Outline

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Candidate’s Background
Candidate’s Background

- Background section should show a candidate’s:
  - Commitment to a health-related research career
    - Professional responsibilities in the grantee institution and elsewhere
    - Relationship to the proposed activities on the career award
  - Prior training and how it relates to the objectives and long-term career plans
  - Research efforts, including any publications, prior research interests, and experience
  - Potential to develop into an independent investigator

- **Tip:** Coordinate with information in the Biographical Sketch, e.g., research and/or clinical training experience that has prepared you for a K
Sample Candidate’s Background

I plan to use the training and research from this award to transition into an independent career as a genetic epidemiologist focusing on genetic risk factors in U.S. Latino and Latin American populations.

Through an ongoing GWAS in 1,600 US Latina cases and 1,300 controls I am currently investigating the possibility that genetic variation could explain the difference in breast cancer incidence between US Latinas and other populations under the mentorship of [Redacted]. However, we have not investigated the association with particular tumor subtypes, which is likely to point us to variants that are more specific and have stronger effects on disease risk. I hypothesize that the variants that are associated with breast cancer risk are different from those that drive progression, and therefore I want to explore this possibility through a GWAS of survival. A K01 career development award will enable me to acquire the training necessary to perfect my skills on whole genome data analysis, to conduct survival analysis, to design my own data collection study, to obtain teaching experience, and to write competitive grants that will allow me to become a successful independent researcher by the end of the award.

I received my undergraduate degree in Anthropology from the University of Buenos Aires, Argentina. As a graduate student in biological anthropology at the University of Oxford, I became increasingly interested in the genetics of populations of mixed ancestry (“admixed” populations) and in studying the genetic etiology of complex traits. I conducted a study of ancestry in a sample of individuals from Buenos Aires, Argentina, which led to my first publication 1.

As a postdoctoral fellow, I have focused my research on the association between genetic ancestry and breast cancer risk in Latinas. In particular, I am the first author on a paper in Cancer Research identifying the association between European genetic ancestry and higher breast cancer risk among Latina women. I led the effort to replicate the results of this association in a Mexican study recently published in Cancer Epidemiology Biomarkers and Prevention. I also conducted an admixture mapping analysis of breast cancer subtypes in African Americans, which resulted in a publication in Cancer Epidemiology Biomarkers and Prevention and wrote a review on ethnic differences regarding breast cancer tumor subtypes.

Therefore, understanding the key risk and clinical predictors in this population is of great public health relevance. As a Latina woman, I am deeply motivated to apply the latest modern molecular and statistical genetic techniques to help understand cancer in this population.
Career Goals & Objectives
Career Goals and Objectives

- **Systematic Plan:**
  - that shows a logical progression from prior research and training experiences to the research and career development experiences that will occur during the career award period and then to independent investigator status
  - that justifies the need for further career development to become an independent investigator
Career Goals and Objectives: Tips

- Tell the reviewers about your scientific history, and how the K award fits into your research career development plans
- If you have changed research direction, discuss reasons for the change
  - Be sure to justify how it will help you to develop your research career
- You should always provide a career development timeline, including plans to apply for subsequent grant support
Sample Career Goals and Objectives

My career goal is to become an established independent researcher working on the genetic epidemiology of cancer in Latinos.

In the short term, I am interested in pursuing genome wide association of breast cancer susceptibility and breast cancer progression in both US Latinas and Latin American women. In particular, I am now working on the first GWAS of breast cancer in Latinas, to identify common risk variants that may be responsible for the observed association between breast cancer risk and genetic ancestry using a combined admixture mapping/genome wide association analysis. The current proposal will extend this work to include analysis of tumor subtype and tumor progression and survival. The survival analysis portion will also allow me to gain experience with statistical methods of survival analysis.

In the long term, I would like to apply these skills to perform more comprehensive studies of genetic and gene environment studies. I would also like to extend the search for genetic variants and environmental risk factors that predispose to tumor subtype specific breast cancer risk and affect progression and survival to Latin American countries beyond those that are part of the US-LACRN.

Expected milestones and outcomes (see Timeline and % effort at the end of the Research Proposal)

**Mentored phase:** During this phase, I will obtain a certificate from the Training in Clinical Research Program after successfully fulfilling all requirements. I also expect to submit and publish two papers reporting the results of the breast cancer tumor subtype specific GWAS in US Latinas and of the breast cancer progression and survival GWAS in US Latinas.

**Independent phase:** I will produce an R01 grant application ready for submission by the end of the third year to extend the breast cancer genetic analysis to other countries of the US-LACRN, with the inclusion of healthy controls. I will have submit and publish a paper reporting the results of the replication of the tumor specific breast cancer risk and progression analysis in Argentina. Finally, I will gain teaching experience in genetic epidemiology as a UCSF K-scholar within the Training in Clinical Research Program.
Candidate’s Plan for Career Development/Training Activities During Award Period
Candidate’s Plan for Career Development / Training Activities During Award Period

- The candidate and the mentor are jointly responsible for the preparation of the career development plan
  - A career development timeline is often helpful
  - A mentoring team (or an advisory committee) to assist with the development of a program of study or to monitor the candidate's progress through the career development program
- The didactic training and the research aspects of the plan must be designed to develop the necessary knowledge and research skills in the proposed scientific area
- Professional responsibilities/activities, including other research projects beyond the minimum required 9 person-months (75% full-time professional effort) commitment to the career award
  - Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator
Candidate’s Plan for Career Development / Training Activities During Award Period: Tips

- Make sure to fully explain any new or enhanced research skills you will acquire or gain as a result of the K
- Stress activities that will enhance your research career, e.g., courses, techniques, methodologies
- Describe any additional, non-research activities in which you expect to participate
- Explain how the activity is related to your research and career development plans
Sample Candidate’s Plan for Career Development / Training Activities During Award Period

Core Training Plan: Clinical and Translational Science Institute Scholars Program (CTSI K-scholars program)

- As a CTSI K-scholar, I will participate in multiple activities that will strengthen my professional development and support my career towards research independence:
  - **A weekly Works-in-Progress Seminar:** It is attended by the K-scholars in groups of 10 with 2 experienced clinical research faculty, an epidemiologist and a biostatistician. The work of scholars is reviewed each week in the first year and each scholar presents in about every 5-6 weeks.
  - **Weekly Methodology Seminars:** These seminars are given by faculty and other invited speakers from other universities.
  - **Lunch with Faculty and Scholars:** This provides a weekly forum for meeting and networking with other scholars and faculty.
  - **Expert Advice and Guidance:** Extensive one-on-one feedback and suggestions on at least one manuscript and one grant.
  - **Teaching:** Part of the commitment as a CTSI K-scholar will involve teaching within the CTSI program
  - **Courses:** 1-year certificate in advance training in clinical research (ATCR)
Sample Candidate's Plan for Career Development / Training Activities During Award Period

Courses required for the advance training in clinical research (ATCR)

- Summer:
  - Designing Clinical Research (EPI 202), Building a Career in Clinical Research (EPI 227), Responsible Conduct of research (EPI 201) (already taken), Introduction to Statistical Computing in Clinical Research (BIOSTAT 212)

- Fall:
  - Epidemiological Methods (EPI 203), Clinical Epidemiology (EPI 204), Biostatistical Methods for Clinical Research I (BIOSTAT 200) (already taken)

- Winter:
  - Clinical Trials (EPI 205), Biostatistical Methods for Clinical Research II (BIOSTAT 208), Data Management (EPI 218)

- Spring:
  - Systematic Reviews/Meta-Analysis (EPI 214), Biostatistical Methods for Clinical Research III (BIOSTAT 209), Publishing and Presenting Clinical Research (EPI 212)
Grant Writing Workshop:

Our Institution’s Training in Clinical Research program offers a grant-writing workshop on an annual basis directed by Dr. Jane Doe. During the workshop attendants discuss the characteristics of successful research grant applications:

- Common mistakes to avoid
- How to write individual components of the application
- What happens after the grant application has been submitted
- How to develop a responsive resubmission if needed

The emphasis is on NIH grants process, but the concepts taught will be applicable to all funding mechanisms. I plan to take this workshop early in the 3rd year of the K award while I am starting to write the R01.
Sample Candidate’s Plan for Career Development / Training Activities During Award Period

Seminars:

Additional seminars I will attend include:

- a monthly Cancer Center Research cancer genetics seminar
- a weekly lab meeting
- a Center for Genes Environment and health monthly meeting (journal clubs and outside speakers on genetics)
- the monthly outside speaker seminars sponsored by the Institute for Human Genetics
- the monthly Quantitative Biology Discussion Group of the Cancer Center
Sample Candidate’s Plan for Career Development / Training Activities During Award Period

Meetings and Conferences:

I will attend and present my work at the following local, regional and national meetings:

- The Breast Oncology Program Retreat at Cancer Center
- Cancer Center Health Disparities Research Symposium
- The Latin American Cancer Epidemiology (LACE) meetings
- The American Association of Cancer Research (AACR)
- The Science of Cancer Health Disparities in Racial/Ethnic Minorities and the Medically Underserved
Sample Candidate’s Plan for Career Development / Training Activities During Award Period

Interactions with mentors, technical advisors and collaborators:

**Dr. Joe Smith** will be the main mentor and advocate for my career. In this capacity, he will meet with me at least once a week during mentored phase of the award to review data and work on data analysis. During the independent phase we will meet once every two weeks to discuss data analysis and grant proposals.

I will have the benefit of co-mentorship from **Dr. Jane Smith**, Professor and Chief of the Division of General Internal Medicine in the Department of Medicine. She is an internationally recognized authority on breast/prostate/colon cancer. We will meet once a month during first year and once every two months during second year. During the first year of the independent phase we will meet once a month to discuss the design of my R01 proposal.

I will also have the opportunity to meet with other senior scientists at my Institution (we will meet on “as needed” basis to address specialized aspects of the project):

**Dr. William Brown**, an expert on genetic epidemiology, will assist me during the elaboration of new projects,

**Dr. John White**, an expert in statistical genetics, leader in cancer genetic epidemiology training will meet with me to review my progress regarding statistical analyses,

**Dr. Joe Gray**, a leading figure in cancer biology, will help me with the interpretation and quality control of the gene expression microarray data and proteomics that will be produced by my collaborator **Dr. William Smith**.
# Sample Candidate’s Plan for Career Development / Training Activities During Award Period

## Timeline and (%) of time devoted to each activity

<table>
<thead>
<tr>
<th>Activity</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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<tbody>
<tr>
<td>Research and didactic activities</td>
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<tr>
<td>Specific aim 1: Analysis of Genome Wide Association (GWAS) data</td>
<td>X (20)</td>
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<td>Specific aim 2: Analysis of GWAS of breast cancer stage and survival</td>
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<td>Specific aim 3: Replication and validation of training set samples</td>
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<td>X (40)</td>
<td>X (30)</td>
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<tr>
<td>Training in Clinical Research (TICR) certificate course</td>
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<td></td>
<td>X (70)</td>
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<td>Grant writing course/Responsible conduct of research course</td>
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<td>Teaching within the TICR program (mentoring students)</td>
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<td>X (8)</td>
<td>X (8)</td>
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<td>Seminars related to Institutional K-scholars program and others</td>
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<td>X (10)</td>
<td>X (7.5)</td>
<td>X (7.5)</td>
<td>X (7.5)</td>
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<tr>
<td>R01 writing and submission</td>
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<td></td>
<td>X (25)</td>
<td>X (20)</td>
<td>X (20)</td>
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<tr>
<td>Preparation and submission of manuscripts</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Meetings with Primary mentor (weekly)</td>
<td>X (2.5)</td>
<td>X (2.5)</td>
<td>X (1.25)</td>
<td>X (1.25)</td>
<td>X (1.25)</td>
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<tr>
<td>Meetings with Co-mentor (bi-weekly)</td>
<td>X (1.25)</td>
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<td>X (0.65)</td>
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<tr>
<td>Meetings with other collaborators (as needed)</td>
<td>X (1.25)</td>
<td>X (1.85)</td>
<td>x (2.0)</td>
<td>X (2.6)</td>
<td>X (2.6)</td>
</tr>
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</table>

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Career Award Review Criteria
Career Award Review Criteria

- **Candidate:**
  - Quality of research, academic and/or clinical record
  - Potential to develop as an independent and productive researcher
  - Commitment to a research career
  - Quality of the letters of reference

- **Career Development Plan/Career Goals & Objectives:**
  - Likelihood that plan will contribute substantially to the scientific development of candidate – Added Value
  - Content, scope, phasing, and duration of the plan in the context of prior experience and stated career objectives
  - Adequate plans for monitoring and evaluating the candidate’s research and career development progress