INFORMATION AND INSTRUCTIONS:

Due to the Coronavirus Disease 2019 (COVID-19) national emergency and pandemic, research activities are subject to additional FSU requirements in order to protect human research participants (participants), particularly in research activities involving in-person or face-to-face activities. In accordance with FSU research policy, human research activities may effective April 26, 2021 and until further notice be conducted under the following conditions:

1. **Remote activities to the extent feasible.** Study activities (e.g., recruitment, consenting, pre- or eligibility screening, enrollment, baseline, initial and/ or follow-up) involving human subjects that feasibly can be done remotely should be done that way.
2. **COVID-19 screening.** Conduct COVID-19 screening before undertaking any in-person activities. For screening tools, consider adapting questions from or using the following COVID-19 screening links: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html# (CDC: see the Self-checker tool) or https://covid19.apple.com/screening (Apple/CDC COVID-19 Screening Tool).
    a. No in-person activity may involve any individual (human subject or study staff) with or who has had COVID-19, or who has been in close contact with someone who has COVID-19, unless the human subject or study staff has completed, at least 14 days before any in-person human research activity, a full FDA authorized or approved COVID-19 vaccination series, or alternatively has completed the CDC-recommended isolation and/or quarantine period. For FDA or CDC COVID-19 information, refer to the OHSP COVID-19 and Human Research Studies web page, also available here: https://www.research.fsu.edu/research-offices/ohsp/covid-19-and-human-research-studies/.
3. **COVID-19 vaccination.** Individuals may take part in an in-person study activity involving human subjects in which activity ALL human subjects and study staff have completed a full FDA authorized or approved COVID-19 vaccination series at least 14 before any in-person human research activity. *Otherwise, COVID-19 precautions are required* (see item 4 below).
    a. A list of FDA authorized or approved COVID-19 vaccinations is available at this FDA COVID-19 Vaccines web page or here: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.
    b. Authoritative COVID-19 vaccination completion must be documented in the study record for each such person (see this CDC web page, under the Vaccination Schedule and Use FAQs: https://www.cdc.gov/vaccines/covid-19/hcp/faq.html#schedule).
    c. COVID-19 vaccination must be listed as a study protocol inclusion criterion.
4. **COVID-19 precautions required.** Social distancing, use of masks and other COVID-19-related precautions are required for any in-person study activity involving human subjects in which activity a human subject or study staff has NOT completed a full FDA authorized or approved COVID-19 vaccination series at least 14 days before any in-person human research activity.
    a. Refer to and adopt the 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.
    b. If social distancing is manifestly not practicable for a specific study intervention (e.g., affixing, applying or fitting human subjects with certain study devices or equipment; direct collection of human subjects' biospecimens; other close proximity—within 6 feet—required to administer or execute a study intervention), then Office of the Vice President for Research (OVPR) review and approval for an exception to social distancing is required. OVPR consideration of an exception will only take place after IRB approval.
    c. No exception for social distancing will be considered for in-person study activities that involve unvaccinated human subjects who are aged 65 years or older, or unvaccinated human subjects of any age with certain underlying health conditions are still considered at higher risk for severe illness

from COVID. These individuals are considered by CDC at higher risk for severe illness from COVID (i.e., resulting in hospitalization, intensive care, need for ventilator or death) (see this CDC web page for a list higher risk health conditions: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html).

d. In any study submission, a detailed description of and rationale for specific study interventions for which social distancing is not practicable must be provided for both IRB and OVPR review. See template language below for implementing this requirement.

5. **Current and previously IRB-approved studies.** For current studies for which resumption of in-person activities with human subjects is planned, a study modification must be submitted in RAMP IRB; the modification must describe how the above conditions are or will be satisfied.
6. **New studies.** New studies must describe how the above conditions are or will be satisfied.
7. **IRB review.** COVID-19 vaccination as a study inclusion criterion and COVID-19 vaccination or COVID-19 precautions will be included among the requirements for satisfying one or more criteria for IRB approval of in-person study activities involving human subjects.
8. **Templates.** Study and consent procedures must adopt, as applicable, the templates in the tables below. Study protocols should, as applicable, describe in the consent sections of the protocol the consent procedures below; the protocol and consent must be consistent. All studies require submission to the FSU IRB through FSU's RAMP IRB module (also at this link: https://myramp.research.fsu.edu/). Modifications to on-going studies also require submission to the IRB before implementation. The usual IRB requirements apply.
9. If your study involves only an in-person or face-to-face *interaction*, refer to Section I of the table below. If your study also or only involves an *intervention*, refer to Section II of the table below. Note that many of the templates are duplicated between the sections.
10. **Failure to use or adapt the applicable templates below will result in your study or modification being returned to you for revisions.**

I. Interactions

As applicable, use one or more of the below templates and related instructions regarding research activities that involve in-person interactions (e.g., interviews, focus groups, surveys or similar interpersonal contacts with participants). 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.

Describing Research Interactions		
1.	Remote interactions	In consent materials, provide a statement to the effect: "We invite you to [insert, e.g., complete a survey, take part in a focus group, or take part in an interview] through a web-based or online program called [insert, e.g., Qualtrics, FSU Zoom; if more than one activity and/or platform is involved, name the platform for each activity]. To protect your privacy as much as possible when you take part, we ask that you find a place where no one else can see or hear when we talk. Later on, we may ask if you would be willing to [insert, e.g., complete the survey, take part in the focus group, or take part in the interview] in person or face-to-face instead. Doing this in-person will mean [insert, e.g., that you come to our office, meet us at (insert location)]." Note: Add to or substitute "through a web-based or online program [insert, e.g., Qualtrics, FSU Zoom]" with "by telephone", "by email" or similar language if applicable.
2.	In-person or face-to-face interactions	In consent materials, provide a statement to the effect: "We invite you to [insert, e.g., complete a survey, take part in a focus group, or take part in an interview] in person or face-to-face. Doing this in-person will mean [insert, e.g., that you come to our office, meet us at (insert location)]." If it becomes necessary, we may ask if you would be willing to [insert, e.g., complete the survey, take part in the focus group, or take part in the interview] through a web-based or online program called [insert, e.g., Qualtrics, FSU Zoom; if more than one activity and/or platform is involved, name the platform for each activity]. If we do this, we will ask that you find a place where no one else can see or hear when we talk so that your privacy is protected as much as possible. Note: Add to or substitute "through a web-based or online program called [insert, e.g., Qualtrics, FSU Zoom]" with "by telephone", "by email" or similar language if applicable.
Describing Risks of Harms and Discomforts of Research Activities		
3.	Risks of harms or discomforts of remote interactions	In consent materials, provide a statement to the effect: "In addition to the other possible harms or discomforts related to research that we told you about, there may be risks with using web-based or online programs. First, someone may try to interfere or tamper with our collection of information from you.

		Second, after we collect information from you, someone may see or take information about you without permission. [insert the following if you will be photographing or video- or audio recording subjects' actions, activities, verbal communications or facial images in addition to or as an alternative to other data collection: "Third, by us [taking pictures of you, videotaping you, recording your voice, or seeing your face], someone outside of the study team may recognize you and know what you said or what you did as part of this study."] If any of these things happen, your privacy and the confidentiality of the information that you provide to us may be violated."
4.	Providing participants with information about steps that the study team is taking to protect against COVID-19-related exposure	Develop a COVID-19 Information Sheet (separate from consent materials; go here 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: "In addition to other steps that we will tell you later about how we are taking steps to protect you from possible harms or discomforts that may result from taking part in our study, we will also take other steps to reduce your exposure to Coronavirus. First, no person may be involved in this study unless they have received a full FDA authorized or approved COVID-19 vaccination series at least 14 days before any in-person human research activity or follow all of our COVID-19 precautions. Also, no person may be involved in this study if they have or has had COVID-19, or who has been in close contact with someone who has COVID-19, unless the human subject or study staff has completed, at least 14 days before any in-person human research activity, a full FDA authorized or approved COVID-19 vaccination series, or alternatively has completed the CDC-recommended isolation and/or quarantine period. We will therefore by asking some questions screen all research participants and study staff to check for COVID-19 vaccination, as well as to see who may be at risk of severe illness or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may been exposed to Coronavirus, then we will ask you not to take part in this study, so please let us know. 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 Coronavirus disease. Please talk to your doctor if you have questions about your own risk for Coronavirus disease.

		Information about persons who are at higher risk of severe illness can be found at the U.S. Centers for Disease Control and Prevention web site at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html. Second, if COVID-19 precautions are required, we will take the following additional steps: we will make sure that at all times everyone stays a safe distance from one another. This is usually called "social distancing." Third, we follow the rules about use of personal protective equipment, such as use of masks, gloves and other equipment. We will provide these masks, gloves and other equipment to you. You must wear these in order to take part in this part of the study. Sometimes study staff may need to be closer to you, but only if absolutely necessary for this study, and we will take all the steps needed to protect you. Fourth, we make sure to clean and sterilize anything that will be touched by you, study staff or anyone else, and we will throw away disposable items like masks and gloves. At certain times we will have you wash and sterilize your hands, and we will do the same. We will provide you with hand wash and hand sanitizer. Fifth, we will limit the number of people in any face-to-face activity, and we will also limit the amount of time that anyone has a face-to-face activity. Only the minimum amount of people and time will be used in this study. If at any time you don't feel safe with the steps that we will take to protect you from exposure to Coronavirus, 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."
5.	Describing risks of harms or discomforts of in-person or face-to-face interactions	ONLY IF YOU DO NOT PROVIDE PROSPECTIVE SUBJECTS WITH THE COVID-19 INFORMATION SHEET ABOVE, then in consent materials provide a statement to the effect: "In addition to other possible harms or discomforts related to research that we told you about, there may be risks by having you take part in our face-to-face study activities during this time of the Coronavirus emergency. First, face-to-face activities and contact with other persons may increase the risk of getting Coronavirus. Experts think that COVID-19 spreads mainly

		through close contact from person to person, including between people who are physically near each other (within about 6 feet). People who are infected but do not show symptoms can also spread the virus to others. Cases of reinfection with COVID-19 have been reported but are rare. We are still learning about how the virus spreads and the severity of illness it causes. Second, getting Coronavirus may result in a person being isolated or quarantined at home and away from work, family and other activities. Third, Coronavirus is, a serious illness that may require medical care including hospital care, long-term disability, and even death. Fourth, certain persons are at higher risk for severe illness from Coronavirus. Persons thought to be at higher risk include: • Being of older age • Prior or current exposure to persons that have Coronavirus whether or not they know it • Persons of any age with serious medical conditions such as Type 2 diabetes, serious heart conditions, Sickle cell disease, obesity (body mass index of 30 or more), chronic kidney disease, COPD, and cancer • Persons who have poor immunity, such as persons under cancer treatment or who have other conditions with weakened immune systems • People who reside in nursing homes or other long-term care facilities Persons who are at higher risk of severe illness from Coronavirus and who are not vaccinated against COVID-19 may not take part in our study. We will therefore by asking some questions screen all research participants and study staff to see who may be at risk of severe illness, or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may been exposed to Coronavirus or are at risk of severe illness, then we will ask you not to take part in this study, so please let us know. While we will take steps to protect you from exposure to Coronavirus when you take part in our face-to-face activities, there is always the chance that you may still be exposed. Also, 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 Coronavirus disease. Please talk to your doctor if you have questions about your own risk for Coronavirus disease.

		Finally, in order to reduce exposure to Coronavirus we will ask you to [insert, e.g., stay at least six feet away from anyone else, including us, during our activities; wear a special mask to cover your mouth and nose; wear gloves to cover your hands; wear other equipment to cover your head and body; sit behind a wall or in another room nearby; wash and sanitize your hands; not to touch your face or anything else during our study activities unless we say it is OK; etc.]. These steps are required. Having to do these things may not be comfortable for you and may cause you to be worried or stressed. In addition to the risks of these Coronavirus-related harms or discomforts, this research may have risks of other Coronavirus-related harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you."
Steps to Protect Study Subjects		
6.	Describing steps to protect study subjects' privacy and confidentiality for remote interactions	In consent materials, provide a statement to the effect: "In addition to the steps we are taking to protect your privacy and confidentiality overall, we will also take other steps to keep people from tampering with our web-based or online activities or taking information without your permission. [Insert the following if not already included in the consent form as specific to remote alternatives: First, we only use web-based and online programs that follow the laws and best standards for protecting against tampering or unauthorized access. Second, we limit who may have access to our [insert the web-based or online activity as applicable, e.g., survey, focus group, or interview] to only persons like you who are invited to take part and to members of my study team. Once the [survey, focus group, interview] is closed to taking part, no one else besides the study team has access. Third, all the information that you provide and which is collected and stored is encrypted, meaning that no one outside of the study team or an authorized person can see or read the information that you provide to us. Fourth, special passwords are required for any member of the study team to see or read the information that you provide. Fifth, we do not ask for your name or any other direct identifier such as a Social Security Number when you reply to a study question. If we do collect your name we do so only to make sure that you get credit for taking part in our study, and your name is kept separate rom your answers. We also make sure that if you accidentally provide us with your name or other direct identifier, that we remove that information from our files. Sixth, we will blur your face in any [pictures, videotape] of you that we take as part of this study. Seventh, after [insert years] all identifying

		information is destroyed. Add other steps to protect subjects' privacy and confidentiality for remote alternatives as may be applicable.] Despite taking all these steps to protect your privacy or the confidentiality of your identifiable information, we are not able to guarantee that people will be unable to tamper with our web-based or online activities or take information without your permission."
Describe how consent will be documented (acknowledged, signed and dated by research participants). All consent must be obtained from participants before they may be involved in any study activity, and such consent documented unless waived by the IRB. The template language below is intended to cover the unique circumstances implicated by the COVID-19 national emergency and pandemic, including having participants take part in face-to-face or in-person activities and obtaining consent through alternative means; modify the template to suit your study situation. Consent information may be provided to prospective participants in advance for their review in advance of obtaining and documenting consent. All other required consent requirements still apply. For further information about consent requirements, refer to consent-related templates as well as the consent-related checklists and worksheets (HRP-314, -317, 410 and 411) used by the IRB and available in FSU's RAMP IRB (or https://myramp.research.fsu.edu/). Most templates may also be located here or at this web page: https://www.research.fsu.edu/research-offices/ohsp/investigator-resources/templates-and-required-forms/.		
7.	Obtaining consent IN PERSON	If consent will be obtained in person, provide a statement to the effect: [Please read this consent information carefully. We provide information about the study that you should think about before deciding whether to take part. We include special information about steps that we will take to prevent your exposure to Coronavirus when you take part in our face-to-face study activities. [Include the following statement if remote activities are included in the study: we will also describe possible risks of harms or discomforts with using web-based or online programs]. If you have any questions about the study and the steps that we will take to protect you, please feel free to contact us at the telephone number or FSU email address provided in this form. Your questions will be answered in confidence. Also, we will answer any questions that you may have after you arrive at our study location. Before you take part in any study activity, we will go over the consent information, and provide you with time to decide whether to take part in our study and to ask us any questions. If you agree to take part, we will then ask you to sign and date this form. We will also sign and date the form. We will keep the original for our records, and provide you with a copy.].

8.	Obtaining consent USING EMAIL OR MAIL	If consent will be obtained by email or mail, provide a statement to the effect: [Please read this consent information carefully. We provide information about the study that you should think about before deciding whether to take part. We include special information about steps that we will take to prevent your exposure to Coronavirus when you take part in our face-to-face study activities. [Include the following statement if remote activities are included in the study: we will also describe possible risks of harms or discomforts with using web-based or online programs]. If you have any questions about the study and the steps that we will take to protect you, please feel free to contact us at the telephone number or email address provided in this form. Your questions will be answered in confidence. Once you let us know that you are interested in taking part in the study, we will then or at a later time go over with you the consent information by telephone or some other means, and provide you with time to decide whether to take part in our study and to ask us any other questions. If you agree to take part, we will then ask you to sign and date this form, then return a copy of the signed and dated form to us. You may send the copy of the signed and dated form to us by attaching a copy to an email addressed to us, using [insert FSU email address]. You may also send a copy of the signed and dated form to us by mailing the copy to us at [insert FSU mailing address]. We will also sign and date the form, keep the original for our records, and provide you with a copy. If convenient for you, we can also go over the consent information again after you arrive at our study location, answer any additional questions that you may have, and you can instead sign and date the form at that time. We will also sign and date the form, keep the original for our records, and provide you with a copy.].
9.	Obtaining consent ELECTRONICALLY/DIGITALLY	If consent will be obtained by electronically (other than by email or mail), provide a statement to the effect: [Please read this consent information carefully. We provide information about the study that you should think about before deciding whether to take part. We include special information about steps that we will take to prevent your exposure to Coronavirus when you take part in our face-to-face study activities. [Include the following statement if remote activities are included in the study: we will also describe possible risks of harms or discomforts with using web-based or online programs]. If you have any questions about the study and the steps that we will take to protect you, please feel free to contact us at the

		telephone number or email address provided in this form. Your questions will be answered in confidence. Once you let us know that you are interested in taking part in the study, we will then or at a later time go over with you the consent information by telephone or some other means, and provide you with time to decide whether to take part in our study and to ask us any other questions. If you agree to take part, we will then ask you to electronically or digitally sign and date this form by [insert method of signing and dating]. Be sure to save a copy of the your signed and dated form. We will automatically receive a copy of your signed form for our own records. If you would like, we can also go over the consent information again after you arrive at our study location, answer any additional questions that you may have, and you can instead sign and date the form at that time. We will also sign and date the form, keep the original for our records, and provide you with a copy.].
10.	Obtaining consent BY TELEPHONE	If consent will be obtained by telephone, provide a statement to the effect: [I will provide you with important information about the study that you should think about before deciding whether to take part. Included is special information about steps that we will take to prevent your exposure to Coronavirus when you take part in our face-to-face study activities. [Include the following statement if remote activities are included in the study: I will also describe possible risks of harms or discomforts with using web-based or online programs]. If you have any questions about the study and the steps that we will take to protect you, please ask or feel free to later contact us at [provide telephone number or FSU email address or at the telephone number of FSU email address that was provided to you earlier]. Your questions will be answered in confidence. Also, we will answer any questions that you may have after you arrive at our study location. If you agree to take part, we will then write down that you agreed by this telephone conversation to take part in our study. We will save a copy of this documentation for our own records. If you would like, we can also go over the consent information again after you arrive at our study location, and provide you with a copy.].

II. Interventions

As applicable, use one or more of the below templates and related instructions regarding research activities that involve in-person interventions (see examples under footnote 1). 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.

Describing Research Interventions

1.	Remote interventions	In consent materials, provide a statement to the effect: "We would like to [do and/or replace] some of our study activities by doing some of these activities [over the telephone, by email, through a web-based or online program called [insert, e.g., Qualtrics, FSU Zoom; if more than method or platform involved, name each method or platform for each activity]. Study activities that we would like to do [over the telephone, by email or through a web-based or online program] include [use the list below as a guide, but be as thorough, descriptive and specific as possible]: • Asking you some questions to see if [you, your child] are eligible to take part in our study. To do this we will use [insert method or platform]. • Obtaining your consent [and agreement or assent of your child] to take part in our study. To do this we will use [insert method or platform]. More about how we will obtain your consent [and agreement or assent of your child] is described below. • Recording your answers to [survey, interview, focus group, test, assessment] questions. To do this we will use [insert method or platform]. • Having you complete a [diary, log] about [your activities, your thoughts, your day, your sleep]. To do this we will use [insert method or platform]. • Using home devices and wearable sensors to collect or store information about you, such as [body measurements, physical activities, movement, blood pressure, body temperature, heart rate]. To do this we will use [insert method or platform]. • [Insert other activities to be done over the telephone, by email or through a web-based or online program]. To protect your privacy as much as possible, we ask that [insert as applicable: when you talk to us or when we record you that you find a place where no one else can see or hear; you leave any diary or log in a safe place and out of reach of others; you put any home device or wearable sensor in a safe place and out of reach of others when not in use]. Later on, we may ask if you would be willing to complete some of our study activities in

		person or face-to-face instead. Doing this in-person will mean [insert, e.g., that you come to our office, meet us at (insert location)]." Note: For activities that will use the same method or platform and to avoid repetition, introduce a combined list of these activities with a statement to the effect: "We will use [the telephone, email, an online, web-based program called [e.g., Qualtrics, FSU Zoom] to conduct [list the activities]."
2.	In-person or face-to-face interventions	We would like to [do and/or replace] some of our study activities by doing these in-person or face-to-face. Doing this will mean [insert, e.g., that you come to our office or laboratory, meet us at (insert location)]." Study activities that we would like to do in person include [use the list below as a guide, but be as thorough, descriptive and specific as possible]: • Asking you some questions to see if [you, your child] are eligible to take part in our study. • Obtaining your consent [and agreement or assent of your child] to take part in our study. More about how we will obtain your consent [and agreement or assent of your child] is described below. • Collecting a [e.g., blood, sputum, tissue, bone] sample or specimen from you by [describe method or means, volume and frequency]. • Provide you with a [e.g., log, diary], go over some instructions and show you how to fill it out. • Taking a [describe test or assessment] to find out [describe purpose, outcome and/or result]. • Completing [describe task or exercise] to find out [describe purpose, outcome and/or result]. • Recording your answers to our [e.g., test, exam, assessment] questions. • [Insert a specific description of all other activities to be done in-person or face-to-face]. If it later becomes necessary, we may ask if you would be willing to do some of these activities [over the telephone, by email, through a web-based or online program called [insert, e.g., Qualtrics, FSU Zoom; if more than method or platform involved, name each method or platform for each activity]. If that happens we will provide more information at a later time."
Describing Risks of Harms and Discomforts of Research Activities		

3.	Describing risks of harms or discomforts of remote interventions	In consent materials, provide a statement to the effect: "In addition to the other possible harms or discomforts related to research that we told you about, there may be risks with using web-based or online programs. First, someone may try to interfere or tamper with our collection of information from you. Second, after we collect information from you, someone may see or take information about you without permission. [insert the following if you will be photographing or video- or audio recording subjects' actions, activities, verbal communications or facial images in addition to or as an alternative to other data collection: "Third, by us [taking pictures of you, videotaping you, recording your voice, or seeing your face], someone outside of the study team may recognize you and know what you said or what you did as part of this study."] If any of these things happen, your privacy and the confidentiality of the information that you provide to us may be violated."
4.	Providing information about steps that the study team is taking to protect against COVID-19-related exposure	Develop a COVID-19 Information Sheet (separate from consent materials; go here 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: "In addition to other steps that we will tell you later about how we are taking steps to protect you from possible harms or discomforts that may result from taking part in our study, we will also take other steps to reduce your exposure to Coronavirus. First, no person may be involved in this study unless they have received a full FDA authorized or approved COVID-19 vaccination series at least 14 days before any in-person human research activity or follow all of our COVID-19 precautions. Also, no person may be involved in this study if they have or has had COVID-19, or who has been in close contact with someone who has COVID-19, unless the human subject or study staff has completed, at least 14 days before any in-person human research activity, a full FDA authorized or approved COVID-19 vaccination series, or alternatively has completed the CDC-recommended isolation and/or quarantine period. We will therefore by asking some questions screen all research participants and study staff to check for COVID-19 vaccination, as well as to see who may be at risk of severe illness or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may been exposed to Coronavirus, then we will ask

		you not to take part in this study, so please let us know. 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 Coronavirus disease. Please talk to your doctor if you have questions about your own risk for Coronavirus disease. Information about persons who are at higher risk of severe illness can be found at the U.S. Centers for Disease Control and Prevention web site at https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html. Second, if COVID-19 precautions are required, we will take the following additional steps: we will make sure that at all times everyone stays a safe distance from one another. This is usually called "social distancing." Third, we follow the rules about use of personal protective equipment, such as use of masks, gloves and other equipment. We will provide these masks, gloves and other equipment to you. You must wear these in order to take part in this part of the study. Sometimes study staff may need to be closer to you, but only if absolutely necessary for this study, and we will take all the steps needed to protect you. Fourth, we make sure to clean and sterilize anything that will be touched by you, study staff or anyone else, and we will throw away disposable items like masks and gloves. At certain times we will have you wash and sterilize your hands, and we will do the same. We will provide you with hand wash and hand sanitizer. Fifth, we will limit the number of people in any face-to-face activity, and we will also limit the amount of time that anyone has a face-to-face activity. Only the minimum amount of people and time will be used in this study. If at any time you don't feel safe with the steps that we will take to protect you from exposure to Coronavirus, 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."
5.	Describing risks of harms or discomforts of in-person interactions	ONLY IF YOU DO NOT PROVIDE PROSPECTIVE SUBJECTS WITH THE COVID-19 INFORMATION SHEET ABOVE, then in consent materials provide a statement to the effect:

		"In addition to other possible harms or discomforts related to research that we told you about, there may be risks by having you take part in our face-to-face study activities during this time of the Coronavirus emergency. First, face-to-face activities and contact with other persons may increase the risk of getting Coronavirus. Experts think that COVID-19 spreads mainly through close contact from person to person, including between people who are physically near each other (within about 6 feet). People who are infected but do not show symptoms can also spread the virus to others. Cases of reinfection with COVID-19 have been reported but are rare. We are still learning about how the virus spreads and the severity of illness it causes. Second, getting Coronavirus may result in a person being isolated or quarantined at home and away from work, family and other activities. Third, Coronavirus is, a serious illness that may require medical care including hospital care, long-term disability, and even death. Fourth, certain persons are at higher risk for severe illness from Coronavirus. Persons thought to be at higher risk include: • Being of older age • Prior or current exposure to persons that have Coronavirus whether or not they know it • Persons of any age with serious medical conditions such as Type 2 diabetes, serious heart conditions, Sickle cell disease, obesity (body mass index of 30 or more), chronic kidney disease, COPD, and cancer • Persons who have poor immunity, such as persons under cancer treatment or who have other conditions with weakened immune systems • People who reside in nursing homes or other long-term care facilities Persons who are at higher risk of severe illness from Coronavirus and who are not vaccinated against COVID-19 may not take part in our study. We will therefore by asking some questions screen all research participants and study staff to see who may be at risk of severe illness, or who have been exposed to Coronavirus. Even after we ask these questions, if you think that at any time before or during this study you may been exposed to Coronavirus or are at risk of severe illness, then we will ask you not to take part in this study, so please let us know. While we will take steps to protect you from exposure to Coronavirus when you take part in our face-to-face activities, there is always the chance that you may still be exposed. Also, 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 Coronavirus disease. Please talk to your doctor if you have questions about your own risk for Coronavirus disease. Finally, in order to reduce exposure to Coronavirus we will ask you to [insert, e.g., stay at least six feet away from anyone else, including us, during our activities; wear a special mask to cover your mouth and nose; wear gloves to cover your hands; wear other equipment to cover your head and body; sit behind a wall or in another room nearby; wash and sanitize your hands; not to touch your face or anything else during our study activities unless we say it is OK; etc.]. These steps are required. Having to do these things may not be comfortable for you and may cause you to be worried or stressed. In addition to the risks of these Coronavirus-related harms or discomforts, this research may have risks of other Coronavirus-related harms or discomforts that are unknown at this time. If in the future we become aware of any additional harms or discomforts that may affect you, we will tell you."
6.	Describing steps to protect study subjects' privacy and confidentiality for remote interactions	In consent materials, provide a statement to the effect: "In addition to the steps we are taking to protect your privacy and confidentiality overall, we will also take other steps to keep people from tampering with our web-based or online activities or taking information without your permission. [Insert the following if not already included in the consent form as specific to remote alternatives: First, we only use web-based and online programs that follow the laws and best standards for protecting against tampering or unauthorized access. Second, we limit who may have access to our [insert the web-based or online activity as applicable] to only persons like you who are invited to take part and to members of my study team. Once the [insert the web-based or online activity as applicable] is closed to taking part, no one else besides the study team has access. Third, all the information that you provide and which is collected and stored is encrypted, meaning that no one outside of the study team or an authorized person can see or read the information that you provide to us. Fourth, special passwords are required for any member of the study team to see or read the information that you provide.

		Fifth, we do not ask for your name or any other direct identifier such as a Social Security Number when you reply to a study question. If we do collect your name we do so only to make sure that you get credit for taking part in our study, and your name is kept separate rom your answers. We also make sure that if you accidentally provide us with your name or other direct identifier, that we remove that information from our files. Sixth, we will blur your face in any [pictures, videotape] of you that we take as part of this study. Seventh, after [insert years] all identifying information is destroyed. Add other steps to protect subjects' privacy and confidentiality for remote alternatives as may be applicable.] Despite taking all these steps to protect your privacy or the confidentiality of your identifiable information, we are not able to guarantee that people will be unable to tamper with our web-based or online activities or take information without your permission."
Describe how consent will be documented (acknowledged, signed and dated by research participants)		
7.	See above Section I, items 7-10, for documenting consent in person, using email/mail, electronically/digitally or by telephone. As needed, revise any template language referring to obtaining consent in-person.	