Dr. Loretta Erhunmwunsee

2022-004: The Impact of Racism-Related Socio-Environmental Factors on African-American Non-Small Cell Lung Cancer (NSCLC) Mutational Signatures

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Summary of CPHS Approved Study

- **Purpose:**
  - Investigate the impact of structural racism on specific lung cancer mutations in African-American (AA)/Black patients
  - Understand how factors may differently affect genes in AA/Black and Non-Hispanic White (NHW) lung cancer patients
  - This study served as the foundation for our recently awarded NIH grant
    - Thank you!!

- **Original Accrual:**
  - N= 60 (40 AA/Black and 20 NHW)

Summary of Changes

- Amendment 1: Alignment with R37
  - Cohort dates, sample size, and aims revision
- Amendment 2: Adding Recruitment Site
- Amendment 3: One-Part Consent
- Amendment 4: Option for Independently Completing Consent

Justification of our Proposed Changes

- We are working with a historically marginalized population that have not been accurately represented across studies
- Adapting to non-traditional methods can be more inclusive for marginalized participants, given that they have a different experience in the research and clinical space
- Important to follow the lead of studies that have successfully recruited and enrolled AA/Black participants
- Patient feedback from initially approved CPHS study has also guided this amendment

Justification of our Proposed Changes: RESPOND

- Emory University was a site for a hallmark study titled: Research on Prostate Cancer in African American Men: Defining the Role of Genetics, Tumor Markers and Stress (RESPOND)
  - Emory is one of our sites in the R37

- RESPOND had a 42% response rate from 4800 AA/Black men, 50% of those respondents completed the study – our project has a 20% completion rate

- It is important to use studies that have successfully enrolled AA/Black participants as a *guide*, thus we are proposing to adopt a similar recruitment strategy to RESPOND

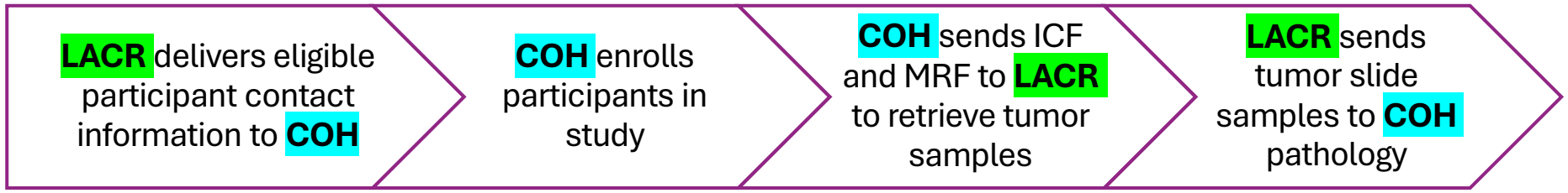
Amendment Change 1: Alignment with R37

- The aims and cohort dates were revised to align with the R37
- R37 funded for recruitment of 300 AA/Black patients across 4 recruitment sites:
  - California (Northern and Southern), Georgia, and Detroit
- Recruitment in **California** was expanded from 40 AA/Black participants to 100 AA/Black participants

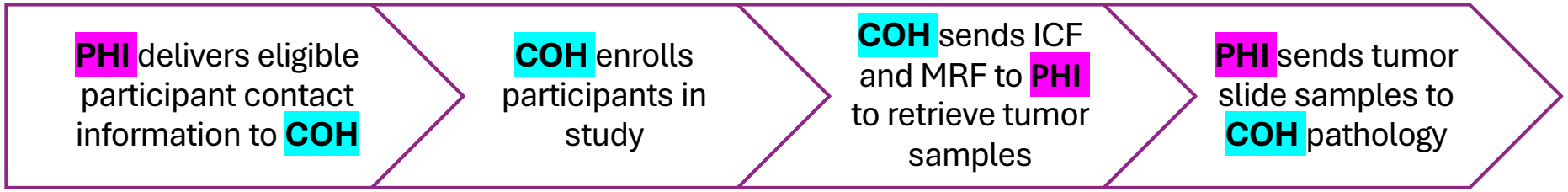
Amendment Change 2: Adding PHI

- **Adding Additional Recruitment Site:**
  - Public Health Institute/Cancer Registry of Greater California (PHI/CGRC) has been added to reach our California accrual goal of **100** Black/AA participants
- **Role:**
  - PHI will deliver data and tumor tissue, in the same manner as LACR

CPHS Currently Approved site activities:



Proposed site activities:



Amendment Change 3: One-Part Consent

- **Original Two-Part Consent Process:**
  - One Consent Information Sheet for the survey (Part 1) and another Signed Informed Consent Form for the Tumor Tissue/Medical Record Request (Part 2)
  - Between Part 1 and Part 2, we have lost ~40% of participants who did not complete Part 2
    - Participant feedback revealed 2-touch points is extensive and burdensome

- **Proposed One-Part Consent:**
  - The RESPOND study (which includes one of our collaborating sites) operated with a one-part consent - had a high accrual and completion N= 1,000
  - Survey and Tumor Tissue/Medical Record Request under <u>one</u> Informed Consent Form
    - One $75 gift card will be sent to participants. This gift card covers $25 for survey completion and $50 for completion of the MRF

Amendment Change 4: Option for Independently Completing Consent

- **Original Consent Process:**
  - Consent forms completed remotely with the participant and study representative
  - Patient feedback:
  - “I do not have time to do another phone call to complete the Part 2 consent. Is there any way I could do it on my own time. I understand the study with the information presented.”
    - Did not continue participation in our research study after discovering we had to do another consent form over the phone

- **Proposed Consent Process:**
  - The RESPOND study operated with independent consent form completion and had a high accrual, N= 1,000
  - Informed Consent Video and Cover Letter included for guidance
  - Participants have the option to contact City of Hope Staff if they wish to undergo remote consenting
  - If patients have not responded to our introductory packet, we will call them to follow-up
  - **We are not revoking the option of study staff completing informed consent with patients - this is just an option that will be available to all participants.**