Biorepository Request for Proposal

While the effects of the pandemic are still emerging, current data suggests certain populations are more vulnerable than others. In addition to those age 65 and older, recent data suggests the virus is having a disproportionate impact on communities of color. According to a recent study from APM Research Lab, African Americans are dying from the virus at nearly three times the rate of white Americans. Further, in 42 states plus Washington D.C., Hispanics/Latinos make up a greater share of confirmed cases than their share of the population. In eight states, it’s more than four times greater. And in states that categorize Native Americans in demographic results, early data indicates dramatically disproportionate rates of infection and death. In New Mexico, for example, Native Americans make up less than 10% of the population but over one-third of coronavirus cases.

As the U.S. continues to face the COVID-19 pandemic, which has disproportionately impacted communities of color, Centene Corporation, a leading multi-national healthcare enterprise, and the National Minority Quality Forum (NMQF), an independent research and educational organization dedicated to ensuring high-risk racial and ethnic populations receive optimal healthcare, announced a research partnership for the Minority and Rural Health Coronavirus Study (MRCS) to assess the impact of COVID-19 on racial minorities and underserved communities across the country.

The National Minority Quality Forum (NMQF) would like to establish a biorepository for serum/plasma, and other types of samples (to be determined) collected from patients undergoing COVID-19 testing. This repository is designed to facilitate research into this emerging disease. This repository will collect, store and distribute research patient blood specimens (samples of whole blood and plasma) for use in future research projects conducted by investigators associated with the MCRS study. The storing and gathering of blood specimens will help MCRS investigators conduct future research and avoid recollecting specimens and data repeatedly. The collection of patient biospecimens in this stored blood specimen, researchers may understand better the clinical and biological dynamic relationship between racial and ethnic minorities and COVID-19, identify and develop new tests for that may identify new ways to treat COVID-19, or develop new products, such as therapeutics. Additionally, these collections will contribute to the development of prognostic biomarkers for COVID-19 among minority groups.

Background

Centene Corporation and the National Minority Quality Forum (NMQF) partnered to study the impact of coronavirus on minorities and rural communities through the Minority and Rural Health Coronavirus Study (MRCS).

Study participants are being recruited from 5 Federal Qualified Health Centers in 5 states. Each center is recruiting 1,000 study participants. MRCS is phasing in FQHCs. Participants are consented to a 5-year study. Each FQHC will offer a free test for the virus and for those who consent to participate in the study they are asked to fill out a presurvey and they receive a SARS antibody test.

Sample Collection:

The 5,000 samples are powered to allow MRCS to have various ancillary studies that have distinct study objectives.

Blood Collection Specifications
We anticipate that specimen collection (up to 10,000) will be completed within five years of study initiation.

Specimen type: whole blood collected from COVID-19 positive and negative research subjects from study sites. Volume: up to 7.5 mL (2 collection vials)

<table>
<thead>
<tr>
<th>Biospecimen</th>
<th>Uses</th>
<th>Storage Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>Genomic studies; source of DNA and RNA</td>
<td>Stored at -80°C if DNA extraction cannot be carried out immediately</td>
</tr>
<tr>
<td>Plasma</td>
<td>Proteomics; Source of DNA; multiple analyte studies</td>
<td>Stored at -80°C</td>
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These ancillary studies will include:

• The **Antibody Testing Study**, which validates the sensitive and specificity of clinical assays to detect and measure variations in the virus ‘s impact on the biology and prognosis of minority populations.
• The **Antibody Quantity Testing Study**, which seeks to determine if SARS-CoV-2 antibody quantities vary by age, gender or race.
• The **Diabetes and Coronavirus Study**, which investigates whether minorities living with diabetes are at a higher risk for poor health outcomes if infected by the virus.
• The **Cardiovascular and Coronavirus Study**, which investigates whether minorities living with diabetes are at a higher risk for poor health outcomes if infected by the virus.
• The **Hispanic Coronavirus Study** examines the COVID 19 with Hispanics as the reference population. Study measurements will include: whole genome sequencing, antibody quantities, basic clinical assays, and social determinant surveys. The objective is to identify any unique risk factors that are associated with poor health outcomes among Hispanics.
• There will also be a **Rural Study, African American Study, a Native American Study, an Asian Study, and a Pulmonary and Coronavirus Study**.

Future studies utilizing the biorepository will require review of the research protocol by an Advisory Steering Committee. This is to ensure that proposed studies are appropriate and feasible, an adequate sample number is available and can be appropriately tested (including considerations for sample stability), all regulatory and fiduciary requirements have been met, and final sample dispositions have occurred.

**Scope**

The main objective of this requirement is to establish a Minority and Rural Health Coronavirus Study (MRCS) Biorepository to accomplish the following in a highly efficient, rapid, secure, and cost-effective manner:
A. Planning and logistics to ensure provision of a technical and administrative infrastructure that supports efficient planning, initiation, implementation, and management of the MRCS biorepository activities.

B. Securing, receiving, cataloging, processing, storing, and disbursing human biological specimens from sponsored studies or studies approved to have their biospecimens and related data/resources included in the MRCS Biorepository.

C. Providing adequate cold storage facilities and equipment for securing, cataloging, processing, storing, and disbursing biospecimens following Biospecimen Repository Best Practices as defined by the CAP Biorepository checklist or International Society of Biological and Experimental Repositories-ISBER http://www.isber.org/ibc.html.

D. Providing a secure back-up system and a plan for disaster recovery.

E. Developing, performing, and maintaining Quality Assurance/Quality Control (QA/QC) Systems for the facility, operations, stored specimens, shipping materials, and personnel in accordance with all applicable Federal, State, and local regulations.

F. Providing a web-based computerized inventory/tracking database for the biospecimens management to support MRCS Biorepository functions/requests.

Basic Requirements

Storage Capacity and Temperature: Estimated number of projected samples to be stored include: 5,000 serum/plasma samples collected over 5 years. Biorepository must be capable of < -80C storage as this is the temperature that the specimens must be stored.

Processing requirements: The biorepository should have the capability of aliquoting and processing plasma/serums and other biological specimens according to the specific research and/or appropriate storage requirements.

Clinical Information Storage Requirements: The biorepository must have the ability to store clinical information, including but not limited to: a) center ID/name, b) unique specimen identification, c) specimen type, d) date of collection and e) study protocol number.

Data Retrieval Requirements: Number of samples stored must be easily identified with easily generated reports that can identify number and specimen types, as well as other associated clinical information on demand.

Specimen Retrieval Requirements: The biorepository must have the capability of easily retrieving, collating, and sending properly stored samples to a designated center as needed. Access to specific samples by researchers will be determined by the individual study that would have been approved by the study Advisory Steering Committee.

Regulatory Requirements: The biorepository must have SOPs and processes that follow the CAP Biorepository checklist or the Biospecimen Repository Best Practices as defined by the International Society of Biological and Experimental Repositories-ISBER http://www.isber.org/ibc.html.

RFP Submission
Please submit a brief proposal, not to exceed 4 pages (8x11 page size with 1 inch margins, no less than 11pt font) answering the following questions no later than 5pm EST on Friday, August 14th, 2020. Your biorepository should be prepared to begin receiving samples starting on or after August 19th.

- Descriptions of SOPs within your organization that address the requirements listed above.
- Detail annual estimates for receiving 5,000 SST 7.5 ml tubes of specimens, processing the samples and aliquoting them into 20,000 .5ml tubes, and storing the 20,000 serum or plasma samples at < -80°C over a 5-year period. Please describe cost per specimen.
- Costs associated with retrieving and shipping stored samples. Please describe the cost per specimen.

If you have any questions please contact:

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