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Page	Question	Response Choices	Help Text
Study Population	Will individuals with limited English proficiency be included in or excluded from this research?	☐ Included ☐ Excluded - safety concerns if participants are unable to communicate with the study team ☐ Excluded - instruments/measures only validated in English ☐ Excluded - no prospect of direct benefit to individual participants ☐ Excluded - minimal risk study ☐ Excluded - lack of budget/resources for translation and interpretation *[provide an explanation in next question]* ☐ Excluded - other reason *[provide an explanation in next question]*	According to federal regulations, the IRB may only approve research where selection of subjects is deemed to be equitable, taking into consideration the purposes of the research and the setting in which the research will be conducted. In order to meet the IRB approval criteria of equitable subject selection, if possible, LEP individuals should not be excluded from research that may have potential benefits. Research that offers the possibility of direct benefit, such as treatment studies that target serious or life-threatening conditions, should make the greatest effort to ensure the research is available equitably, without excluding individuals unnecessarily. When research is greater than minimal risk without the prospect of direct benefit, the exclusion of LEP subjects may be justifiable. Additionally, in some situations, the instruments used in the research cannot be translated to multiple languages or are not validated in other languages, making it impossible to conduct the research in any language other than English.
Study Procedures	Will the investigator obtain information or biospecimens for the purpose of screening, recruiting or determining the eligibility of prospective subjects?	☐ The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative. ☐ The investigator will obtain identifiable private information by accessing records. ☐ The investigator will obtain identifiable biospecimens by accessing stored identifiable biospecimens. ☐ None of the above	
Study Procedures	Is a separate protocol document being uploaded that contains a detailed description of the study's methodology and procedures?	☐ Yes ☐ No	

<u>If a separate protocol document is NOT uploaded</u>, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include: • A statement explaining the study design • A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated • A description of all research measures/tests/interventions that will be used (if applicable) • A detailed description or list of all secondary data elements and/or secondary specimens that will be obtained and how they will be used (if applicable) *See the help text for additional guidance*.	Free Text Response	
<u>If a separate protocol document is uploaded</u>, provide all of the following information: 1. References to the specific protocol sections where the study design and procedures are described 2. A statement explaining the study design 3. A lay language overview of all research procedures 4. A description of whether there are any local changes to the protocol's procedures, and if so, what those changes are (i.e. different, omitted, or additional procedures) 5. Any necessary clarifications of the protocol's content (i.e. what local standard of care or routine practice is)	Free Text Response	

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Study Procedures	Regarding the study procedures described above, differentiate between: - procedures that are performed exclusively for research purposes or involve alterations of routine procedures for research purposes VERSUS - procedures that would take place in the same manner regardless of the research (i.e. standard medical or psychological tests and procedures, routine educational practices, quality improvement initiatives, etc.)	Free Text Response	
Project Details	Select all types of secondary information and/or specimens that apply to this study (selections will branch):	☐ Protected Health Information (PHI) ☐ Secondary data/specimens NOT from a research registry or repository ☐ Accessing information/specimens from a research registry or repository (Usage Protocol) ☐ Analysis of data Information/specimens originally collected for a previous research study ☐ Publicly available information/specimens ☐ Government-generated or collected information that was or will be obtained for non-research activities *[only applicable to research conducted by or on behalf of a Federal department or agency]* ☐ No secondary data/specimens will be used	Protected Health Information (PHI) is identifiable health information maintained by a covered entity (e.g., healthcare provider or insurance company). See HIPAA guidance documents at http://www.research.vcu.edu/human_research/hipaa-guidance.htm to determine if your study involves PHI. "Publicly available information" is identifiable information that is available to members of the general public: a) with no restrictions (e.g. use of archives at a public library) b) upon request (e.g. certain government or institutional records) or c) if the only requirement for obtaining the information is paying a user fee, registering, or signing in as a visitor (e.g. identifiable biospecimens available to anyone for a fee)
Data Confidentiality and Storage	If research data that contains any of the 18 HIPAA identifiers will be released to person(s) or group(s) outside of the VCU study team, identify the data recipient(s) along with their institutional or organizational affiliation(s).	Free Text Response	
Data Retention	Select all of the ways information obtained during screening will be handled for individuals who DO NOT qualify for the study:	☐ Immediately destroy the information ☐ Store until the end of study & then destroy ☐ Use as ""screening failure"" data by members of the study team ☐ Provided to others outside of the research team (with the participant's permission) ☐ Request permission from participant to maintain the information ☐ Other ☐ N/A - study does not require screening procedures	

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Future Sharing Plan	Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting (i.e. future sharing) by the investigators or staff?	☐ Yes ☐ No	
Future Sharing Plan	Will this study intentionally maintain identifiable or de-identified (coded) private information or biospecimens (including DNA) for the purpose of conducting unspecified future research? (selections will branch)	☐ Yes - Contributing to an existing registry or repository ☐ Yes - Creating a new registry or repository at VCU ☐ Yes - Submitting data to an NIH genomic data repository ☐ No - Only maintaining anonymized data/specimens for future research ☐ No - Not maintaining any data/specimens for future research	Registries / Repositories encompass an organized collection of identifiable information (registry) or specimen (repository) intentionally maintained with participant consent for the purpose of conducting future research.
Future Sharing Plan	**After a research study is completed, investigators may be required or asked to share the study's data (e.g. ClinicalTrials.gov reporting, sponsor or publication requirements, etc.), or they may desire to share their research information/specimens with others to advance science (e.g. open science, future research, conferences, educational training, etc.)**		
Future Sharing Plan	Identify all reasonably foreseeable recipient(s) of this study's information or specimens, regardless of identifiability, after the research study has been completed:	☐ Results reporting on ClinicalTrials.gov ☐ Funding agency or sponsor requirements for data sharing (i.e. NIH data sharing policies) ☐ Data sharing as a condition (or option) of manuscript publication ☐ Data sharing as a condition for accessing a specific location or population ☐ Open science website ☐ VCU Scholars Compass ☐ Sharing with other researchers outside of a registry/repository ☐ Use by the PI/study team for a subsequent research study ☐ Presented at conferences ☐ Used for educational training (i.e., training students, classroom presentations) ☐ Other sharing recipient ☐ No sharing anticipated at this time and will submit an amendment when known	
Future Sharing Plan	Describe the nature of the research information and/or specimens that will be shared with each recipient selected above:	Free Text Response	

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<table>
<tr><th>Page</th><th>Question</th><th>Response Choices</th><th>Help Text</th></tr>
<tr><td>Future Sharing Plan</td><td>For each sharing recipient selected above, explain what form the information/specimens will be in when they are shared:
• De-identified form (i.e. coded, pseudonymized)
• Anonymized form
• Aggregate form
• Other form
See help text for definitions</td><td>Free Text Response</td><td>The VCU IRB uses the following terminology regarding the identifiability of data and specimens:
<u>Identifiable Data/Specimens</u>
Identifiers are attached to the research data/specimens
<table><tr><th>Date of Birth</th><th>Last Visit</th><th>Gender</th><th>Diagnosis</th></tr><tr><td>6/30/84</td><td>8/1/18</td><td>Female</td><td>Diabetes</td></tr><tr><td>1/1/65</td><td>8/20/18</td><td>Male</td><td>Flu</td></tr></table>
<u>De-identified Data/Specimens (also called Coded or Pseudonymized)</u>
The identifying information is replaced with a number, letter, symbol, or combination thereof (i.e., the code). Identifiers are not attached to the research data/specimens but rather, are kept in a separate location or file called the linkage code or code key.
<table><tr><th>Age</th><th>Last Visit</th><th>Gender</th><th>Diagnosis</th></tr><tr><td>34</td><td>Wk 1</td><td>Female</td><td>Diabetes</td></tr><tr><td>35</td><td>Wk 2</td><td>Male</td><td>Flu</td></tr></table>
<u>Linkage Code = Code Key</u>
<table><tr><th>Last Visit</th><th>Visit Code</th><th></th><th>ID</th><th>Name</th></tr><tr><td>8/1/18-8/7/18</td><td>Wk 1</td><td></td><td>1</td><td>John Doe</td></tr></table>
<u>Anonymous Data/Specimens</u>
All direct and indirect identifying information that would enable the investigator to know the subject's identity has been removed or replaced with a number, letter, symbol, or combination thereof. A linkage code is not kept, and it is not possible to re-identify the subject.
<table><tr><th>Age Group</th><th>Days Btw Visits</th><th>Gender</th><th>Diagnosis</th></tr><tr><td>35-40</td><td>114</td><td>Female</td><td>Diabetes</td></tr><tr><td>45-50</td><td>98</td><td>Male</td><td>Flu</td></tr></table></td></tr>
<tr><td>Future Sharing Plan</td><td>If information/specimens will be de-identified before being shared, explain the de-identification methods that will be used by the investigator.

Explain how the identifiable data elements in the shared dataset or specimens will be de-identified (i.e. re-coded to not be directly identifiable) and where the VCU investigator will maintain the linkage code.</td><td>Free Text Response</td><td></td></tr>
<tr><td>Future Sharing Plan</td><td>If information/specimens will be anonymized before being shared, explain the anonymization methods that will be used by the investigator.

Address how both individual data points and combinations of data will be anonymized to ensure that the identities of research subjects cannot be readily ascertained with the data or specimens.</td><td>Free Text Response</td><td></td></tr>
</table>

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Future Sharing Plan	Explain how the proposed sharing with each recipient is not inconsistent with what participants would have reasonably understood from the consent document about the uses of their information.	Free Text Response	For all studies, including exempt studies, sharing must not be inconsistent with what was stated in the study's consent document(s) or information sheet(s) as such sharing would violate the ethical principle of Respect for Persons. In cases where data/specimens were originally collected under a waiver of informed consent, the IRB will evaluate whether the information being shared is readily identifiable, and if so, whether the proposed sharing would qualify for a waiver of all elements of consent under 46.116. For studies initially approved after March 1, 2018 and all studies that have converted to the 2018 Common Rule: Individual-level data with no identifiers attached may be shared for the purposes of future research only when such sharing is in accordance with the consent form that the individual signed or agreed to [See 2018 Common Rule 46.116(b)(9)(i)].
Future Sharing Plan	The Principal Investigator certifies that • the 18 HIPAA identifiers will be removed prior to releasing the shared dataset/specimens and • if a linkage code is created, it will be maintained at VCU and not released to the sharing recipient under any circumstances;	☐ Yes ☐ No ☐ N/A - No sharing will occur	When the research data is considered to be Protected Health information (PHI), this plan must meet the HIPAA Privacy Rule's standards for de-identification. Linkage Code = Code Key A document or file that links the identifying information of a subject to the assigned code value or subject ID.
Future Sharing Plan	The Principal Investigator certifies that the following conditions will be met whenever research information and/or specimens are shared: • The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the sharing recipient; • The PI will have no knowledge that the remaining information could be used alone or in combination with any other information to identify the participants represented in the data. • **The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.**	☐ Yes ☐ No ☐ N/A - No sharing will occur	

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Pertinent and Incidental Findings	Is it likely investigators could discover a participant's previously unknown condition (e.g. disease, suicidal thoughts, wrong paternity, pregnancy, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:	☐ Yes ☐ No	
	Explain what actions or procedures should research personnel take to handle such a discovery:	Free Text	
	Describe any possible pertinent or incidental findings stemming from research-only procedures that may be of importance to a subject's health or well-being or which may relate to illegal or reportable activities.	Free Text	
	Will findings be disclosed to participants and/or any other person/group outside of the study team?	☐ Yes ☐ No	
	Describe a communication plan addressing: 1. What criteria will be used to determine which pertinent and/or incidental findings will be communicated, including the following for health-related findings: • The reliability of the tests/images, such as being done in a CLIA-certified lab, • Whether the meaning and significance of the findings are known, • Whether the findings reveal a significant risk of a serious health condition, • Whether there is an accepted treatment for the health condition revealed by the findings, and • The risks both of knowing and not knowing the findings, including risks to family members from genetic testing results. 2. What information will be provided during the consent process about the plans for communicating pertinent and/or incidental findings; 3. Whether the participants will be given the option of refusing communication of some or all types of pertinent and/or incidental findings to themselves, their family members, and/or any other individuals or groups; and 4. To whom and by whom the findings will be communicated, when, and how.	Free Text Response	_If results may be of clinical significance, federal regulations require that testing results used in clinical management must have been obtained in a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory. For more information: http://wwwn.cdc.gov/clia/regs/toc.aspx _If genetic testing results are unlikely to have clinical implications, then a statement that the results will not be made available to participants may be appropriate. _If you are not using a CLIA-certified laboratory for your results, but you receive results that have clinical implications, will you be sending those particular findings to a CLIA-certified Laboratory before sharing them with subjects? _Some participants may not want to receive test results, regardless of the outcome. Consider whether the consent form should provide participants with an option to decline results.
	If pertinent and/or incidental findings will not be disclosed, explain why not:	Free Text Response	
Conflict of Interest	To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?	Free Text Response	Non-financial interests could include such things as: - utilizing your unlicensed intellectual property in the study, - serving as an unpaid advisory board member or officer/director with a related entity, and - equity or business ownership in a company that has yet to make a profit and is related to this project - conflicts of time/effort, -personal and professional relationships/affiliations, - intellectual passions or personal beliefs - other factors that could create bias in the study

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Other VCU Requirements	Does this study involve obtaining information from VCU students' educational records (see help text)?	☐ Yes ☐ No	For guidance, see https://rar.vcu.edu/records/ VCU Records and Registration website about FERPA: https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/
Other VCU Requirements	Does this study involve the VCU site, or any sites under the VCU IRB's oversight, obtaining data in, or from, the European Economic Area? (see Help Text for list of countries included in the EEA)	☐ Yes ☐ No	European Economic Area (EEA) - data obtained in, or from, the EEA is subject to the European Union's General Data Protection Regulation (GDPR) requirements. The European Economic Area is comprised of 28 states of the European Union (EU), and four additional countries. The EU states are: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the UK. The four additional countries under the EEA are: Iceland, Liechtenstein, and Norway, and Switzerland.
Other VCU Requirements	Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research. *Note: If the data falls into Category 1, a data security management plan is required by University Information Security Office.* *See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan.*	☐ Category 1: all data that require breach notifications in the event of improper release, including all non-publicly available personally identifiable information covered by FERPA or HIPAA regulations. ☐ Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications. ☐ Category 3: all non-proprietary data that is considered publicly available for unrestricted use and disclosure. Such information is available to all members of the University community and to all individuals and entities external to the University.	VCU Information Security Standards (incl. Data Classification Standard): (http://go.vcu.edu/itstandard) VCU Data Classification Tool: (http://go.vcu.edu/dataclassification) VCU IT Policies (incl. Information Security Policy) (http://go.vcu.edu/itpolicy) To create a data security plan, visit: (https://dms.vcu.edu), click on Projects, then select Create New Project.
Other VCU Requirements	Does your study involve a satisfaction survey administered to VCUHS patients? *See Help Text*	☐ Yes ☐ No ☐ Not Applicable	CMS regulations prohibit administration of survey questions that mimic those found in the following CMS CAHPS surveys (CGCAHPS (outpatient), HCAHPS (inpatient), and OASCAHPS (outpatient/ambulatory surgery)) to research participants who are VCUHS patients if any form of incentive is offered for study participation. To ensure survey questions do not violate CMS regulations, the VCUHS Department of Patient Centered Services must screen all satisfaction surveys to be administered to VCUHS patients for research purposes if any form of incentive is offered.
Other VCU Requirements	Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, VCU Medical Center downtown)?	☐ Yes ☐ No	See the VCU Health System Research in Patient Care Areas policy (https://research.vcu.edu/compliance_program/vcuhs_policies.htm)
Other VCU Requirements	Does this project involve the use of Bio-Hazardous Substances such as gene transfer, use of organisms or their products, biological toxins, and/or viruses?	☐ Yes ☐ No	For guidance, see https://srm.vcu.edu/ Please refer to the VCU Biosafety Office for information on completing the necessary documentation for biohazardous agents and/or recombinant DNA (rDNA) materials. http://www.vcu.edu/oehs/chemical/biosafe/bioreginfo.pdf Contact Information for the Biosafety Office at 804 828-6347 or extension 400-4984.

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Other VCU Requirements	Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?	☐ Yes ☐ No	To contact the Radiation Safety Section, call 804 828-9131, or view their website at: https://srm.vcu.edu/ For additional guidance, please review Guidelines for IRB Protocols Involving the Use of Ionizing Radiation available at https://srm.vcu.edu/media/safety-amp-risk-management/assets/radiation-safety/Obtaining%20Approval%20to%20Use%20Radioactive%20Materials%20or%20Radiation-Producing%20Devices%20for%20Human%20Use.pdf
Other VCU Requirements	Does this study involve stem cells?	☐ Yes ☐ No	For guidance, contact the Office of Research Integrity and Ethics (ORIE) at: https://research.vcu.edu/orie/