Attestation Guidance

• If at least one person on a study will be consenting/engaging in direct in-person interaction with participants (indicated in 2.1 of the iStar application), the “Attest to COVID-19 Policies” activity will appear on the study landing page.
  - Once an individual completes the attestation, that person will not have to attest again. His/her/zir attestation will apply automatically to all other studies on which that individual is listed in 2.1 as consenting or interacting.

• The activity link will always show on the study, but if the person has already signed off or will not consent/interact with patients, the person will get a message informing him/her/zir that he/she/ze does not need to fill out the form.

AIs will have a required field to upload their PI level plan approval notice. That field is hidden and not required for anyone who is not the PI.

Human Subjects Research Attestation

1. The USC Guidelines for Resuming Research Operations.
2. Only engage in research activities aligned with the research phase the university is in (e.g., Phase 2a1, Phase 3, etc.; See USC COVID-19 Research Ramp Up Table indicating the current phase the university has entered into).
3. Complete the USC required COVID-19 training through TrojanLearn.
4. Follow the PI-level plan approved by the school/department/center/facility and the approved School-Level research transition.
5. Adhere to the COVID-19 guidelines issued by the CDC, State of California, Cal-Osha, City of Los Angeles, and USC EHS’s Keck School of Medicine, LAC DHS, HR, Provost’s office, and DPS, as appropriate to the study context. Explain which of these applies to this study context.
6. Ensure that all spaces/locations where research activities involving human research subjects will be present (e.g., campus labs and offices, of-site locations) will provide at minimum 6-foot spacing with 10-foot social distancing highly desirable for multiple hour periods. If the research activities are taking place at Keck Hospital, at least 6-foot physical distance will be maintained whenever possible and direct contact with research participants will only take place when required by a study procedure.
7. Prior to engaging in on and off-campus research activities involving direct participant interaction, relevant members of the team will have completed the USC Wellness Assessment/Coronavirus Screening Questionnaire and offered appropriate/correct responses before engaging in direct interaction with participants.
8. Prior to engaging in on and off-campus research activities involving direct participant interaction, will administrate the USC Wellness Assessment/Coronavirus Screening Questionnaire to all potential participants and participants and ensure that you have received appropriate/correct responses before engaging in direct interaction with participants. If you do not expect to use this tool, you must explain how you intend to ensure participants have been screened in an equivalent manner that provides you with sufficient information to determine whether you may move forward with the research activities (e.g., you believe the questions are not culturally appropriate or sensitive).
9. Share the COVID-19 Information Sheet with participants prior to interacting with them.
10. Wear a facemask or covering whenever other personnel and/or participants are present in the research/data collection space and always outside in public spaces.
11. Ensure that potential participants and participants wear facemasks or coverings whenever other personnel or other participants are present.
12. Follow disinfecting protocols as set out by the department, lab, or location where data collection is taking place.
13. Ensure that disinfecting wipes or hand sanitizer are available wherever participants must touch shared items such pens, electronic devices, or medical equipment.

Guidelines stated above only ensure a minimum level of protection that must be afforded to members of the research team and participants. The research team will follow USC reporting guidelines related to COVID-19 infections. Personnel working or learning on campus or working with others in the field who test or have tested positive for COVID-19 at an outside facility must self-report the positive COVID-19 test result to the appropriate USC department: USC 24/7 Hotline at (213)-740-6291 for faculty, staff, or other individuals; and the USC Student Health Office, (213)-740-6355 for students.

* Please upload your PI level plan approval notice.

```plaintext
name        Version Modified
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dogep.pdf(0.31)   ---       0.01       6/29/2020 11:09 AM
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**Signature**

- [ ] Yes
- [ ] No
- [ ] Clear

Name: [REDACTED]

Date: Wed Jul 01 16:05:34 2020
• Once all individuals required to do so have signed their attestation, an email will get sent out to the PI/Faculty Advisor/Study Coordinator.

All necessary individuals have attested to COVID-19 Policies

All study personnel who have been identified in 2.1 of the iStar application as obtaining consent or interacting with participants have completed their attestations. If changes to study personnel are made, new personnel who will obtain consent or interact with participants will have to attest if that person has not already done so for a different study already approved by the IRB. If they do not complete an attestation, they will not be allowed to obtain consent or interact with participants.

You may now proceed with the study and move forward with the submission process.

• Page 9 of the application has a new question that will guide researchers to the activity (can execute on the study itself on page 9, or on the main study).

9.1.1. * Will anyone on this study have direct in-person interaction with participants?  ● Yes  ○ No  Clear

If the PI or any other study personnel will engage in direct in-person interaction with participants as a part of the study design, the PI must submit the PI-Level IRB approval notice you received from your school/department/center. Please have these individuals on your study complete an IRB attestation by executing the activity by clicking on the button below or on the main study workspace, under the "Prepare" subheading.

NOTE: These will be the individuals you have indicated "Yes" under Section 2.1 to either "Will obtain participants’ informed consent:" or "Will intervene with research participants:".

Current State
- Pre Submission
- Edit Study
- Printer Friendly Version

My Activities
- Prepare
  - Submission Instructions
- Send Study Ready Notification
- Attest to COVID-19 Policies
- USC studies will be halted from executing any “Submit” activities until all individuals (who need to attest) have attested.

**Submit Application**

Could not execute the Submit Application activity due to one or more errors:
An individual in the study team has not yet provided their electronic signature for the COVID-19 Policy Attestation. Please have access to the study and execute the ‘Attest to COVID-19 Policies’ activity. If you are attempting to add an individual onto a study via ‘Edit Study Personnel’, please have the individual log on to iStar and fill out the attestation on their dashboard.

Study: [name]

**Submit Application to HSIRB**

Use this form to submit your completed application for approval.

- Potential Conflicts of Interest:
  - Funding sources on this study (from item 4.4):
    - **Sponsor:** [name], **Nam ed PI:** [name], **Institution awarded the grant:** [name], **Grant-award number:** [number], **Type of Funding:** [type], **Documents:** [document]

  Select any (and all) of your disclosed financial interests (from diSClose) that relate to this study:
  - Submit Application to SBIRB, to BIRB
  - Submit Response to Cancer Center/Response to Contingencies, Department Reviewer, Division Reviewer, Expedited Reviewer, Faculty Advisor, IRB Committee, IRB Staff, Scientific Reviewer

- On approved studies, there will be a box with the names of individuals who have not yet signed their attestations (on existing non-exempt studies).
Individuals obtaining consent/interacting with participants cannot be added onto approved non-exempt IRB studies via "edit study personnel (unless they have already listed as consenting on another study)."

![Edit Study Personnel](image)

With this activity you can alter some of the personnel or personnel information on the study.

- Changes to key personnel (Principal Investigator, Faculty Advisor)

Please note that study personnel that do not have current required certifications such as Human Subjects and (in the case of clinical trials) Good Clinical Practice, cannot take part in study related activities until those certifications have been obtained or made current.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Organization</th>
<th>Study Role</th>
<th>Certifications</th>
<th>Obtain Consent</th>
<th>Interact with Participants</th>
<th>Access to Identifiable Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blockland</td>
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<td></td>
<td>Principal Investigator</td>
<td>HS, HIPAA</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
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<td></td>
<td>Faculty Advisor</td>
<td>HS</td>
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<td>no</td>
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<td></td>
<td>Data Collection/Manager</td>
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<tr>
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<td></td>
<td>Research Assistant or Associate</td>
<td>HS, GCP</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>
• The individual will need to login and access the attestation on his/her/zir dashboard (seen as they login) if he/she/ze is to be added via amendment or “edit study personnel.” If the individual has filled the attestation out already, he/she/ze will get an error message. After completing the activity, he/she/ze can be added onto the study via “edit study personnel.”
• When trying to submit amendments using any of the following activities, if everyone who is to be added onto study who needs to attest, hasn’t attested, there will be an error.

  - Submit to IRB, Submit Response to Pre-Review Reviewer/to IRB Staff/to Expedited Reviewer/to Contingencies.