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| COVID-19 Contingency Protocol **This protocol is intended to cover only temporary changes to an approved study’s  protocol/smartform during the COVID-19 pandemic.** |
| **Instructions:**   * This form should be filled out and completed by the VCU Principal Investigator, or by the study team in communication with the Principal Investigator. * This protocol is only for temporary changes to an approved study’s protocol/smartform during the COVID-19 pandemic. * If permanent changes are desired, those changes should be made directly in the smartform and other approved documents. * **This form must be submitted to the IRB for review and approval prior to implementation, with the exception of changes made to avoid apparent immediate hazard to a study participant.**    + Changes implemented to avoid immediate hazard to a participant may be implemented without prior IRB approval but must be reported to the IRB using the RAMS-IRB reporting function within 30 days as required by [WPP VIII-5 section 2.7](https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/VCUIRBWrittenPoliciesandProceduresv9-28-2020.pdf#page=103) (see also 45 CFR 46.108(a)(3) and 21 CFR 56.108(a)(4)). * When submitting this COVID-19 Contingency Protocol, changes are not required within the RAMS-IRB smartform. Simply upload this protocol and any other revised documents.   + The completed COVID-19 Contingency Protocol should be uploaded as a new document in an amendment in RAMS-IRB ([https//:www.irb.research.vcu.edu](file:///C:\Users\christinawright\Downloads\https\:www.irb.research.vcu.edu); click the “Create New Amendment” button).   + For ease of reference, please name the document in RAMS as “COVID-19 Contingency Protocol HM########”   + In the amendment, you are strongly encouraged to NOT make other changes. If other changes are made and if edits to those changes are needed, it may slow down the review and approval of this COVID-19 Contingency Protocol’s time-sensitive changes.   + If your study has not already converted to the updated smartform, you will be required to convert at this time. * When the COVID-19 pandemic resolves, notify the IRB by logging a public comment in RAMS-IRB when you are returning to previously approved research procedures and retiring the COVID-19 Contingency documents. |
| **VCU IRB #:**HM  **VCU Principal Investigator:** |
| 1. \* **Does this study have any non-VCU sites that are relying on VCU IRB for review?** *Relying sites (if any) are**listed on the Types of Sites smartform page.*   **No – go to question 2**  **Yes – answer next questions**  **1A*. If yes,* which sites does this COVID-19 Contingency Protocol apply to?**  **All sites that are relying on VCU IRB will follow this Protocol.**  **\* Does each PI of a relying site agree to follow all applicable local institutional policies (i.e. telework, procurement, information security policies) in place of the VCU-specific policies that are referenced in this document throughout the period this contingency protocol is in effect?**  Yes – all local PIs have confirmed agreement  **OR**  **Only certain sites that are relying on VCU IRB will follow this Protocol.**   1. **List the relying sites that will follow VCU’s COVID-19 Contingency Protocol:**   **\* Does each PI of a relying site agree to follow all applicable local institutional policies (i.e. telework, procurement, information security policies) in place of the VCU-specific policies that are referenced in this document throughout the period this contingency protocol is in effect?**  Yes – the PIs of the sites listed above have confirmed agreement   1. **List the relying sites that are submitting a separate contingency protocol for review:**   *Upload the separate, local contingency protocol(s) that are being submitted by the sites listed above when submitting the amendment for this Protocol. Name those plans in RAMS-IRB as “COVID-19 Contingency Protocol HM######## Site Name”* |
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| 1. \* **Describe all modifications that will or might be made in order to carry out the research procedures (i.e. who, when, where, how of new/altered procedures, list paused procedures/methods. Give yourself options.)**.  * *New off-campus locations need to be specified if they will be used, such as new lab collection sites, community meeting locations, home visits, etc.* * *Response must be study-specific and in sufficient detail that someone could replicate your methods.* * *Do not specify changes to routine clinical care or activities that occur outside of the research study.* |
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| 1. \* **Describe all modifications that will or might be made to recruitment procedures: (i.e. who, when, where, how, limiting enrollment of certain population(s))** |
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| 1. \* **Describe whether and how you will communicate the changes made in this contingency protocol to active participants and confirm that they agree to continue participating in the study:** |
| 1. \* **Describe all modifications that will or might be made to the method/process of obtaining consent for new participants (i.e. who, when, where, how the initial consent discussion occurs):** |
| **5A.**\* **Does your currently approved study involve participants signing consent/assent documents?**  **N/A** – my study is approved as an exempt study and when applicable, participants will indicate agreement in another way instead of physically signing  **N/A** – my study is no longer enrolling/consenting participants (accrual completed)  **N/A** – my study is going to hold on accrual of new participants until this COVID-19 period is over  **No** – my study already has an approved waiver of documentation of consent (signature) for the population we will continue to enroll  **No**  – my study already has an approved waiver of all consent/assent for the subjects we will continue to enroll/collect data on (e.g. chart review studies)  **Yes** – my study is a greater than minimal risk study and gets signed consent/assent *(most full board studies)*  **How will you obtain the consent/assent signature following the consent discussion?** *For remote consent signature options, see this* [*comparison chart*](https://research.vcu.edu/human_research/RemoteConsentComparisonChart.pdf)  Will continue to obtain in-person signed consent/assent as outlined in the approved smartform.  [DocuSign](https://ts.vcu.edu/askit/university-resources/docusign/) – regular or FDA Part 11 DocuSign *(not approved for obtaining child assent)*  FDA’s [COVID MyStudies App](https://www.fda.gov/drugs/science-and-research-drugs/covid-mystudies-application-app?utm_campaign=FDA%20Provides%20Method%20to%20Obtain%20Informed%20Consent%20Electronically%20During%20COVID-19&utm_medium=email&utm_source=Eloqua) *(only for FDA studies with an IND or IDE)*  Children will be asked to give verbal assent instead of signing  Participants will sign with a witness, scan/photograph their signed consent/assent, and email/fax it to the study team *(Note the study should ensure a version date or number is on all pages of the consent form to confirm the correct version was used)*  Participants will mail the physically signed consent/assent form to the study team *(Note: study activities may not begin until the form is received)*  Other – describe here:  **Yes** – my study is a minimal risk study and gets signed consent/assent *(expedited & a few full board studies)*  **Will you continue to obtain signed consent/assent during this COVID-19 period?**  **Yes – after the telephone/video consent discussion, we will obtain the consent/assent signature in one or more of the following ways:**  *For remote consent signature options, see this* [*comparison chart*](https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/RemoteConsentComparisonChart.pdf)  [DocuSign](https://ts.vcu.edu/askit/university-resources/docusign/) – regular or FDA Part 11 DocuSign *(not approved for obtaining child assent)*  Children will be asked to give verbal assent instead of signing  Participants will sign with a witness, scan/photograph their signed consent/assent, and email/fax it to the study team *(Note the study should ensure a version date or number is on all pages of the consent form to confirm the correct version was used)*  Participants will mail the physically signed consent/assent form to the study team *(Note: study activities may not begin until the form is received)*  Other – describe here:  **OR**  **No – we will not require participants to sign the form.**   1. **We will conduct the consent/assent discussion in one or more of the following ways:**   Telephone or videoconference consent/assent discussion  Online consent/assent materials with a way to indicate agreement *(i.e. an “Agree” button on a survey)*  Other verbal consent/assent in-person with subjects – describe here:  **ii.** \* **To justify a waiver of the consent/assent signature (waiver of documentation of consent), explain**  **1) why the study’s activities involve only risks that are comparable to the risks of everyday life, AND**  **2) why the study activities would not otherwise require signed consent if they were performed outside this study** *(e.g. people do not routinely sign consent for blood draws, but they do for surgery)***.**    **5B.**\* **Does your currently approved study involve participants signing HIPAA authorization (either a separate form or combined with the consent form)?**  **N/A** – my study does not involve HIPAA  **N/A** – my study involves HIPAA but is no longer enrolling participants (accrual completed)  **N/A** – my study is going to hold on accrual of new participants until this COVID-19 period is over  **No** – my study already has an approved partial waiver of the authorization signature for the population we will continue to enroll *(Q1 on the Partial Waiver page has the 2nd box checked)*  **No**  – my study has one of the following HIPAA pathways approved for the subjects we will continue to enroll/collect data on: 1) full waiver of authorization, 2) limited data set, or 3) de-identified data *(verify the approved pathways with Q4 on the HIPAA page of the smartform)*  **Yes** – my study obtains signed HIPAA authorization *(applicable to exempt, expedited and full board studies)*  **Will you continue to obtain signed authorization during this COVID-19 period?**  **Yes –we will obtain the authorization signature in one or more of the following ways:**  *For remote consent signature options, see this* [*comparison chart*](https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/RemoteConsentComparisonChart.pdf)  [DocuSign](https://ts.vcu.edu/askit/university-resources/docusign/) – regular or FDA Part 11 DocuSign *(not approved for obtaining child assent)*  Participants will sign with a witness, scan/photograph their signed authorization, and email/fax it to the study team *(Note the study should ensure a version date or number is on all pages of the form to confirm the correct version was used)*  Participants will mail the physically signed form to the study team *(Note: study activities may not begin until the form is received)*  Other – describe here:  **OR**  **No – we will not require participants to sign the form**  **To justify a waiver of the authorization signature (partial waiver of authorization),**   1. **the PI certifies that the following statements are true:** 2. Waiving the signature of authorization would pose no greater than minimal risk to participants’ privacy because appropriate privacy and confidentiality protections for the study data will be maintained. PHI collected in the study will be maintained according to HIPAA standards. 3. No one other than the PI and authorized research personnel on this study will have access to the PHI. 4. The authorization signature cannot practicably be obtained because of the public health guidelines/requirements in effect during this COVID-19 pandemic.   **b) the PI also agrees to the following:**  A) The identifiers used for this research study will not be used for any other purpose or disclosed to any other person or entity (aside from members of the research team identified in this application), except as required by law.  B) If at any time I want to reuse this information for other purposes or disclose the information to other individuals, I will seek approval from the IRB/Privacy Board.  C) I will comply with VCU HIPAA policies and procedures and to the use and disclosure restrictions described above.  D) I assume responsibility for all uses and disclosures of the PHI by members of my study team.  \*I agree to all of the above |
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| 1. \* **Describe all study-specific risk minimization procedures that will or might be used that go above and beyond the** [**baseline health and safety requirements**](https://together.vcu.edu/) **of the University, VCU Health System, Commonwealth of Virginia or off-site location policies** *(e.g. asking new screening questions before in-person interventions, special cleaning protocols, new withdrawal criteria, new stopping criteria, etc.)*: |
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| 1. \* **Check all applicable modifications that will or might be made to reduce the risk of loss of privacy:**   Protections when conducting phone or video conferenced interventions or interactions:  Conducting study interactions in locations that maximize privacy (limited people around, closing doors, monitoring voice volume, etc.)  Leaving generic voicemail messages that limit study identifiers, such as study names, clinics, study topics, etc.  Ensuring participants have a method of directly contacting the study team only (i.e. not lines answered by family members of the study team, using Google Voice)  Asking the participant to move to a location where they will not be overheard or are comfortable answering questions in their location.  Offering other options of ways to complete the interaction (i.e. online) if desired  Other – describe here: \_\_\_\_\_  Protections when conducting internet-based interactions (e.g. online surveys):  Asking the participant to move to a location where they will be comfortable answering questions  Offering a way to save and return to the online material if privacy is compromised  Offering other options of ways to complete the interaction (i.e. by phone) if desired  Other – describe here: \_\_\_\_\_  Protections when mailing documents to/from participants:  Confirming/verifying the accuracy of mailing addresses before sending  Ensuring the participant is able to safely receive mailed documents and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it, return address and document headers limits study identifiers, such as study names, clinics, study topics, etc.)  Minimizing use of participant identifiers on mailed documents (i.e. using study IDs instead of direct identifiers)  Providing a return mailing address label or pre-addressed envelope that you will be able to identify as study-related (i.e. limiting unauthorized access)  Offering other options of ways to complete the interaction (i.e. by phone or online) if desired  Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer  Storing physical documents only in locations that maximize privacy (limited people around, locked drawers/cabinets, etc.)  Other – describe here: \_\_\_\_\_  Protections when analyzing study data in an off-campus location:  Working only in locations that maximize privacy (limited people around, closing doors, closing documents before walking away, etc.)  Other – describe here: \_\_\_\_\_  Other privacy protections not mentioned above – describe below:  \_\_\_\_\_ |
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| 1. \* **The PI confirms that when teleworking, all members of the VCU study team will comply with all applicable University policies about information security.**   I agree |
| 1. \* **Check all applicable modifications that will or might be made to data storage and data transfer procedures to reduce the risk of loss of confidentiality:**   Protections for paper documents  Maintaining control of documents at all times when used at an off-campus location  Storing documents in a secure (preferably locked) location  Limiting access by unauthorized individuals (e.g. outline expectations with family members)  Protections for home computers/devices used to access or use study data  Limiting access by unauthorized individuals who might also use a device (e.g. outline expectations with family members, individual logins, a separate account)  Remotely accessing VCU network storage to store data  Other – describe here: \_\_\_\_\_  Protections for email/online communications  Only using VCU/VCU Health email addresses for study-related communications  Only using VCU/VCU Health–approved methods of teleconferencing or video conferencing (e.g. [Zoom](https://ts.vcu.edu/askit/video-services/video-conferencing-support/zoom-desktop-conferencing/))  Only using HIPAA-compliant systems if conducting telemedicine visits (i.e. [Zoom](https://ts.vcu.edu/askit/video-services/video-conferencing-support/zoom-desktop-conferencing/); contact VCU Information Security about approved systems to use and about recording sessions)  Other – describe here: \_\_\_\_\_  Protections for electronic files/data - *See* [*https://ts.vcu.edu/about-us/information-security/data-management-system/*](https://ts.vcu.edu/about-us/information-security/data-management-system/)  Only using VCU-approved methods of data transfer of files (Dropbox may not be used)  Using VCU-approved data collection tools and apps (i.e. REDCap, Qualtrics)  Remotely accessing VCU network storage to store data  Keeping the study’s code key on the VCU network storage (not local storage)  Other – describe here: \_\_\_\_\_  Other confidentiality protections – describe below:  \_\_\_\_\_ |
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| 1. **\* The PI confirms that compensation procedures will comply with VCU Procurement policies:** <https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/#.UyG8RfldWCk>   I agree |
| 1. **Describe any modifications that will or might be made to the method of compensation (e.g. switch from cash to electronic giftcard):**      * *Payment apps such as Venmo or Paypal are generally not approved by VCU Procurement.* * *Changes to the amount or schedule of compensation must be modified in the smartform (and ICF) and approved by the IRB.* |
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| **Instructions for revising other study documents:**   * Consent/assent documents: It is recommended to submit separate, temporary consent/assent documents that are aligned with this COVID-19 contingency plan instead of replacing the previously approved ones.   + *This will enable the study team to switch back to previously approved versions when this contingency protocol is retired.*   + *If you create modified consent forms for the COVID-19 contingency plan, please upload as a new document and name in RAMS-IRB as “COVID-19 Contingency Consent Form.” For studies with multiple consent forms, include a descriptor at the end of this document name to identify which group the document applies to.* * New measures and/or recruitment materials that will be used under the contingency protocol must be provided to the IRB (i.e. new surveys) as uploaded documents in RAMS-IRB.   + *Please name these documents in RAMS-IRB with “COVID-19” at the beginning of the document name.* |