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| **INFORMATION AND INSTRUCTIONS**:  Due to the Coronavirus Disease 2019 (COVID-19) national emergency and pandemic, certain procedures are required in order to protect human research participants (participants) in research activities involving in-person activities. Other procedures are optional.   1. FSU COVID-19 Policy for Research Activities Involving In-person Activities:    1. No in-person activity may involve any individual (human research participants (human subjects) or study staff—vaccinated or unvaccinated) who (1) tests positive for COVID-19 or (2) has been in close contact with someone who has COVID-19, within at least the past 10 days of a positive COVID-19 test or close contact;    2. Use of masks by human subjects or study staff involved in any in-person activity is strongly recommended; masks may be required in designated healthcare locations (researchers should confirm with their location point-of-contact for details);    3. Full COVID-19 vaccination of human subjects or study staff involved in any in-person activity is strongly recommended. 2. Required procedures include the following:    1. Research protocols involving in-person research activities must include a description, in the procedures section of a protocol, about how the FSU policy requirements above in section 1a-c will be implemented.       1. **COVID-19 screening.** The protocol shall describe how COVID-19 screening will be conducted before undertaking any in-person activities. For screening tools, consider adapting questions from or using the following COVID-19 screening link: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/coronavirus-self-checker.html> (CDC Coronavirus Self-Checker tool).       2. **Notifying prospective human subjects.** The protocol shall describe how prospective subjects will be notified about the FSU policy requirements above in section 1a-c. See section 2b below.    2. Consent materials must include a statement to the effect that no in-person activity may involve any individual (human research participants (human subjects) or study staff—vaccinated or unvaccinated) who (1) tests positive for COVID-19 or (2) has been in close contact with someone who has COVID-19, within at least the past 10 days of a positive COVID-19 test or close contact; that prospective subjects will be screened for this purpose; and that for any in-person research activity the use of masks is strongly recommended (and may be required in certain locations) as is a full COVID-19 vaccination. See below template for sample language. 3. Guidance:    1. IRB review will include review of researchers’ compliance with the above policy and procedures. Plan early, accordingly and carefully.    2. For questions regarding the policy and procedures: if you have a current FSU IRB submission for which you have a question about applying the policy and procedures, contact OHSP by submitting a Comment in your study's [RAMP IRB](https://myramp.research.fsu.edu/) workspace, under Next Steps; there, in response to the question about who should receive the email notification about your comment, select "IRB Coordinator." This will help to ensure that the IRB Coordinator assigned to your submission will receive a notification that your comment has been posted in your RAMP IRB workspace. Alternatively and if you have not yet submitted your study, contact [**OHSP**](mailto:humansubjects@fsu.edu) and an IRB Coordinator will follow-up with you on your COVID-19 policy or procedure question.    3. **Remote activities to the extent feasible.** Whenever feasible, researchers may for certain study activities (e.g., recruitment, consenting, pre- or eligibility screening, enrollment, baseline, initial and/ or follow-up) involving human subjects consider the use of remote instead of in-person activities.    4. **COVID-19 vaccination.**       1. A vaccinated individual is a person who has completed a full FDA authorized or approved COVID-19 vaccination series for the [CDC-recommended *minimum period of time*](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html).       2. COVID-19 vaccination resources.          1. A list of FDA authorized or approved COVID-19 vaccinations is available at this FDA COVID-19 Vaccines [web page](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines) or here: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.          2. For information about COVID-19 vaccination completion documentation, see this CDC web page, under the Vaccination Schedule and Use FAQs: <https://www.cdc.gov/vaccines/covid-19/hcp/faq.html#schedule>).    5. **Other COVID-19 precautions.** Other than vaccination, other COVID-19 precautions may include social distancing, use of masks, sanitizing, use of other personal protective equipment and isolation/quarantine.       1. Refer to COVID-19-related precautions at these CDC web pages: <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/returning-to-work.html#protect>; <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>.       2. Some individuals are considered at higher risk of severe illness from COVID-19, including older persons and individuals with certain underlying health conditions. See this CDC web page for a list of higher risk health condition: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>.    6. **Templates.** The templates in the tables below provide language that may be used to notify human subjects about COVID-19 policy and procedures. **Failure to use or adapt the applicable templates below may result in delay in review of your submission or your study or modification being returned to you for revisions.** |

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| TEMPLATES | | | |
| As applicable, use a template below and related instructions for in-person research activities to notify human subjects about COVID-19 policy, procedures and precautions. The templates may be used for new studies or ongoing studies. Please note that the IRB may, depending upon study activities and the acceptability of the proposed activities, require modifications. | | | |
| Separate Information Sheet as Addendum to Informed Consent | | | |
|  | Providing participants with an information sheet, added as a separate document to the consent form or in the consent process, that describes steps that the study team is taking to protect participants and others against COVID-19-related exposure. The separate COVID-19 Information Sheet does not requires subjects’ signature. | | Develop a COVID-19 Information Sheet (separate from consent materials; go [here](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/PIO1G5381K8UOSS4GEA9CLIG00/HRP-502iC-Information%20Sheet%20Template%20%28COVID-19%29%2020211228.docx) to download the Information Sheet template for your use) that is provided to participants. The Information Sheet does not require a signature block for study subjects; the Information Sheet provides a statement to the effect:  “We want you to know about what we will do to help protect you and others from COVID-19.  **First**, completion of a [full COVID-19 vaccination](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html) is strongly recommended. No in-person activity may involve any individual—vaccinated or unvaccinated—who tests positive for COVID-19 or has been in close contact with someone who has COVID-19, within at least the past 10 days of a positive COVID-19 test or close contact.  We will therefore ask some questions to screen research participants and study staff to see if they have tested positive for COVID-19 or been exposed to someone with COVID-19 within at least 10 days after testing positive or close contact. If you think that at any time before or while taking part in this study you tested positive for COVID-19 or were in close contact with someone with COVID-19, or if you do not want to tell us if you have tested positive or were in close contact, within at least 10 days after testing positive or close contact, then you may not take part in this study. Letting us know about your positive test or close contact is your choice. Study staff may or may not include licensed medical doctors and may not be able to give you any medical advice on your own risk for COVID-19, so please talk to your own doctor if you have questions. Information about COVID-19 can be found at this web site: <https://www.cdc.gov/coronavirus/2019-ncov/your-health/index.html>.    **Second**, we will try to make sure when possible that everyone stays a safe distance (6 feet) from one another. This is called “social distancing.” We will let you know if for some activities study staff may need to be closer to you, but staff will only be closer if absolutely necessary. We will take all the steps needed to protect you.  **Third**, use of masks are strongly recommended. We will let you know whether for some activities you should wear a mask. In those cases, if you don’t want to use a mask then we may take other precautions to protect you and others. If needed we will provide masks to you.  **Fourth**, we make sure to clean anything that will be touched by you or anyone else, and we will throw away disposable items like masks and gloves. At certain times we may ask you to wash or sterilize your hands, and we will do the same. We will provide you with hand wash and sanitizer.  **Fifth**, we may limit the number of people and time in any face-to-face activity to only the minimum amount required.  If at any time you don’t feel safe with the steps that we will take to protect you and others from exposure to COVID-19, please let us know and we will stop. We want to be sure to answer your questions and to take any other steps that you feel we should take to protect you while you are taking part in this activity.” |
| Language to Include in Informed Consent | | | |
|  | Adding language to the consent form that describes steps that the study team is taking to protect participants and others against COVID-19-related exposure. Subjects’ signatures on consent forms are generally required unless otherwise and specifically waived by the IRB. | Include in the consent form language to the effect:  “We want you to know about what we will do to help protect you and others from COVID-19.  **First**, completion of a [full COVID-19 vaccination](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html) is strongly recommended. No in-person activity may involve any individual—vaccinated or unvaccinated—who tests positive for COVID-19 or has been in close contact with someone who has COVID-19, within at least the past 10 days of a positive COVID-19 test or close contact.  We will therefore ask some questions to screen research participants and study staff to see if they have tested positive for COVID-19 or been exposed to someone with COVID-19 within at least 10 days after testing positive or close contact. If you think that at any time before or while taking part in this study you tested positive for COVID-19 or were in close contact with someone with COVID-19, or if you do not want to tell us if you have tested positive or were in close contact, within at least 10 days after testing positive or close contact, then you may not take part in this study. Letting us know about your positive test or close contact is your choice. Study staff may or may not include licensed medical doctors and may not be able to give you any medical advice on your own risk for COVID-19, so please talk to your own doctor if you have questions. Information about COVID-19 can be found at this web site: <https://www.cdc.gov/coronavirus/2019-ncov/your-health/index.html>.  **Second**, we will try to make sure when possible that everyone stays a safe distance (6 feet) from one another. This is called “social distancing.” We will let you know if for some activities study staff may need to be closer to you, but staff will only be closer if absolutely necessary. We will take all the steps needed to protect you.  **Third**, use of masks are strongly recommended. We will let you know whether for some activities you should wear a mask. In those cases, if you don’t want to use a mask then we may take other precautions to protect you and others. If needed we will provide masks to you.  **Fourth**, we make sure to clean anything that will be touched by you or anyone else, and we will throw away disposable items like masks and gloves. At certain times we may ask you to wash or sterilize your hands, and we will do the same. We will provide you with hand wash and sanitizer.  **Fifth**, we may limit the number of people and time in any face-to-face activity to only the minimum amount required.  If at any time you don’t feel safe with the steps that we will take to protect you and others from exposure to COVID-19, please let us know and we will stop. We want to be sure to answer your questions and to take any other steps that you feel we should take to protect you while you are taking part in this activity.” | |