientific premise, there are remaining concerns in the experimental approach section. Together, the overall impact of the proposal is considered to be moderately high.

### **1. Significance:**

#### **Strengths**

- The proposed study can address the genetic causes of cancer health disparities in kidney cancer.

#### **Weaknesses**

- It would have been important to dissect the genetic difference between clear cell versus papillary RCC (instead of only racial disparities).

### **2. Investigator(s):**

#### **Strengths**

- The investigators (PI and co-investigators) are highly qualified to conduct the proposed study as evident by the publications.

#### **Weaknesses**

- None noted

### **3. Innovation:**

#### **Strengths**

- There are limited data for the genetic basis (Met, VHL etc) of renal cancer growth. The whole genome analysis can improve our understanding of the genetic causes of kidney cancer, with importance to health disparities.

#### **Weaknesses**

- The innovative information expected to be generated from this study are limited.

### **4. Approach:**

#### **Strengths**

- The proposed study is based on some important preliminary data.

#### **Weaknesses**

- The feasibility of Aim-3 is totally dependent on the success of Aim-2.
- How the genetic difference between clear cell versus papillary RCC will be addressed.
- It is still not clear how the variants will be segregated, and there are weaknesses in the scientific rigor.

### **5. Environment:**

#### **Strengths**

- The research environment at the Yale University is outstanding.

#### **Weaknesses**

- None noted

### **Protections for Human Subjects:**

Not Applicable (No Human Subjects)

### **Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable

**Resource Sharing Plans:**

Acceptable

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**Additional Comments to Applicant:**

- Some of the concerns raised during the previous review have been addressed. However, there are still remaining concerns.

**CRITIQUE 3**

Significance: 3

Investigator(s): 1

Innovation: 4

Approach: 7

Environment: 1

**Overall Impact:** Renal cell carcinoma is a lethal GU malignancy, with African Americans (AA) exhibiting higher incidence and mortality rates than Caucasians. In addition, ethnicity-associated differences are also observed in the distribution of RCC histologic subtypes, with the frequency of pRCC being more frequent in AAs when compared to Caucasian. Several risk factors for RCC have been identified including obesity, male gender, smoking, kidney disease, yet they do not fully account for the observed disparate RCC burdens in the AA population. This proposal accordingly attempts to determine whether there are molecular/genetic differences between AA versus Caucasian RCCs that could inform on additional molecular etiologic factors potentially contributing to RCC disparities. The strengths of the proposal include the stellar investigative team, adequate physical and computational resources available to conduct the studies, feasibility of the proposed informatics pipelines. However, there are several key weaknesses in the proposal including: Aims are highly descriptive in nature and overtly ambitious in scope; prior studies on molecular differences between ccRCC and pRCC are not discussed in this context and whether any effort to follow on these prior studies to initially test for specific molecular differences in AA versus Caucasian RCCs is missing; lack of solid preliminary data informing on the likelihood of genetic differences existing between AA versus Caucasian RCC cases. In response to the comments on pilot data from the initial submission, the investigators have included some preliminary results showing a heavier inherited mutational burden in AAs affecting 14 kidney cancer associated genes using the 1000 genomes and the ExAC databases. However, a proper null/background control is missing in these analyses. For example, how do the burden test results compare to assessments of random sets of 14 genes that are not associated with kidney cancer, permuted multiple times? no approach was provided on how ethnicity-associated differences in germline/somatic variants will be assessed in the context of clinical outcomes; the investigators propose to validate the germline differences in a fresh FFPE cohort in Aim 4. Given the possibility of ascertainment bias in hospital-based case cohorts with co-morbidities, it is important to include at-risk non-RCC AA and Caucasian controls derived locally for the germline studies; given the migratory patterns of AA's within United States, it is possible that any distinct RCC mutational signature/panel in

AAs might be influenced by differences in geographical location of AAs (in other words, local environment), and the proposal does not address this significant pitfall; confirmation of representative genomics signals using orthogonal platforms are not provided especially given that Aim 4 will be using FFPE samples; plans for wet-lab assessments on informatics-predicted deleterious events missing; the proposal lacks any mechanistic studies; aims appear inter-dependent and are based on the success of identifying molecular differences in AA versus Caucasian RCC cases. Overall, the weaknesses markedly outweigh the strengths of the proposal, significantly diminishing the impact of the proposal.

**Protections for Human Subjects:**

Unacceptable Risks and/or Inadequate Protections

- The proposal utilizes blood/discarded tissues from human subjects with demographic and comorbid information, and will perform genome-scale profiling including genotyping. As such, details should be provided on how all this information will be secured, deidentified, and plans for IRBs specifically to disseminate the genetic information in accordance with NIH GDS policies.

**Vertebrate Animals:**

Not Applicable (No Vertebrate Animals)

**Biohazards:**

Not Applicable (No Biohazards)

**Resubmission:**

- While this A1 proposal attempted to address some of the concerns raised in the initial submission, the key weaknesses have not been satisfactorily resolved.

**Resource Sharing Plans:**

Acceptable

**Authentication of Key Biological and/or Chemical Resources:**

Not Applicable (No Relevant Resources)

**Budget and Period of Support:**

Recommend as Requested

**SCIENTIFIC REVIEW OFFICER'S NOTES:**

The applicant proposes to use tumor tissues and blood from patients undergoing kidney cancer surgery in the planned research, but claims the project as a No Human Subjects study. Based on the NIH SF424 application guideline, "If the answer is "No" to the question (**Are Human Subjects Involved**) but your proposed research involves human specimens and/or data from subjects you must provide a justification in this section for your claim that no human subjects are involved". The applicant does not include a justification for why the project using human biospecimens are not human subjects research. If the human bio-specimens are considered as human subjects, a plan for protection of human subjects should be submitted.

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Footnotes for 1 R01 CA209781-01A1; PI Name: Gerstein, Mark Bender

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.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](http://grants.nih.gov/grants/peer_review_process.htm#scoring).



MEETING ROSTER  
Center for Scientific Review Special Emphasis Panel

CENTER FOR SCIENTIFIC REVIEW  
PAR Panel: Basic Research in Cancer Health Disparities/Diversity  
ZRG1 OBT-B (55)  
03/30/2017 - 03/31/2017

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> and NOT-OD-15-106 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html>, including removal of the application from immediate review.

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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.