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| VCU IRB Contingency Protocol **This protocol is intended to cover only temporary changes to an approved study’s  protocol/smartform under emergency or exceptional circumstances** |
| This protocol is only for temporary changes to an approved study’s protocol/smartform during the exceptional or emergency circumstances that will be defined in this document under question #1 (i.e. an adaptive protocol plan for crises, emergencies, and major disruptions to normal study conduct). If permanent changes are desired, those changes should be made directly in the smartform and other approved documents.  **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 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 Contingency Protocol, changes are not required within the RAMS-IRB smartform. Simply upload this protocol and any other revised documents.   + The completed Contingency Protocol should be submitted 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 “Contingency Protocol HM########”   + In the amendment, you are encouraged NOT to make other changes except if prompted to by instructions in this protocol. If other changes are made and if edits to those changes are needed, it may slow down the review and approval of this Contingency Protocol’s time-sensitive changes. |
| **VCU IRB #:**HM  **VCU Principal Investigator:**  **Study Title:**  **Contingency Protocol Title (include the circumstance as an identifier such as adding “COVID contingency” to the title):**  **Version Number and Date:** |
| 1. **\* Do you already have any IRB-approved Contingency Protocols (i.e., COVID-19)?**   **No** – go to question #2  **Yes**  **1a. \* If yes, list the IRB-approved Contingency Protocols with their effective dates (start and end):**   |  |  |  | | --- | --- | --- | | **Contingency Protocol Title** | **Start Date** | **End Date** | |  |  |  | |  |  |  |   **1b. \* Is this a revised version of one of the Contingency Protocols listed above (i.e., an amended version)?**  **No**  **Yes**   * If yes, which Contingency Protocol above is being revised? * If yes, describe the changes being made: |

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| *If amending this protocol, do not delete information; instead add a new paragraph labeled with the date of this revision that describes what is stopping, changing, or starting* |
| SCOPE OF CONTINGENCY PROTOCOL |
| **2.** \* **Describe the specific situation(s) in which you would follow these contingency procedures instead of the regular approved protocol:**    **3.** \* **Describe the anticipated duration (if known) ) in which you would follow these contingency procedures instead of the regular approved protocol:** *Use general, relative time points, not exact dates* |
| 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 5  **Yes** – answer next questions  **4a*. If yes,* which sites does this 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 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 “Contingency Protocol HM######## Site Name”* |
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| STUDY PROCEDURES AND RISKS |
| 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 locations where research procedures will take place need to be specified, such as new lab collection sites, community locations, home visits, etc.* * *New off-campus locations must be added as non-VCU sites on the Types of Sites page of the smartform* * *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.* |
| 1. \* **If study procedures will be stopped or revised for some or all participants, describe how this will impact participants’ safety and wellbeing:** |
| 1. \* **Describe any additional study-specific risk minimization procedures:** *(e.g., asking new screening questions before in-person interventions, new withdrawal criteria, new stopping criteria, etc.)*: |
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| RECRUITMENT PROCEDURES |
| 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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| CONSENT PROCEDURES |
| 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)* |
| 1. \* **Do the consent modifications require a waiver of all consent, some elements of consent, or consent documentation (signatures)?**   **Yes** – update the Consent Process page of the smartform to add a Contingency consent group and to request the appropriate waiver  **No** |
| 1. \* **Do the consent modifications require a waiver of all HIPAA authorization, some elements of authorization, or authorization signatures?**   **Yes** – update the HIPAA page of the smartform to request the appropriate waiver  **No** |
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| PRIVACY AND CONFIDENTIALITY PROTECTIONS |
| 1. \* **Check all applicable modifications that will or might be made to reduce the risk of loss of privacy:**   Protections when conducting remote interventions or interactions:  Conducting study interactions in locations that maximize privacy (limited people around, closing doors, monitoring voice volume, etc.)  Leaving/sending generic voicemail messages that limit study identifiers, such as names, study titles, clinics, study topics, etc.  Obtaining permission prior to sending text messages  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 be comfortable answering questions  Ensuring non-participating individuals are not captured on recordings or in photos  Offering other options of ways to complete the interaction (i.e. online, paper, phone) if desired  Other – describe here: \_\_\_\_\_  Protections when mailing documents to/from participants:  Obtaining permission to mail study materials  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)  Using return address labels and document headers that avoid 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  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.)  Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)  Obtaining explicit parental permission before disseminating or sharing recordings or photos of children  Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing  Only publishing or presenting aggregate results or findings (i.e. no individual-level information)  Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images – describe here: \_\_\_\_\_  Other – describe here: \_\_\_\_\_  Other privacy protections not mentioned above – describe below:  \_\_\_\_\_ |
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| 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  Storing documents in a secure (preferably locked) location  Maintaining control of documents at all times when used at an off-campus location  Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)  Storing paper documents in a secure location accessible only to authorized study personnel  Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy  Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies  Limiting access by unauthorized individuals (e.g. outline expectations with family members, coworkers)  Other – describe here: \_\_\_\_\_  Protections for research specimens  Maintaining control of specimens at all times, including when at an off-campus location  Storing specimens in a secure location accessible only to authorized study personnel  Labeling specimens with subject ID or other coded information instead of direct identifiers  Final destruction of specimens will be devoid of any identifiable information  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 storage, transmission and transfer (Dropbox may not be used)  Remotely accessing VCU network storage to store data when at off-campus locations  Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)  Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu) sing VCU-approved data collection tools and apps (i.e. REDCap, Qualtrics)  De-identifying the research data by replacing subjects’ names with assigned subject IDs  Storing the study’s linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)  Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies  Other – describe here: \_\_\_\_\_  Other confidentiality protections – describe below:  \_\_\_\_\_ |
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| COMPENSATION PROCEDURES |
| 1. **Describe any modifications that will or might be made to the method of compensation (e.g. switch from cash to electronic gift card):**      * *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.* |
| 1. **If compensation modifications are planned, 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/](https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/#.UyG8RfldWCk)   I agree |
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| OTHER CONTINGENCY DOCUMENTS |
| **Instructions for revising other study documents:**   * Consent/assent documents: It is recommended to submit separate, temporary consent/assent documents that are aligned with this 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 contingency plan, upload as a new document and name in RAMS-IRB as “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 communications to participants, measures and/or recruitment materials that will be used under the contingency protocol must be provided to the IRB (i.e., announcements to subjects regarding changes, new surveys) as uploaded documents in RAMS-IRB.   + *Name these documents in RAMS-IRB with “Contingency” at the beginning of the document name.* |