

**DETERMINATION OF HUMAN SUBJECTS RESEARCH**  
*Documentation for Projects not Requiring IRB Oversight.***INFORMATION ABOUT THIS FORM**

- Submission of this form to the IRB-HSR is OPTIONAL. Even if you do not submit to the IRB-HSR you are encouraged to complete it and keep it with your files as documentation that IRB oversight is not applicable per current regulations.
- It is strongly recommended that the determination be made by more than one person from the project team.
- The project team must follow the Institutional Security Policies and HIPAA Security regulations for protecting the information. See Appendix B.
- If the project has external funding the project team must contact the School of Medicine Grants and Contracts Office or OSP. If identifiable data will be shared outside of UVA the project team must take the applicable steps described in sections 1G and 1H.
- If the project did not involve human subject research or a clinical investigation and a Journal requires documentation of IRB review the team should complete and submit this form to the IRB-HSR.
- Consult with the IRB for Social and Behavioral Sciences (IRB-SBS) regarding the difference between an Improvement Project and Research if an Improvement Project does not involve improving the quality of health care delivery.
- Also consult with the IRB-SBS if this project involves evaluating an educational process or curriculum and does not involve access to patients' health information.
- Data may NOT be published with any HIPAA identifiers (see Appendix A).
- **If the project is an Improvement Project, the project must be described in any dissemination of information as an Improvement Project and NOT as research.**
- Activities that meet the definition of Human Subject Research/ Clinical Investigation WILL REQUIRE SUBMISSION of a protocol to the IRB-HSR.

**If you submit this form to the IRB-HSR, the following steps should be taken:**

Enter responses electronically and Email the completed form to [IRBHRSR@virginia.edu](mailto:IRBHRSR@virginia.edu) for pre-review.

An IRB staff member will reply with any changes to be made and respond within 10 business days.

**For further guidance refer to:**

- OHRP Guidance at <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm#c1>

Date of Submission	<u>19 July 2021</u>
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UVA Messenger Mail Box #	<u>N/A</u>
Project/Protocol Title	<u>Intimate Partner Violence Assessment Program Evaluation</u>
External Funding Source	<u>N/A</u>
Purpose of the Project	<u>Conduct a systematic program evaluation of the IPV screening program currently being utilized in the ED of UVA Medical Center</u>
<b>Brief Summary of Project</b> 500 words or less. 1. <i>If you will be receiving data/ specimens explain where they will come from, and the reason for which they were originally collected.</i> 2. <i>Be specific about what identifiers will be received/collected/sent outside of UVA (see Appendix A).</i> 3. <i>Specify exactly what other information will be received/collected/sent outside of UVA</i> 4. <i>Please also explain what you will do with the data/specimens for this project at UVA.</i> 5. <i>Describe the scope of this project ( e.g. objectives, methods of data collection, interpretation and analysis.)</i>	<b>1. Data will be collected from:</b> <u>An anonymous questionnaire administered to ED nurses, social workers and providers to help identify barriers and facilitators to intimate partner violence screening tools currently utilized in the ED. There is a portion at the top of the questionnaire asking the participant to identify their job such as RN, LPN, social worker, and provider. The goal of the questionnaire is to identify barriers and facilitators (aids) to intimate partner screening.</u>  <u>Thirteen data elements requested from a data analyst employed by UVA Medical Center to help identify IPV screening rates, number of positive intimate partner violence screens, demographics of patients, trauma vs non-trauma of patients screened. Of the patients that screen positive and patients that screen negative, how many patients are trauma and non-trauma. Data request will be from January 1 - December 31, 2019 and June to August 2021.</u>  <b>2. No unique patient identifiers will collected. Only demographics to be collected are age, race, gender, trauma vs non-trauma, types of injuries (face/head/neck, etc). No data will be sent outside of the UVA.</b>  <b>3. Other information includes obtaining the ED hospital policy for intimate partner violence screening. The number of patients seen in the ED per year, number of registered nurses, licensed practical nurses, providers, social workers, length of nursing orientation, nursing turnover rate, and ED service line.</b>  <b>4. The data will be used for a institutional assessment for a program evaluation and data from the electronic health record (rates of screen completion and positive and negative screens) will help compare rates of intimate partner screening before the</b>

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	<p><b><u>Hurt Insult Threaten Hit (HITS) tool implementation by social work and after implementation. This date will be used to create recommendations for the intimate partner screening program.</u></b></p> <p><b><u>5. The object of this project is a program evaluation of the intimate partner screening program. Methods of data collection is data retrieval utilizing a data analyst, and a 5-point Likert scale questionnaire administered to ED staff.</u></b></p> <p>–</p>
<p><b>If this project involves interaction, will participants reimbursed for time/travel or provided compensation r?</b></p> <p>. <input type="checkbox"/> NA – No interaction <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO</p>	<p><b><u>If YES, complete Appendix F</u></b></p>

***If you check an item under question # 1 below YOU ARE DONE. DO NOT ANSWER ANY ADDITIONAL QUESTIONS. If you do NOT check an item under #1 proceed to #2.***

**1. Examples of Activities that do NOT require IRB-HSR review**

Indicate by checking below the activities associated with your project.

*If you check any item under this question (# 1), do not answer questions# 2 and 3. Your project does not require IRB approval of a research protocol.*

1A.  A **case series** involving up to 3 UVA patients.

**NOTE:** Any health information in the case series must be de-identified per HIPAA regulations (see Appendix A) in the publication

1B.  Specimens came from a **cadaver /specimen donor is now deceased.**

**Do not check if specimen is from a fetus.**

**NOTE:** Any published health information must be de-identified per HIPAA regulations (see Appendix A).

1C.  **Decedent** Research (all potential subjects are deceased): If the study team will be reviewing medical records of former patients from UVA the researcher must complete [a Request for Medical Records \(non-patient care purposes\)](#) and submit this to the UVA Health System Department of Health Information Services (HIS).

**NOTE:** Any published health information must be de-identified per HIPAA regulations (see Appendix A).

Do you affirm that the requested access to a decedent's protected health information is solely for research, and that the information requested is necessary for research purposes the following?  Yes  No

1D.  Establish a **database/registry for clinical care or an improvement project.** The primary reason for establishing this database is for clinical purposes or future improvement projects (e.g. Performance Improvement, Practice Improvement, Quality Improvement). **However, if you wish to do research with data from this database an additional IRB approval of a protocol may be required. Contact the IRB office if you have questions.**

**All personnel working on the project will review the Privacy Plan found in [Appendix B](#) prior to beginning work on the project.**

- If the database will be stored in a place other than a UVA HIPAA compliant server, a review by InfoSec will be required.
- If the services of a company are being sought (e.g. cloud services), a contract which includes a BAA will be required.
- If the contributors to the database include non-UVA sites, and the health information meets the criteria of a Limited Dataset, a HIPAA Data Use Agreement must be signed by each contributing institution. Consult with the Office of General Council as they create this agreement.

1E.  **Preparatory to Research Activity**

The most common time this is applicable is if the researcher wishes to review charts to design a research study or to assess the feasibility of conducting a study. IRB approval is NOT required if NO HIPAA identifiers will be collected. The researcher must, however, complete a [Request for Medical Records or Statistical Data Form](#) and submit this to the UVA Health System Department of Health Information Services (HIS).

For additional info see [http://www.virginia.edu/vpr/irb/HSR\\_docs/Preparatory\\_to\\_Research\\_Activities.doc](http://www.virginia.edu/vpr/irb/HSR_docs/Preparatory_to_Research_Activities.doc)

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1F.  **Public Data Sets** if all of the following conditions are met:

- Research will NOT involve merging any of the data sets in such a way that individuals might be identified
- Researcher will NOT enhance the public data set with identifiable, or potentially identifiable data (see No HIPAA identifiers listed in Appendix A added).
- Researcher will NOT use a *restricted data set*\*  
\**Restricted data set*- special files distributed by federal agencies and research organizations upon which use restrictions are imposed. These files often contain data such as Social Security numbers, names, or extensive life history markers that might enable an unauthorized user to identify a participant.
- Researcher will use a Public Data Set that is included on the list [of IRB-HSR approved Public Data Sets](#)
- What is name of Public Data Set from the list you plan to use? \_\_\_\_\_
- Researcher will NOT use data from the NIH GWAS (Genome Wide Association Studies) data repository
- The data host does not require the researcher or the researcher's institution to sign a Data Use Agreement. (*check 11 below* )

1G.  **Contributing Data/ Specimens for Research: Sending Data/Specimens outside of UVA for research and the following criteria are met:**

- The data/specimen, in its entirety, was collected for purposes other than the research project to be done by those with whom you are sharing the data/specimens. These data/specimens must be "on the shelf" (e.g. in Medical Records/ Pathology at the time this document is completed).
- Individuals releasing the data/specimens are NOT working in collaboration with the recipients on the research project.
- Data/ samples must meet the HIPAA criteria of Limited Data Set or completely de-identified data at the time of release, unless you are contracting with the recipients outside of UVA to de-identify the data or partially de-identify it to create a Limited Data Set. If so, contact Medical Center Procurement to establish a HIPAA Business Associate Agreement (BAA) with the recipient for this purpose. All datasets will be reviewed by the Clinical Data Repository to confirm they meet one of these criteria. Completely de-identified data have none of the HIPAA identifiers listed in Appendix A. A Limited Data Set may contain dates directly related to patients, such as birth dates or dates of admission or treatment, and city or town, state and zip code, but none of the other identifiers listed in Appendix A.
- Study team must obtain an Agreement with the School of Medicine Office of Grants and Contracts prior to sending Limited Data Set or completely de-identified data/specimens. If the data/specimens meet the criteria of a Limited Data Set, the School of Medicine Office of Grants and Contracts will incorporate a HIPAA Data Use Agreement into the Agreement.
- If the original data/ specimens were collected for research purposes the study team confirms the secondary use does not disagree with language in the consent under which the data/specimens were obtained. (*e.g. consent states tissue will be discarded after the original study is completed/ consent states data will not be used for future studies/ consent states no genetic research will be conducted on the specimens etc.*)

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- 1H.  **Project was or will be conducted as a Health Care Delivery Improvement Project (e.g. Performance Improvement, Practice Improvement, Quality Improvement). An Improvement Project is one that meets either of the criteria listed below.**

**Additional Information may be found at [Improvement Project vs Research- UVA Guidance](#)**

**Please indicate which criteria your project meets**

Implementing an accepted practice to improve the delivery or quality of care or services (including, but not limited to education, training and changing procedures related to care or services) if the purposes are limited to altering the utilization of an accepted practice and collecting data or biospecimens to evaluate the effects on the utilization of the practice.

**If checked** describe how this project will potentially improve delivery or quality of care or services at UVA:

Data collection and analysis, including the use of biospecimens, for an institution's own internal operational monitoring and program improvement purposes, if the data/biospecimen collection and analysis is limited to the use of data or biospecimens originally collected for any purpose other than the currently proposed activity, or is obtained through oral or written communications with individuals (e.g., surveys or interviews).

**If checked** describe HOW this project will potentially improve delivery or quality of care or services at UVA:

**Also consider the following:**

- ➔ If you wish to publish your finding and the Journal requires documentation of IRB review, complete the information on page 2 and submit this form to the IRB-HSR.
- ➔ Do you plan to send health information and /or specimens outside of UVA with any HIPAA identifiers (see Appendix A), to a recipient that is working on the Improvement Project?
  - -If the recipient is a health care provider or a health plan that has also treated or paid for the treatment of the patient, you may proceed.
  - -If the recipient is not a health care provider or a health plan that has also treated or paid for the treatment of the patient, you must first contact Medical Center Procurement to determine whether you need to establish a HIPAA Business Associate Agreement (BAA) with the recipient. The BAA will allow you to release identifiable information outside of UVA for the Improvement Project under the conditions specified in the BAA. See the following link for additional info: <http://www.procurement.virginia.edu/pagebusinessadd>
- ➔ You are responsible for following UVA HIPAA regulations to protect any identifiable health information you collect as part of this project.

- 1I.  **Research using Coded Data/Specimens or Creation of a Database/Repository including Coded Data/Specimens where the following are true:**

Data/Specimen will not be submitted to the FDA AND satisfies the following conditions:

- The data/specimen, in its entirety, were or will be collected for purposes other than this project
- The person providing the specimens/ data to the researcher will not otherwise be involved in this project, (e.g. interpretation or analysis of the data or creation and publication or presentation of research results, researcher receiving the data/specimens does not have access to the key to the code.)
- No data will be given back to the source of the specimens/data.
- The researcher only receives data/specimen, that are not readily identifiable (e.g. without any HIPAA identifiers except items # 2 or 3 in **Appendix A** (e.g. Limited Data Set)

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- The entity releasing the data/specimens will retain a key to the code or a link which may be used to re-identify the donor. The key to the code will not be shared with the research team. The code cannot be derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security number, mother's maiden name, first 3 letters of last name.)
- The specimens DO NOT include viable embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines.
- If receiving data from outside of UVA, an Agreement will be obtained by OSPR or the School of Medicine Office of Grants and Contracts prior to receiving the data.
- If the project team unexpectedly learns the identity of a living individual or wishes to identify the individual(s) from the coded data/specimens the research will require further IRB review.
- One of the following is required: *Check one*

<input type="checkbox"/>	<p>a. A signed agreement is required between the person releasing the specimens/ data and the researcher receiving the specimens/data stipulating the key to the code will never be released to the researcher. <i>Check one of the options below:</i></p> <p><input type="checkbox"/> Source of data/specimens <u>internal</u> to UVA.  <b><i>If checked complete Appendix D and file with study files.</i></b></p> <p><input type="checkbox"/> Source of data/specimens <u>external</u> to UVA. If checked, agreement from UVA Grants and Contracts Office will include equivalent terms.</p>
<input type="checkbox"/>	<p>b. Confirmation of IRB approval of written policies and operating procedures for a repository or data management center that prohibit the release of the key to the researchers under any circumstances, until the individuals from whom the information or specimens were collected are deceased.</p>
<input type="checkbox"/>	<p>c. There are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.</p>

### **Genomic Data Sharing**

Will this study involve genomic data sharing?    Yes    No

IF YES, I confirm I am aware that the content of the consent form used to collect the original specimens will influence whether this data is able to be submitted to the NIH Genomic Dataset and may therefore affect NIH funding opportunities.    Yes    No

### **Do NOT check this box if:**

- The investigator will obtain information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens.
- The investigator obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.
- The investigator will be obtaining the data via a process like a medical record review where identifiers will be viewed.
- The data specimens or cell lines were collected after January 25, 2015, were collected without written consent for research\* and will be used in the future for Genomic Data Sharing.

See: GENOME DATA SHARING POLICY- <https://gds.nih.gov/>

\* Research includes large-scale data such as genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data.

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1J.  Research using data/specimens, which cannot be readily identifiable OR creation of a database/repository using data/specimens, which cannot be readily identifiable, where the following are true:

Data/ Specimen will not be submitted to the FDA AND satisfies the following conditions:

- The data/specimen, in its entirety, was collected for purposes other than this project (*e.g. clinical care or blood samples left over from a study evaluating a new diabetes drug to conduct a new study on genetic predisposition of diabetic patients to Alzheimer's disease.*)
- The researcher receives only data/specimen, that are not readily identifiable (e.g. without any HIPAA identifiers except items # 2 or 3 in **Appendix A** (e.g. Limited Data Set)
- The specimens DO NOT include viable human embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines AND
- If receiving data from outside of UVA an Agreement will be obtained by OSP or the School of Medicine Office of Grants and Contracts prior to receiving the data.

**You May check this box if:**

- The data/specimen was collected solely for clinical purposes [for example, normally discarded tissue] **OR**
- The data/specimen was collected solely for unrelated research purposes, with no "extra" data/specimen collected for use in this project. If the data/ specimens were collected with the use of a consent form, the supplier confirms the secondary use does not disagree with language in the consent under which the data/specimens were obtained (*e.g. consent states tissue will be discarded after the original study is completed/ consent states data will not be used for future studies/ consent states no genetic research will be conducted on the specimens etc.* ). **OR**
- The specimen is a de-identified cell line.

**Do NOT check this box if:**

- The investigator will obtain information or biospecimens through intervention or interaction with the individual, and, uses, studies, or analyzes the information or biospecimens.
- The investigator obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.
- The investigator will be obtaining the data via a process like a chart review where identifiers will be viewed. (See Appendix A.)
- The data specimens or cell lines were collected after January 25, 2015, were collected without written consent for research\* and will be used in the future for Genomic Data Sharing See: GENOME DATA SHARING POLICY- <https://gds.nih.gov/>  
*\* Research includes large-scale data such as genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data.*

Will you obtain, use, study or analyze data that includes HIPAA identifier #2 or 3 from Appendix A?

YES  NO

If YES, complete Appendix E and keep it with your files.

1K.  Receipt of Data from dbGap for which dbGaP **DOES NOT** require IRB approval:

- *The requirement for IRB approval may be found in the DUC on the GWAS website.*

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- When you receive this signed document back from the IRB, submit it to the Grants & Contracts office to obtain the signature of the Institutional Official on the Institutional Certification form.
- If you check this box, you are not required to check any other box in this section.

**1L.  Receipt of Data from dbGaP for which dbGaP DOES require IRB approval and the following criteria apply:**

- You will only receive de-identified data from dbGaP.
- The dbGaP Data Use Committee (DUC) requires IRB approval.  
*The requirement for IRB approval may be found in the DUC on the GWAS website.*
- You did not submit any of the original data from this dataset to dbGaP
- You will not collaborate with others on this project who submitted any of the original data from this dataset to dbGaP

✓ Attach Appendix C to this submission and submit it with this form to the IRB-HSR.

✓ Contact School of Medicine Office of Grants and Contracts to obtain an Agreement and a dbGaP Data Request Form/Institutional Certification.

**1M.  Medical Practice and Innovative Therapy:** A commonly cited definition of medical practice describes an activity that is designed solely to enhance the well-being of an individual patient. A type of medical practice that is often confused with research is a class of activities that has been called “innovative therapy.” Basically, innovative therapy describes an activity that is designed solely to benefit individual patient(s) but in which the ability of the activity to result in the desired outcome is to some degree unproven.

**1N.  Medical Practice for the Benefit of Others:** In some situations, the goal of medical practice is to benefit people other than those directly affected by the health care intervention. Examples of medical practice for the benefit of others include blood donation and some vaccination programs. In terms of the research/non-research issue, the critical feature of this form of medical practice is that the goal of the activity is to benefit a well-defined group of people in a predictable way.

**1O.  Public Health Practice:** Public health practice is similar to medical practice for the benefit of others in that the activity involves people who do not directly benefit from the intervention. The most common situation in which there is confusion about the distinction between a public health practice and research is with public health practices that require the review of private, identifiable information about health status. Examples of public health practices that often do not involve research include surveillance (e.g., monitoring of diseases) and program evaluation (e.g., immunization coverage or use of clinical preventive services such as mammography). See OHRP Guidance titled “Activities Deemed Not to be Research: Public Health Surveillance 2018 Requirements” for additional information.

**1P.  Resource Utilization Review:** Medical record review is often conducted to evaluate the use of resources in a specific health care activity. Terms such as *cost control* are used to describe this class of activity, but the terms *utilization review* or *resource utilization review* are more general and often more accurately reflect the fundamental goal of projects in this category. Although a research project may involve review of resource utilization, the term *resource utilization review* usually refers to a non-research activity.

**1Q.  Scholarly and journalistic activities** (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. This category concerns scholarly and journalistic activities often conducted in various fields that focus directly on the specific individuals about whom information is collected and used, without extending that information to draw generalizations about other individuals or groups. In some cases, these activities can be designed to affect those individuals’ reputations,

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and to deliberately expose the individuals to public scrutiny or even possible harm, such as losing their positions or employment. The human subject protection regulations were not intended to cover individuals who are the focus of such scholarly and journalistic activities. Consequently, the protections afforded by 45 CFR part 46, including the requirement that risks to subjects be minimized, are inappropriate for these activities. For example, a journalist or a biographer might collect and present factual information to support their presentation of the character of an individual to show that the individual does not deserve the positive reputation he or she enjoys in society. Such fields of inquiry generally have their own codes of ethics. In contrast, if the activity involves collecting and using information about individuals for the purpose of drawing generalizations about such individuals or a population of which they are members, then the activity does not fit the parameters of this exception, and the activity may fall within the 2018 Requirements' definition of "research."

**1R  Education:**

Consult with the IRB for Social and Behavioral Sciences (IRB-SBS) if this is an improvement project that does not involve improving the quality of health care delivery or if this is a project to evaluate an educational process or curriculum change.

**IS  Program Evaluation**

Program evaluation is a systematic method for collecting, analyzing, and using information to answer questions about programs that are in place, particularly about their effectiveness and efficiency.

Program evaluation may include:

- feasibility evaluations to ensure that a program or portion of the program is feasible, appropriate, and acceptable before it is fully implemented.
- formative evaluations that occur during the program implementation or process and may lead to changes in the program before the program is completed.
- summative evaluations that occur at the end of the program implementation.
- program process evaluation, program impact evaluation and program outcome evaluations that focus on how a program was implemented and how it operated; evaluates outcomes and impact.

The methodology employed to collect and analyze data may resemble research; however, the purpose of the project is not to create generalizable knowledge. The information gleaned from program evaluation efforts is generally used to improve a particular program, and not to generate generalizable knowledge, even though results are sometimes shared outside of the institution.

**Any activity, meeting one of the above categories, is determined by the IRB-HSR to NOT represent human subject research and therefore no submission to the IRB-HSR is required. However, it is recommended that investigators document their determination by placing a copy of this completed application in your files to address any future queries about the project.**

**[If you checked an item under question # 1 YOU ARE DONE. DO NOT ANSWER ANY ADDITIONAL QUESTIONS.](#)**  
**[If you did not check an item under #1 proceed to #2.](#)**

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**2. Research/Clinical Investigation Determination: Check the applicable option below:**

- 2A.**  The activity employs a systematic approach involving predetermined methods for studying a specific topic, answering a specific research question, testing a specific hypothesis, or developing a theory  
**AND**  
the activity is intended to contribute to generalized knowledge by extending the results beyond a single individual or an internal unit (e.g., publications or presentations outside of the UVA).
- 2B.**  The activity involves the use of a drug, excluding an FDA approved drug in the course of medical practice, in one or more human subjects.
- 2C.**  The activity involves the use of a medical device, excluding an FDA approved device in the course of medical practice, in one or more human subjects.
- 2D.**  The results of the project are required to be submitted to or held for inspection by the FDA.
- 2E.**  The activity involves the testing of a medical device using specimens from one or more human subjects and the results are being submitted to the FDA for approval of the device.
- 2F.**  The activity involves one or more individuals who are or become participants in research, either as a recipient of the test article (i.e., drug, biological product, medical device, food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug & Cosmetic Act) or as a control.
- 2G.**  The activity involves one or more individuals who participate in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control.
- 2H.**  **None of the above.** This project does not meet the definition of research and therefore does not require IRB review. **You are not required to answer any additional questions.**

<b>Brief summary of work to be done under this project (200 words or less)</b>	<hr/>
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[If you checked an item under # 2 other than "NONE OF THE ABOVE" continue to # 3.](#)

**3. Human Subject Determination: Check the applicable option below:**

- 3A.  A human subject is a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information. (e.g., interviews, surveys, physical procedures, manipulations of the subject's environment, private or limited access internet sites, or any other direct contact or communication with a subject, review of private information such as medical records).
- 3B.  The investigator is obtaining identifiable private information about living individuals (e.g. chart review, lab studies on tissues or specimens, information from data or tissue repository).
- 3C.  The data or specimens from living individuals are received by or provided to the investigator with identifiable private information.
- 3D.  The data or specimens from living individuals are coded and there is a link that would allow the data or samples to be identified. The link may be held by either party. *If the link is held by someone outside UVA, this project may be considered to not involve human subjects-, but this determination must be made by the IRB, and therefore an IRB submission other than this form is required.*
- 3E.  The data includes information from an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.
- 3F.  **None of the above:** Project does not involve human subjects and therefore does not require IRB review. **If you checked this option you are not required to answer any additional questions.**

**If you checked any item other than "NONE OF THE ABOVE" you are doing Human Subject Research.**

- **DO NOT SUBMIT THIS FORM**
- **Go to Protocol Builder to create an IRB submission for a new protocol ([www.irb.virginia.edu](http://www.irb.virginia.edu))**

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UVA IRB-HSR Study Tracking # 23332

**Project is determined to NOT meet the criteria of Research with Human Subjects or a Clinical Investigation and therefore is not subject to IRB-HSR Review.**

*All project team personnel are required to follow all requirements described in this form and follow:*

- *Procurement requirements if participants will be compensated for their time*
- *UVA Information Security policies to protect the data: See Appendix B: Privacy Plan.*

**Pick One**

- No health information/specimens are to be collected or used for this project
- Health information/specimens to be collected or used for this project meet the criteria of Deidentified under HIPAA (No identifiers as noted in Appendix A may be collected/ used.)
- Health information collected meets the criteria of identifiable
- Health Information meets the criteria of Limited Dataset.  
HIPAA Data Use Agreement is required to share data outside of UVA.
- Data/Specimens used in this project are coded:

**Check if applicable**

- Your project was determined to be QI-Improvement Project. If you decide to publish results of this project you must describe the project in the publication as QI and NOT as research.

**IF SENDING OR RECEIVING DATA/SPECIMENS**

- Provide this signed form to School of Medicine Office of Grants and Contracts and/or Medical Center Procurement if your project has external funding or plans to share data/specimens outside of UVA.

Contact the IRB if anything concerning this project changes that might affect the non-human subject determination.

- Project is determined to be Human Subjects Research or a Clinical Investigation** and must be submitted to the IRB-HSR for review and approval prior to implementation. Please go the Protocol Builder to create your submission. <https://www.irb.virginia.edu/>

**Name of IRB Staff:** Kristin Shelby

**Date:** 07-28-21

Website: <http://www.virginia.edu/vpr/irb/hsr/index.html>

Phone: 434-924-2620 Fax: 434-924-2932 Box 800483

## APPENDIX A: HIPAA Identifiers

1. Name
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of the zip code if, according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people and (2) The initial 3 digits of a zip code for all such geographic units containing 20,000 is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older. <i>[This means you may record the year but not record the month or day of any date related to the subject if the subject is under the age of 89. In addition if the subject is over the age of 89 you may not record their age and you may not record the month, day or year of any date indicative of age ( except that you may aggregate them into a category "Age&gt;90" ]</i>
4. Telephone numbers
5. Fax numbers
6. Electronic mail addresses
7. Social Security number
8. Medical Record number
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, code that is derived from or related to information about the individual (e.g. initials, last 4 digits of Social Security #, mother's maiden name, first 3 letters of last name.)
19. Any other information that could be used alone or in combination with other information to identify an individual. (e.g. rare disease, study team or company has access to the health information and a HIPAA identifier or the key to the code.)

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## Appendix B: Privacy Plan

### The following procedures must also be followed.

- Only investigators for this study and clinicians caring for the patient will have access to the data. They will each use a unique login ID and password that will keep confidential. The password should meet or exceed the standards described on the Information Technology Services (ITS) webpage about [The Importance of Choosing Strong Passwords](#).
- Each investigator will sign the [University's Electronic Access Agreement](#) forward the signed agreement to the appropriate department as instructed on the form.

If you currently have access to clinical data it is likely that you have already signed this form. You are not required to sign it again.

- UVA University Data Protection Standards will be followed <http://www.virginia.edu/informationsecurity/dataprotection>.
- If identifiable data is transferred to any other location such as a desktop, laptop, memory stick, CD etc. the researcher must follow the University's "[Electronic Storage of Highly Sensitive Data](#) Policy". Additional requirements may be found in the Universities [Requirements for Securing Electronic Devices](#).
- If identifiable health information is taken away from the [UVA Health System](#), Medical Center Policy # 0218 will be followed.
- The data will be securely removed from the server, additional computer(s), and electronic media according to the University's [Electronic Data Removal Policy](#).
- The data will be encrypted or removed if the electronic device is sent outside of UVA for repair according to the University's [Electronic Data Removal Policy](#).
- If PHI will be faxed, researchers will follow the [Health System Policy # 0194](#).
- If PHI will be emailed, researchers will follow the [Health System Policy # 0193](#) and [University Data Protection Standards](#).
- The data may not be analyzed for any other study without additional IRB approval.
- If you are using patient information you must follow [Health System Policy # 0021](#).
- Both data on paper and stored electronically will follow the [University's Record Management policy](#) and the Commonwealth statute regarding the Destruction of Public Records.

### **Summary of Requirements to Comply with UVA Health System, Medical Center and University Policies and Guidance as noted above:**

#### **Highly Sensitive Data** is:

- personal information that can lead to identity theft if exposed or
- health information that reveals an individual's health condition and/or history of health services use.

**Protected Health Information (PHI)** a type of Highly Sensitive Data, is health information combined with a HIPAA identifier

**Identifiable Health Information** under HIPAA regulations is considered to be *Highly Sensitive Data at UVA*

A **Limited Data Set (LDS)** under HIPAA regulations is considered to be *Moderately Sensitive Data* at UVA. The only HIPAA identifiers associated with data: dates and or postal address information limited to town or city, state, and zip code.

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<b>Highly Sensitive Data (Identifiable Health Info per HIPAA )</b>	<b>Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)</b>
<i>General Issues</i>	<i>General Issues</i>
Discussions in private Do not share with those not on the study team or those who do not have a need to know.	Do not share with those not on the study team or those who do not have a need to know
Password protect	Password protect
Physically secure (lock) hard copies at all times if not directly supervised. If not supervised hard copies must have double protection (e.g. lock on room OR cabinet AND in building requiring swipe card for entrance).	Physically secure (lock) hard copies at all times if not directly supervised.
For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.	For electronic documents turn off File Sharing; turn on firewalls; use up to date antivirus and antispyware; delete data securely.
Encrypt See <a href="#">Encryption Solutions Guidance</a> <i>Files on Health System Network drives are automatically encrypted. If not stored there it is study teams responsibility to make sure data are encrypted.</i>	
If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVA Purchase order.	If device sent out for service or repair, encrypt or remove data AND contract for repair using a UVA Purchase order.
Store files on a network drive specifically designated for storing this type of data, e.g. high-level security servers managed by Information Technology Services or the “F” and “O” managed by Heath Systems Computing Services. You may access it via a shortcut icon on your desktop, but you are not allowed to take it off line to a local drive such as the desktop of your computer (e.g. C drive) or to an individual Use Device*. May access via VPN	
Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place	Do not share with sponsor or other outside group before consent is obtained or the IRB has granted appropriate approvals and contract/ MTA is in place
If collected without consent/ HIPAA authorization will NOT be allowed to leave UVA HIPAA covered entity unless disclosure is approved by the IRB and the disclosure is tracked in EPIC	If collected without consent/ HIPAA authorization will NOT be allowed to leave UVA HIPAA covered entity unless disclosure is approved by the IRB and an MTA is in place prior to sharing of data

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<b>Highly Sensitive Data (Identifiable Health Info per HIPAA )</b>	<b>Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)</b>
<i>Individual-Use Device</i>	<i>Individual-Use Device</i>
Do not save to individual-use device* without written approval of your Department AND VP or Dean. If approval obtained, data must be password protected and encrypted.	
Do not save an email attachment containing HSD to an individual use device ( e.g. smart phone)	
<i>E Mail</i>	<i>E Mail</i>
Do not share via email with Outlook Web/ or forward email using other email vendors like Gmail/ Yahoo	
Do not send via email on smart phone unless phone is set up by Health System	
Email may include name, medical record number or Social Security number only if sending email to or from a person with * HS in their email address. <i>NOTE: VPR &amp; IRB staff do not meet this criteria!</i>	In addition to sharing LDS, may include initials if persons sending and receiving email work within the UVA HIPAA covered entity.**
<i>FAX</i>	<i>FAX</i>
Verify FAX number before faxing	Verify FAX number before faxing
Use Fax Cover Sheet with Confidentiality Statement	Use Fax Cover Sheet with Confidentiality Statement
Verify receiving fax machine is in a restricted access area	Verify receiving fax machine is in a restricted access area
Verify intended recipient is clearly indicated	Verify intended recipient is clearly indicated
Recipient is alerted to the pending transmission and is available to pick it up immediately	Recipient is alerted to the pending transmission and is available to pick it up immediately

<b>Highly Sensitive Data (Identifiable Health Info per HIPAA )</b>	<b>Moderately Sensitive Data (Limited Data Set and De-identified data per HIPAA)</b>
<i>Electronic Data Collection &amp; Sharing</i> (e.g. smart phone app, electronic consent using tablet etc.) MUST consult with ISPRO or Health System Web Development Office: 434-243-6702 University Side: <a href="mailto:IT-Security@virginia.edu">IT-Security@virginia.edu</a> Health System: <a href="#">Web Development Center:</a> Contract must include required security measures.	<i>Electronic Data Collection &amp; Sharing</i>
May NOT be stored in places like UVABox, UVACollab, QuestionPro. May also NOT be stored in non-UVA licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.	May be stored in places like UVABox, UVACollab, QuestionPro. May NOT be stored in non-UVA licensed cloud providers, such as Dropbox, Google Drive, SkyDrive, Survey Monkey, etc.
<b>LOST OR STOLEN:</b>	<b>LOST OR STOLEN:</b>
Must report in accordance with protocol/ in accordance with the <a href="#">Information Security Incident Reporting Policy</a>	Must report in accordance with protocol/ in accordance with the <a href="#">Information Security Incident Reporting Policy</a>

\* *Individual Use Device – examples include smart phone, CD, flash (thumb) drive, laptop, C drive of your computer.*

\*\**The UVA HIPAA covered entity includes the UVA VP Office of Research, the Health System, School of Medicine, School of Nursing, Nutrition Services (Morrison’s), the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory, the Exercise Physiology Laboratory and the UVA Center for Survey Research.*

## Research Involving De-identified Data from dbGap

Project Title: \_\_\_\_\_

Name of dbGaP datasets from which you will receive data: \_\_\_\_\_

Project Summary: \_\_\_\_\_

1. Do you confirm the following?  Yes  No
- a. You will only receive de-identified data from dbGaP.
  - b. The dbGaP Data Use Committee (DUC) requires IRB approval.
  - c. You did not submit any of the original data from this dataset to dbGaP
  - d. You will not collaborate with others on this project who submitted any of the original data from this dataset to dbGaP
  - e. That if you unexpectedly learn the identity of one or more living individuals or wish to identify the individual(s), you will obtain an additional IRB approval.
2. Do you plan to combine the data you receive with any additional data that would allow you to determine the identity of the subject?  Yes  No
3. Will the research be limited to the use of this existing data?  Yes  No
4. Do you confirm the data you receive will not be shared outside of UVA?  Yes  No

For additional information see [NIH dbGaP policies](#).

\_\_\_\_\_  
Principal Investigator Name (PRINT)

\_\_\_\_\_  
Date

IRB-HSR Office Use Only:

IRB-HSR # \_\_\_\_\_

Revised: 2/6/13

Appendix D:

**CODED RESEARCH DATA/SPECIMENS AGREEMENT**

THIS AGREEMENT dated \_\_\_\_\_, 20\_\_, is entered into by \_\_\_\_\_ (the “Data Source”) and \_\_\_\_\_ (the “Researcher”).

Recitals

- a. The Data Source is providing coded, de-identified data (private health information about individuals or tissue specimens, referred to herein as the “Data”) to the Researcher for a research project concerning \_\_\_\_\_ (the “Project”).
- b. The Researcher wishes the Project to be considered research involving coded private information or biological specimens under 45 CFR Part 46.
- c. To satisfy the conditions of the Office for Human Research Protections guidance on research involving coded private information or biological specimens, the Data Source and the Researcher wish to enter into this Agreement.

In consideration of the above, the parties agree that:

- 1. De-identified Data. The Data Source shall provide to the Researcher only Data that has been de-identified through the removal of all the identifiers listed on Attachment A.
- 2. Origin of Data. The parties agree that:
  - i. The Data were not collected specifically for the Project through an interaction or intervention with living individuals, but are instead either existing or future data collected for other purposes; and
  - ii. The Data Source will not otherwise be involved in the Project, such as in interpretation or analysis of the Data or creation and publication or presentation of research results.
- 3. Coding of Data. The parties acknowledge that the Data is “coded” by association with a number, letter or symbol, and that the Data Source holds a key to decipher the codes and link the Data back to information (such as name or social security number) that would identify individuals to whom the private information or specimens pertain. The code may not be derived from or related to information about the individual, such as initials or last four digits of Social Security Numbers.

4. Prohibition on Disclosure. The Data Source may not release the key for deciphering the codes to the Researcher, unless the Researcher presents documentation of an Investigational Review Board review of the Project as human research, with appropriate action, such as a finding of exemption, waiver of informed consent, or signed informed consents of any individuals whose Data may be re-identified through release of the key.
5. Governing Law. This agreement shall be governed by the laws of the Commonwealth of Virginia.

\_\_\_\_\_  
(Data Source)Print Name

\_\_\_\_\_  
(Data Source) Title

\_\_\_\_\_  
Date: \_\_\_\_\_

\_\_\_\_\_  
(Data Source)Signature

---

\_\_\_\_\_  
(Researcher)Print Name

\_\_\_\_\_  
(Researcher) Title

\_\_\_\_\_  
Date: \_\_\_\_\_

\_\_\_\_\_  
(Researcher)Signature

**Attachment A: HIPAA Identifiers (Limited Data Set)**

YES	NO	
		1. Name
		2. Postal address information, other than town or city, state, and zip code
		3. Telephone numbers
		4. Fax numbers
		5. Electronic mail addresses
		6. Social Security number
		7. Medical Record number
		8. Health plan beneficiary numbers
		9. Account numbers
		10. Certificate/license numbers
		11. Vehicle identifiers and serial numbers, including license plate numbers
		12. Device identifiers and serial numbers
		13. Web Universal Resource Locators (URLs)
		14. Internet Protocol (IP) address numbers
		15. Biometric identifiers, including finger and voice prints
		16. Full face photographic images and any comparable images



Appendix E:

HIPAA Data Use Agreement

IRB-HSR# OR UVA Study Tracking# \_\_\_\_\_

INSTRUCTIONS: Data being used in this protocol meets the criteria of a Limited Data Set per HIPAA regulations. To comply with HIPAA regulations the principal investigator of this protocol must sign this memo regarding Limited Data Sets. This memo must be filed with your regulatory files and kept for 6 years from the date of this determination.

This memorandum is designed to permit you to use and disclose a "Limited Data Set" of patients' health information for UVA in compliance with the HIPAA Privacy Rule, 45 CFR Parts 160 and 164, subparts A and E.1.

1. Except as otherwise specified in this memorandum, you may use and disclose the Limited Data Set for research purposes only as described above. You represent that the Limited Data Set is the minimum amount of data necessary for the conduct of the Research.
2. You agree not to use or disclose the Limited Data Set for research purposes other than as permitted by this Agreement or as otherwise required by law.
3. You agree to use appropriate safeguards as described above to prevent the use or disclosure of the Limited Data Set other than as provided for by this Agreement.
4. You agree to promptly report to the IRB for Health Sciences Research Office any use or disclosure of the Limited Data Set not described in this memo of which you become aware.
5. You agree not to attempt to identify the patients to whom the information contained in the Limited Data Set pertains in order to contact those individuals for purposes of research.

\_\_\_\_\_  
Signature: Principal Investigator

\_\_\_\_\_  
Date

## Payment

### INSTRUCTIONS:

What is the difference between compensation and reimbursement?

A reimbursement is used when the subject is paid back for travel expenses such as mileage, lodging, food while traveling. Receipts or mileage must be submitted for a reimbursement.

Compensation is "payment" for things such as time, discomfort, inconvenience.

Total possible compensation should reflect the true value of the total possible dollar amount per participant for one year involvement in the study whether it be cash, check, gift card, goods, etc. or a combination of these items.

Retention "Gifts" - gifts may be given to a subject periodically during the study to remind them they are in the study. Sponsors may provide such items as water bottles, birthday cards etc. to the subject. NOTE: Cash or gift cards are NOT allowed as retention items.

### 1. Are subjects being reimbursed for travel expenses?

#### INSTRUCTIONS:

- If subject will NOT submit receipts for actual expenses (e.g. hotel, food, you MUST answer this NO.
- If subjects will have mileage/distance traveled, calculated and confirmed \*via Mapquest for example, this questions should be answered YES
- Reimbursements must be paid with Oracle Expenditure types found under the Travel Heading.
- For instructions on how to process a reimbursement please see "Goods and Services Procurement Guide" at <http://www.procurement.virginia.edu/main/>. You may also call the Procurement Help Desk at 924-4212.
- The money will not be reportable to the IRS as income, but will be withheld if the subject owes money to the state.

Answer/Response:

► IF YES, explain rate/ amount/ upper limits of reimbursements.

Answer/Response:

► IF YES, Do you confirm you are aware of the following procedures to follow for reimbursements?

#### INSTRUCTIONS

- Subject will submit receipts for actual expenses (e.g. hotel, food)
- Reimbursements must be paid with Oracle Expenditure types found under the Travel Heading.
- For instructions on how to process a reimbursement see "Goods and Services Procurement Guide" at <http://www.procurement.virginia.edu/main/>. You may also call the Procurement Help Desk at 924-4212. The money will not be reportable to the IRS as income, but will be withheld if the subject owes money to the state.

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- Reimbursements may not be done with gift cards

Answer/Response:  Yes  No

**2. Are subjects compensated for being in this study?**

Answer/Response:  Yes  No

▶ IF YES, answer the following questions (2a-2d).

**2a. What is the maximum TOTAL compensation to be given over the duration of the protocol?**

Answer/Response: \_\_\_\_\_

**2b. Explain compensation to be given.** Answer/Response: \_\_\_\_\_

**2c. Is payment pro-rated?**

e.g. some compensation is given even if subjects do not complete the entire study

Answer/Response:  Yes  No

If No, explain why payment cannot be pro-rated. Answer/Response: \_\_\_\_\_

**2d. Is money paid from UVa or State funds (including grant funds) or will items such as gift cards be distributed through UVa?**

**INSTRUCTIONS**

Examples of when to say no:

- Researcher is using their own personal funds to compensate participants.
- Compensation is coming from a UVa Foundation and therefore not subject to UVA financial policies and procedures.

Examples of when to say yes:

- Sponsor, via a grant or contract, sends money to OSP/ SOM Grants and Contracts office to cover cost of compensation to be given to subjects. Subjects are then paid via Oracle system
- UVA researcher purchases gift cards for distribution to subjects and there is NO outside sponsor.
- Sponsor purchases gift cards/ debit cards and sends to UVa for study team to distribute to the subjects.

Answer/Response:  Yes  No

▶ IF YES, answer the following questions [2d(i)-2d(ii)].

**2d(i). How will the researcher compensate the subjects?** Answer/Response:

- Check issued to participant via UVA Oracle or State system
- Petty cash account\*

\*Per [UVa Policy](#) petty cash payments are limited to a maximum of \$100 per payment and \$599 per calendar year per individual.

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- Gift card/Debit Card
- Other type of compensation:  
Specify **Answer/Response:** \_\_\_\_\_

**2d(ii). Which category/ categories best describes the process of compensation?**

Choose one of the following 3 options

- All compensation will be made via check issued to participant via UVA Oracle or State system  
**The preferred method**

- Compensation will include an alternative method (petty cash, gift card, other) and tax information will be collected, securely stored, and submitted electronically to Procurement Services as required.

► If this box is checked and an alternate method will be used, justify why you are unable to issue checks through the UVa Oracle or state system.

[Guidance to answer this question.](#)

*See question:* When is it justifiable to provide compensation using an alternative method of payment while still collecting tax information?

**Answer/Response:** \_\_\_\_\_

**IMPORTANT:** If you check this box you will be required to submit the subjects' name, Social Security number, full address and amount of payment to Procurement at the end of each calendar year. The Office of the VP for Research will send you instructions on this procedure at a later date.

If the sponsor is providing the gift card/debit card and sending to UVA study team for distribution, please include the statement "SPONSOR REQUEST" under the request for justification.

- Compensation will include an alternative method (petty cash, gift card, other) and tax information cannot be collected. Total possible compensation per participant for participating in the research study over one year is limited to <=\$50.

**INSTRUCTIONS:** If the subject will receive <\$50/year in this study check this option and insert the following answer to both questions below. Subjects will be compensated \$50 or less per year for this protocol and subjects may hesitate to enroll in the study if it requires they share their Social Security number for such a small amount of money.

► If an alternate method will be used justify why you are unable to issue checks through the UVa Oracle or state system:

[Guidance to answer this question.](#)

*See question:* When is it justifiable to provide compensation using an alternative method of payment while still collecting tax information?

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Answer/Response:

► If you are unable to collect the tax information justify why it cannot be collected.

Answer/Response:

Guidance to answer this question.

See *question*: When is it justifiable to provide compensation if the tax information cannot be collected?

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