IRB Application (Version 1.0)

1.0 General Information

***Please enter the full title of your study:**

Behavioral responses to novel SARS corona virus outbreak and subsequent shelter-in-place and work-from-home policies.

***Please enter the Study Alias you would like to use to reference the study:**

COVID-19 behavioral responses
* This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.

2.0 Add Department(s)

2.1 List departments associated with this study:

Primary Dept?	Department Name
◉	[redacted]

3.0 Assign key study personnel(KSP) access to the study

3.1 *Please add a Principal Investigator for the study:

[redacted]

Select if applicable

☐ Student ☐ Department Chair

If the Principal Investigator for a Human Subjects protocol is a Student, the name of the Faculty Advisor must be supplied below.

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

[redacted]
Co-Investigator

[redacted]
Co-Investigator

B) Research Support Staff

3.3 *Please add a Study Contact:

[redacted]

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) can typically be someone other than the Principal Investigator themselves).

3.4 For applicable Human Subjects Research, please add a Faculty Advisor:

3.5 For applicable Human Subjects Research, please select the Designated Department Approval (s):

[redacted]

Dean

Add the name of the individual authorized to approve and sign off on this protocol from your Department (e.g. the Department Chair or Dean).

3.6 If applicable, please select the Administrative Assistant(s):

Administrative Assistants have READ-ONLY access to submissions in iRIS.

4.0 Contact Information and Additional Study Personnel

4.1 Form Version 10 - published 8/10/15

4.2 The primary mechanism for CPHS communication with you will be through IRIS Correspondence, however, we may need to call you for clarification. Please provide names and contact numbers as outlined below. Please make sure these individuals have a good knowledge of the protocol. For most studies the Principal Investigator and study coordinator are listed as the primary and secondary contacts.

	Name	Office Phone	Pager/Cell Phone
* Primary Contact	[redacted]	[redacted]	[redacted]
Secondary Contact			

4.3 List Study Personnel who are not listed in the [redacted] White Pages Directory (not [redacted] employees or guests) and specify their roles on this study.

Key study personnel are defined as personnel responsible for the design, conduct, or reporting of the proposed research or other educational activities.
*** NOTE: Human subjects training certification and research conflict of interest forms are required for Key Study Personnel. Only Human subjects training certification is required for Non-key Study Personnel.**

Name	Affiliation	E-mail address	Role in this study	Comments - describe role on study	
No records have been added					

5.0 Locations

5.1 * Is the research being conducted at the Clinical Research Unit (CRU) or are other CRU services being requested?

NOTE: If YES, you will be required to complete some additional questions within this application and your application will be routed automatically to the CRU for review.

○ Yes ◉ No

5.2 * Is the research being conducted at a Memorial Hermann Healthcare System facility? ***("Research" includes clinical trials, as well as any studies that involve retrospective or prospective data, including any access to electronic medical records.)***

Please note: **If the research will be conducted at a Memorial Hermann Healthcare System facility, remember to complete and attach the Memorial Hermann Application Form which you can find under the Review Board Forms section when you are putting together the submission packet.**

○ Yes ◉ No

5.3 Please identify other locations or facilities not listed above where the research is being conducted.

Select all that apply:

- ☐ BBS - Behavioral and Biomedical Sciences Building
- ☐ Ben Taub General Hospital (Harris Health)
- ☐ HCPC - Harris County Psychiatric Center
- ☐ Hermann Medical Plaza (UT Clinics)
- ☐ HISD - Houston Independent School District
- ☐ Houston Medical Center Building
- ☐ IMM - Institute of Molecular Medicine
- ☐ LBJ Hospital (Harris Health)
- ☐ M. D. Anderson
- ☐ Methodist Hospital
- ☐ St. Luke's Episcopal Hospital
- ☐ Texas Childrens' Hospital
- ☐ Texas Heart Institute
- ☐ Thomas Street Clinic (Harris Health)
- ☐ UT - School of Dentistry
- ☐ UT Professional Building
- ☐ UT - School of Nursing
- ☐ UT - School of Public Health
- ☐ Valley Baptist Medical Center - Brownsville (VBMC)
- ☐ Veterans Affairs Medical Center
- ☐ OTHER

Please identify additional locations or facilities not listed above:

Please be reminded that if you are conducting research at facilities other that UT, MHH, THI and HCHD, you must ensure you have all the necessary approvals required by that facility including review and approval by their IRB.

6.0 Funding Source

6.1 * Have you applied for or have you already received funding or support for this research proposal?

○ Yes ◉ No

6.2 Please identify how this study is funded or supported. If the agency/sponsor is not listed, please call the iRIS Support line at 713-500-3470 for assistance. You can select more than one agency.

	Sponsor	Funding
Federal - NIH		
Private - Non-profit		
Academic Health Center		
Other		
Federal		
Internal - UTHSC-H		
Pharmaceutical or Device Manufacturer		
State Agency		

6.3 If this is an industry sponsored clinical trial, provide contact information for the sponsor for IRB fee billing purposes.

Contact Name	Contact Phone Number	Contact E-mail address	Additional information (if necessary)

6.4 Status of funding:

Please select one:

- ○ Applied/Pending
- ○ Approved
- ◉ Not Applicable

6.5 **If this is investigator initiated research for which you have applied/received monetary or in-kind support from industry sponsors, please describe in detail. Include details on kind of support, who has oversight over the research project and who has ownership of the data.**

7.0 Study Summary

7.1 *** Summarize the proposed research using non-technical language. Limit to about 250 words. This summary will be used as a reference throughout the course of the study by reviewers and will appear in the "Study Summary" section in iRIS. Please include the following in your summary:**

- **the purpose**
- **research design**
- **procedures to be used**
- **risks and potential benefits and**
- **importance of knowledge that may reasonably be expected to result**

The purpose of this study is to investigate the association between the SARS CoV2/COVID-19 pandemic and subsequent shelter-in-place and work-from-home policies with behaviors that promote or are harmful to health

This is a cross-sectional analysis of a convience sample of adults currently residing in the US.

Participants will be asked to complete a 15-20 minute survey online using the UTHealth Redcap platform. Invitations to participate on the co-investigators social media platforms will be initiated upon IRB approval. Participants will be provided a brief description of the study before asking if they would like to participate. After consenting to participate, the participant will provide information to confirm eligibility (over 18 years of age, reside in US, albe to read/write English). They will then be asked to complete the survey.

The survey will ask a series of validated questions in the following domains:

- substance use
- sleep
- physical activity
- sedentary behavior
- intimate partner violence
- financial/job status
- mental health

There are minimal risks to participants. All data are anonymous. A breach of confidentiality is the only known risk, however the lack of identifiable information makes this risk highly unlikely. Benefits beyond contributing to science are minimal. Participants will not be compensated for participating.

As a result of COVID-19 pandemic, and subsequent self-quarantine polices, the daily lifestyle/behavioral patterns of many individuals changed drastically with perhaps unintended consequences and results. For instance, there have been anecdotal reports of beneficial changes in sleep patterns as a result of work-from-home policies. Alternatively, law enforcement officials have indicated unusual increases in domestic disturbances and reports of violence. The reasons behind these changes in behavioral patterns may be useful for future behavioral interventions intended to improve long-term health.

8.0 Determining Review Type

8.1 *** The purpose of this panel is to allow IRIS to branch to simpler versions of the application for certain types of proposals (e.g. when you are uncertain whether the activity you are conducting needs to be reviewed and approved by the IRB). Please select the appropriate option:**

NOTE: MEDICAL SCHOOL ONLY: Studies that do not qualify for the exempt or expedited review process will require a Departmental Research Review form to be attached to the submission. The exempt criteria are listed in the next panel and the expedited criteria are listed in the bubble to the right. If you do not believe that your protocol qualifies for either category, a Departmental Research Review form will need to be uploaded in the Study Documents section

of the submission packet. For more information can be found on the **Departmental Research Review information page.**

Your submission will be returned to you if this form is not included.

- ○ Humanitarian Use Device - NOT as part of a research study
- ○ Request for permission to rely on IRB approval from an IRB with whom UT Houston has signed a reliance agreement (all UT System Component IRBs, NICHD Federated IRB , Baylor College of Medicine, Chesapeake IRB, BRANY IRB, Quorum IRB, WIRB/WCG IRB, IRBshare, etc.)
- ○ Requesting assistance in whether or not formal IRB review is appropriate. See HELP bubble.
- ◉ None of the above - Requesting review by [redacted] IRB

9.0 Subject Contact Question

9.1 * Does this study involve contact with subjects?

- ○ My study does not involve contact with subjects.
- ◉ My study involves contact with subjects (including "in-person", e-mail, phone, anonymous or online surveys, etc.).

If the study involves contact with subjects, select an option below:

- ◉ My study ONLY involves normal education practices, educational tests, surveys, interviews, or observations of public behavior.
- ○ My study involves interventions, drugs or devices, clinical observations, or other study procedures.

10.0 Exempt Categories 1, 2 and 3

10.1 * Describe the study population for this research:

Inclusion criteria: Eligible participants will be adults (>=18 years) that currently live in the United States. Exclusion criteria: This study will only be offered in English language, therefore those not able to read or write in English will not be eligible to participate.

10.2 * Does this study involve children?

○ Yes ◉ No

10.3 Describe the recruitment process.

Potential participants will be recruited through online based social media platforms, mainly Twitter and Facebook. [redacted] manages a Facebook page, "Your Local Epidemiologist" with around 2,000 followers. We intend to engage these Facebook users, as well as the other investigators social media platforms to expand our online reach to as many users as possible.

We intend to enroll 1,000 participants in the study.

10.4 Describe the consent process. For research involving children, discuss the process for obtaining parental permission.

Participants will be provided an informed consent document within the survey, for which they will be required to review and "agree to participate" or "do not agree to participate" before proceeding in the survey.

10.5 How many participants will be approached for participation?

5000

What is the target enrollment for this research study?

1000

10.6 * Select the research activities or procedures.

- [ ] Interviews
- [ ] Educational tests
- [ ] Questionnaires
- [x] Surveys
- [ ] Observations
- [ ] Focus groups
- [ ] Other

*** Describe the research activites/procedures below:**

Participants will be invited to complete an online survey.

Notifications on the co-investigators social media platforms will be initiated upon IRB approval. Participants will be provided a brief description of the study before asking if they would like to participate. After consenting to participate, the participant will provide information to confirm eligibility. They will then be asked to complete the survey. The survey will take approximately 15-20 minutes to complete.

The survey will ask a series of validated questions in the following domains:
o substance use
o sleep
o physical activity
o sedentary behavior
o intimate partner violence
o financial/job status
o mental health

10.7 * Will you have identifiers? (Identifiers include all 18 HIPAA identifiers including Name, MRN, etc.)

(•) Yes ( ) No

Provide additional details below:

WE will collect zip code in which the participant resides in order to match the participant with stay-at-home policies where the participant lives.

If applicable, upload the following into the submission packet:

- ***Surveys and questionnaires***
- ***Outline of interview questions***
- ***School approval letters***
- ***Letters of support***

11.0 HIPAA (Health Insurance Portability and Accountability Act)

11.1 * HIPAA Privacy Rule - Choose one of the following options regarding how you will access protected health information for the purpose of this study.

(•) We will seek individual authorization from each individual and will attach the Authorization to use PHI form or include the HIPAA authorization language within the consent document. (NOTE: Selecting this option will bring you to the end of the application.)

- ○ We are requesting waiver of the requirement to seek individual authorization.
- ○ We will use or disclose a limited dataset. A data use agreement between the researcher and covered entity includes statements that the recipient of the data set will NOT identify the individuals.
- ○ Does not apply – we will not access protected health information. (PHI includes BOTH medical data and personally identifiable information. This means the research will not involve accessing medical records, laboratory records or any other type of health record.).

12.0 Statement of Investigator

12.1 * "I have discussed the protocol with all of my collaborators. The research is NOT underway and WILL NOT BEGIN until approved by the CPHS."

- ◉ Agree ○ Disagree

INFORMED CONSENT TO TAKE PART IN RESEARCH

Study Title:	Behavioral responses to the novel coronavirus (SARS CoV2)/COVID-19 pandemic and subsequent shelter-in-place and work-from-home policies.
Principal Investigator:	[redacted]
Study Contact:	[redacted]

Introduction and Purpose: We would like you to consider taking part in research on your experiences during the coronavirus outbreak in the United States. Eventually, we hope to use what we learn from this study to inform future research on health and unhealthy human behaviors. Your participation is voluntary and you can stop at any time without penalty.

Procedures: As part of this research, you will first be asked questions about behaviors you engaged in during the coronavirus outbreak. Specifically, we will ask about physical activity and sleep patterns, alcohol and substance use, mental health, at-home violence, work patterns, and social distancing practices. It will take about 10-minutes to answer the questions. You do not have to answer any questions that you do not wish to answer.

Confidentiality: Your privacy is very important to us which is why we are not collecting personal information about you. All survey responses will be anonymous and will not be linked back to you.

Questions: If you have questions about this study or need to report any problems please call [redacted] and ask to speak to someone about the COVID-19 Behaviors Study.

If you have any questions about your participation in this research, you can call the [redacted] Institutional Review Board (IRB) at [redacted] The IRB is a committee that has reviewed and approved this research study [redacted].

Contact Name: [redacted]
Telephone Number: [redacted]

[redacted]
IRB NUMBER: [redacted]
IRB APPROVAL DATE: 04/14/2020

[redacted]

Committee for the Protection of Human Subjects

[redacted]

[redacted]

April 14, 2020

[redacted] - *Behavioral responses to novel SARS corona virus outbreak and subsequent shelter-in-place and work-from-home policies.*

The above named project is determined to qualify for exempt status according to 45 CFR 46.101(b)

CATEGORY #2 *: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:*

a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND ,

b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(NOTE: The exemption under Category 2 DOES NOT APPLY to research involving survey or interview procedures or observation of public behavior when individuals under the age of 18 are subjects of the activity except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.)

CHANGES: Should you choose to make any changes to the protocol that would involve the inclusion of human subjects or identified data from humans, please submit the change via iRIS to the Committee for the Protection of Human Subjects for review.

INFORMED CONSENT DETERMINATION:
Waiver of Documentation of Informed Consent

INFORMED CONSENT: When Informed consent is required, it must be obtained by the PI or designee(s), using the format and procedures approved by the CPHS. The PI is responsible to instruct the designee in the methods approved by the CPHS for the consent process. The individual obtaining informed consent must also sign the consent document. Please note that only copies of the stamped approved informed consent form can be used when obtaining consent.

HEALTH INSURANCE PORTABILITY and ACCOUNTABILITY ACT (HIPAA):
Exempt from HIPAA

STUDY CLOSURES: Upon completion of your project, submission of a study closure report is required. The study closure report should be submitted once all data has been collected and analyzed.

Should you have any questions, please contact the Office of Research Support Committees at [redacted]