

## COVID-19 Impact on Health and Well-being Survey Data Sharing Agreement and Proposal Form

### Background and Guiding Principles

The COVID-19 Impact on Health and Well-being Survey was designed to examine how mental health and well-being are impacted by shelter in place/home mandates. This survey was created as a result of collaborative efforts involving UTRGV Departments of Population Health & Biostatistics, Family Medicine, Psychological Sciences and Sociology. The survey instrument was created using REDCap, is available in English/Spanish, designed to be anonymous and takes approximately 15-20 minutes to complete. Please see Table 1 for a general overview of survey content. Most survey sections including demographics ask specifically how daily living has been impacted by sheltering in place/home due to the COVID-19 pandemic. All data collected from the survey will be housed at UTRGV School of Medicine, Department of Population Health & Biostatistics.

### Study Sample

A snowball sampling method was employed to recruit non-institutionalized adults 18 years and older who were currently sheltering in place. A list of community organizations (hospitals, clinics, non-profits, institutes of higher education) with active e-mail distribution lists or social media pages were asked to promote the use and sharing of survey among members. Weekly recruitment reports summarizing key demographic information of respondents were used to inform subsequent waves of targeted recruitment to diversify sample. We also partnered with Area Health Education Centers (AHEC) in our geographic region to administer the survey over the phone to clinic populations. This ensured the inclusion of hard to reach populations among respondents (e.g. rural, underserved, uninsured). Given our affiliation to a Hispanic serving institution and our geographic region along the Texas-Mexico border, we also initially failed to recruit African American/Black respondents. To date, we have collected over 600 responses to our survey. The majority of our respondents are female (70%), half are Hispanic and most live in Texas, although we have received responses from over 27 states.

**Table 1:** General Topics Assessed in COVID-19 Mental Health and Well-being Survey

|                 |  |                       |                      |
|-----------------|--|-----------------------|----------------------|
| Demographics    | Trust in COVID-19 Related Health Information | Family Function       | Abuse                |
| Depression      | Compliance with Shelter in Home Mandates     | Physical Activity     | Financial Stress     |
| Anxiety         | Social Network                               | Religion/Spirituality | Loneliness           |
| Health Literacy | Resources                                    | Resilience            | Neighborhood Factors |

### Future Collaborations

There is potential for rich data to be generated by this study and these data are intended to provide a broad resource for secondary data analyses on the impact of mental health and well-being while sheltering in place/home. Principal and co-investigators will have the opportunity to develop an area of interest that leads to scientific papers including the opportunity for first authorship. Primary investigators will be granted sufficient time to analyze and publish their primary research initiatives. Outside collaborators are also welcomed to develop research questions.

### Current Investigators

Principal Investigators (Population Health & Biostatistics):  
Candace Robledo, PhD, MPH (candace.robledo@utrgv.edu)  
Jay Morrow, DVM, MPH (jay.morrow@utrgv.edu)

#### Co-Investigators

Michael Machiorlatti, PhD (Biostatistics)  
Belinda Reininger, (Public Health)  
Deepu George, PhD, LMFT (Behavioral Health Care)  
Dean Kyne, PhD (Emergency Management/Preparedness)  
Ruby Charak, PhD (Psychological Sciences)

## Principles and Procedures for Data Sharing

1. A group of faculty and staff has been central to the development of the COVID-19 Impact on Mental Health and Well-being survey and data collection. Consultation with and inclusion of one or more of these investigators depending on the project is needed for approval. Dr. Candace Robledo, and Dr. Jay Morrow, co-PIs, have played an essential role in generating the survey and should be on each paper or acknowledged in recognition of their role in the design, recruitment, organization, oversight and the collection of data. Dr. Robledo and Morrow's role will be active and supportive in the preparation of manuscripts.
2. The Core PIs must review all manuscripts using survey data before they go out so that major inconsistencies in data and messages can be detected and adjusted as necessary.
3. All persons handling the data must be added to the Committee for the Protection of Human Subjects approval for these data.
4. An application with required preliminary information must be submitted to the corresponding PI. At this point authorship should be agreed, and if appropriate collaborative agreements drawn up.
5. Acknowledgements of the core team should be made in all presentations using this data. The team's contribution is essential in order to gather data. Names should be requested from corresponding PI.

## Submitting a Proposal to COVID-19 Impact on Health and Well-being Working Group

### **Guidelines for Authorship**

For resulting publications from original data collected using survey tool, the study team will conform to the most recent version of the International Committee of Medical Journal Editor's Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/>). Briefly, authorship credit is based on 1) substantial contribution to the conception and design, or acquisition of data, or analysis and content; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. Order of authorship reflects descending order of contribution; last author contributes the least. However, authorship can be *a priori* decided using another weighing such as in alphabetical order.

Investigators listed on the original IRB application constitute the working group. A Writing Group led by the Writing Group Leader (first author) will be established based on interest and anticipated collaborative participation. Working group members should contact the Writing Group Leader if interested in collaborating. Membership in the writing group is subject to change depending on member contributions. The Writing Group Leader is also responsible to ensure that everyone in writing group is in compliance with the data usage agreement. If the writing group leader fails to adhere to the mutually agreed upon procedures and timeline, he/she may forfeit his/her role as Writing Group Leader and will seek Dr. Candace Robledo's approval and or assistance in reassigning the position.

### **Submitting a Proposal**

Any investigator wishing to propose a research question or others who wish to develop a collaborative relationship with the working group should:

1. Send a proposal to Dr. Candace Robledo, Principal Investigator, Department of Population Health & Biostatistics. Proposal (**see appendix**) should be sent electronically to: [candace.robledo@utrgv.edu](mailto:candace.robledo@utrgv.edu).
2. Dr. Robledo will maintain a bibliography of published work and a spreadsheet of accepted proposal topics with lead author, current status, and timeline. If a proposal is judged feasible, of substantial scientific interest, and is not currently under consideration by another investigator, the proposing investigator will be given approval to move forward.

## Data Use Agreement

*Submission of a proposal (see attached) is indication of your agreement to follow the guidelines described in our data use agreement and when applicable share data from original survey tool back with UTRGV.*

### **Definitions**

*Data* refers to de-identified data collected from the COVID-19 Mental Health and Well-being survey managed by the Department of Population Health & Biostatistics.

*Approved users* are individuals listed as authors for proposed research projects.

*Recipients* are individuals that will lead the scientific investigation using the Data and are responsible for obtaining Institutional Review Board or appropriate institutional assurance board/authority approval, if applicable, and for overseeing Approved users.

The *research proposal* refers to the document that describes the project to be undertaken by the recipient and that has been submitted to and reviewed by Dr. Candace Robledo and other working group members.

### **Conditions**

This data use agreement is not transferable or assignable and any substantive change to the scope of the research project requires approval. The data will be used by the recipient for analysis as described in their proposal. Recipient agrees that data will not be used for any research activity outside the original scope of the approved research project.

The recipient agrees that data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from who the data was obtained.

The recipient agrees to retain control over the data and will not transfer data to any other entity or any individual other than the approved user. The recipient is responsible for limiting access to the data to the recipient and other approved users. The recipient shall destroy data when the research that is subject to this agreement has been completed. Notification of data destruction will be sent to the principal investigator upon completion of the research project.

### **Termination**

This data use agreement will terminate in three years. At any time, either party may terminate this agreement upon thirty (30) days' written notice to the other party. Upon termination, the data should be destroyed, and the recipient must send notification stating destruction of all data and material to the principal investigator. If Dr. Candace Robledo determines that the recipient has violated any terms of this data use agreement, she may terminate this agreement immediately upon written notice and will direct recipient to destroy the data. The recipient understands that if a violation has occurred, the working group may refuse to release further data to the recipient, either for this research project or future projects.

## Proposal Form

|  |                                 |       |            |
|--|---------------------------------|-------|------------|
| Proposed/Tentative Title:  |                                 | Date: |            |
| Name of applicant:   |                                 |       |            |
| Address of applicant   |                                 |       |            |
| Phone number of applicant:   |                                 |       |            |
| Email address of applicant:  |                                 |       |            |
| Brief description of the objective of the manuscript/Primary Outcomes/Significance/Data Needed:<br><b>Purpose:</b> |                                 |       |            |
| Target Journal (s):  |                                 |       |            |
| Authorship*  |                                 |       | Initialed: |
|  | 1 <sup>st</sup> Author          |       |            |
|  | Co-equal Author (if applicable) |       |            |
|  | Corresponding/Senior Author     |       |            |
|  | Contributing Authors            |       |            |
|  | Senior Author                   |       |            |
| Data Format Required: (i.e. SAS, SPSS, Excel)  |                                 |       |            |
| Start date   |                                 |       |            |
| Approved by:   | Candace Robledo                 |       |            |
|  |                                 |       |            |
| Date:  |                                 |       |            |

**\*All authors handling data need to complete the course in research ethics and submit a certificate to [candace.robledo@utrgv.edu](mailto:candace.robledo@utrgv.edu) to comply with IRB requirements.**