**ADMINISTRATIVE PRE-REVIEW CHECKLIST and LIMITED IRB REVIEW**

 **New Exempt Application**

**IRB-HSR #** **PI Name:       Outside Sponsor** [ ]  **NA** [ ] **Yes If yes: Sponsor**

*If YES, verify agency is listed as sponsor on Protocol Coversheet and as Sponsor in IRB Online.*

*If the only studies funded by the grant meet exempt criteria, the IRB is not required to review the grant application funding this study.*

**Is study funded by Grant from a non-Common Rule agency (e.g. FDA/Justice)?**  [ ] **No** [ ]  **Yes- If yes: GIRB #**

*If YES, verify agency is listed as sponsor on Protocol Coversheet and as Sponsor in IRB Online.*

*For additional information refer to AG 3-1 and the* [*Optional Review Checklist*](#_Optional_Review_Checklist)*.*

**Compliance Approvals Needed Per Coversheet (e.g. InfoSec, IBC, CRPC, GMEC)?**

*Update the Regulatory Page to reflect this information.*

**Exempt Criteria:** *Add info to IRB Online/ Regulatory*

**Check all applicable exempt category/categories:**

[ ]  Category 1 [ ]  Category 2(i) [ ]  Category 2(ii) [ ]  Category 2(iii)

[ ]  Category 3(i)(A) [ ]  Category 3(i)(B) [ ]  Category 3(i)(C) [ ]  Category 3(ii) [ ]  Category 3(iii)

[ ]  Category 4(i) [ ]  Category 4(ii) [ ]  Category 4(iii) [ ]  Category 4(iv)

[ ]  Category 6

*NOTE: If Category 3 is chosen, IRB staff should refer to* [*SACHRP Recommendations on Benign Behavioral Intervention*](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html) *. If Category 3iii is chosen, the study team must submit the agreement provided to the subject for the subject to authorize deception*

**Additional Items: check all that apply**

[ ]  Recruitment Materials- Complete the [Recruitment Section](#_RECRUITMENT)

[ ] Limited IRB Review is required –Complete the [Limited IRB Review Section](#_LIMITED_IRB_REVIEW).

[ ]  Study is funded by the NIH and is exempt under Category 2(iii), 3(c) or 4(iii).

* *If checked check “COC without Expiration Date” in IRB Online/ Regulatory page*

[ ]  If Health Information being collected in this study - *complete the* [*HIPAA Section*](#_HIPAA)

**If study involves identifiable health information, is at least one member of personnel employed by UVA HIPAA Covered Entity?**

[ ]  **NA** [ ]  **Yes** [ ]  **No** *For UVA this includes the following areas, UVA Health including the School of Medicine & the School of Nursing, the Sheila C. Johnson Center, the Exercise and Sports Injury Laboratory and the Exercise Physiology Laboratory.*

[ ]  If Waiver of HIPAA Authorization is requested – complete the [Waiver of HIPAA Authorization Section](#_WAIVER_OF_HIPAA_1)

 *This section must be completed if applicable.*

[ ]  If Alteration of HIPAA Authorization is requested- complete the [Alteration of HIPAA Authorization section.](#_ALTERATION_OF_HIPPA)

 *This section must be completed if applicable.*

[ ] Unaffiliated Investigator –Complete [Unaffiliated Investigator](#_UNAFFILIATED_INVESTIGATOR,_ACCESS) Section.

 *This section must be completed if applicable.*

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**IRB-HSR Staff Member Approving:**

# **HIPAA**

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| *Check all applicable items below (De-identified, Limited Data Set, or Identifiable Data)**More than one category may apply: example- data being kept at UVA is identifiable, while data going to central registry is a LDS.* [ ]  **De-identified OR No Health Information collected** *HIPAA not applicable.* *On Regulatory Page mark the following:**HIPAA- de-identified and/ or no health information (no consent)* [ ]  **Limited Data Set**- - *Verify Appendix H of the Exempt Application is completed*.*Note:* For subjects over the age of 89, their date of birth and age may be recorded.*If data at UVA is a LDS* s*end PI-*[*Data Use Agreement*](https://research.virginia.edu/sites/vpr/files/2019-08/Data_Use_Agreement_Memo_PI_Instructions.doc)  *and add comment to assurance form:* DUA is included in the Exempt Application – Appendix H. I[ ]  Recipient Outside UVA: Outside entity will get LDS identifiers: dates, address info and or code- but not key to code. *TIP: SOM Grants and Contracts office will obtain a signed HIPAA DUA with outside recipient in the contract.* *On Regulatory Page mark the following:**HIPAA- Limited Data Set.**Under Data Use Agreement section mark the following:**Data Use Agreement: Protocol Specific**Data Use Agreement Type- Recipient Outside of UVA**Add comment to assurance form:* *HIPAA DUA will be obtained by OSP/ SOM Office of Grants and Contracts.* [ ]  No Recipient Outside UVA. LDS identifiers will be kept at UVA but not shared outside of UVA. *On Regulatory Page mark the following:**HIPAA- Limited Data Set.**Under Data Use Agreement section mark the following:**Data Use Agreement: Protocol Specific**Data Use Agreement Type- PI*[ ]  **Identifiable Data**[ ]  Internal-*Identifiers not given to or seen by anyone from outside entity- no additional documentation required.**On Regulatory Page mark the following:**HIPAA- Identifiable-Internal Use- No Tracking Required (no consent)* *NOTE: Identifiable health info may also be shared with the following areas without tracking the disclosure as agreements are in place to protect the information:** *VP Office of Research*
* *Nutrition Services (Morrison’s)*
* *UVA Center for Survey Research*

[ ]  External *give PI Tracking Instructions**On Regulatory Page mark the following:**HIPAA- Identifiable-External Disclosure- Tracking Required (no consent)* **Was more than one category (de-identified, limited data set, identifiable) above chosen?** [ ]  **Yes** [ ]  **No***If YES (e.g. identifiable at UVA and limited data set sent outside of UVA) add a comment to the comment field on the main page of the protocol in IRB Online and in the Assurance Form comment field describing the situation.**[e.g.: Data at UVA Identifiable, Data going outside of UVA is a LDS” ]***IF IDENTIFIABLE- SEE THE** [**WAIVER OF HIPAA AUTHORIZATION**](#_WAIVER_OF_HIPAA_1) **SECTION.** |

# **WAIVER OF HIPAA AUTHORIZATION**

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| **IF IDENTIFIABLE, does the protocol or part of the protocol meet the criteria for Waiver of HIPAA authorization?**[ ]  Yes [ ]  No1. *The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based in, at least, the presence of the following elements:*
2. *An adequate plan to protect the identifiers from improper use and disclosure.*
3. *An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and*
4. *Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.*
5. *The research could not practicably be conducted without the waiver or alteration and*
6. *The research could not practicably be conducted without access to and use of the protected health information*

**If NO, do not complete any additional info on this page. See [Alteration of HIPAA Authorization.](#_ALTERATION_OF_HIPPA)****If YES, include the following information in the comment field of the Assurance Form:**This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for:[ ]  a screening log[ ]  the main study[ ]  the continued use of data collected under parental/guardian permission. [ ]  *other- insert*:      * + The following HIPAA identifiers will be collected:
	+ The PHI, deemed to be the minimum necessary for this protocol includes (***insert***      )

[ ]  **Justification for Waiver of HIPAA Authorization: Main Study** A Waiver of HIPAA Authorization is appropriate for the main study because:\*The research involves no more than minimal risk to the subjects because <INSERT STUDY SPECIFIC REASON>the study involves review of medical records only. The only risk related to study participation is the risk of loss of privacy and confidentiality. These risks are minimized by procedures outlined in the Privacy Plan and Data Security Plan. With these measures in place the risk to privacy and loss of confidentiality do not exceed the potential or magnitude of risk related to loss of privacy and confidentiality encountered while living everyday life. \*The waiver or alterations will not adversely affect the rights and welfare of the subjects because <INSERT STUDY SPECIFIC REASONS>>of procedures outlined in the Data Security Plan. Data to be collected is of a not sensitive natures such that any inadvertent release would not likely result in physical, emotional, psychological, social, educational, or financial harm nor is it likely that there would be any negative effect on family or other relationships. There is no intervention or interaction with the subjects in this study. \*The research could not practicably be carried out without the waiver or alteration because <INSERT STUDY SPECIFIC REASONS>1. The sample size required is so large (e.g., population-based studies, epidemiology trials) that including only those samples/records/data for which consent can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed. 2. The subjects for whom records would be reviewed are no longer followed and may be lost to follow-up3. Not having access to data from all patients would create selection bias and therefore affect the statistical outcome of the research; and\*Whenever appropriate, the subjects will be provided with additional pertinent information after participation |
| **ALTERATION OF HIPPA AUTHORIZATION FOR VERBAL AUTHORIZATION** **Since the study does not Qualify for Waiver of HIPAA Authorization, does the study qualify, per criteria listed below, for alteration of the HIPAA authorization to allow for verbal/oral authorization?** Yes [ ]  No [ ] 1. *The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based in, at least, the presence of the following elements:*
* *An adequate plan to protect the identifiers from improper use and disclosure.*
* *An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and*
* *Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.*
1. *The research could not practicably be conducted without the waiver or alteration and*
2. *The research could not practicably be conducted without access to and use of the protected health information*

***If NO:***Study team must obtain a signature from each subject on the written HIPAA Authorization Form. Provide the study team with the HIPAA Authorization form ***If YES,* include the following statement in the comment field of the Assurance Form.** Alteration of HIPAA Authorization granted under 45CFR164.512(i)(2) to obtain an oral HIPAA authorization. for:[ ]  questionnaires [ ]  the study. **The IRB determined that obtaining written HIPAA authorization would be impracticable because:*****Choose from the following options:*** [ ]  study will be conducted over the phone or via email- making obtaining written HIPAA authorization impracticable. [ ]  study will be conducted in a public area with oral consent under DHHS regulations. Requiring a written HIPAA authorization would seriously limit recruitment. [ ]  the sample size required is so large that including only data for which written authorization can be obtained would prohibit conclusions to be drawn or bias the sample such that conclusions would be skewed. [ ]  of ethical concerns created by the risk of creating additional threats to privacy by having to link otherwise de-identified data with identifiers in order to contact individuals to seek authorization[ ]  other ***explain***       |
| **LIMITED IRB REVIEW**

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| **Is study exempt under 45CFR46.104(d) Category 2iii or 3(i)(c ?** [ ]  Yes [ ]  No**If YES, is the Data Security Plan and Privacy Plan adequate *[per 45CFR46.111(a)(7)]* to protect the privacy interests of subjects and the confidentiality of identifiable data?** [ ]  Yes [ ]  No**Is approval from InfoSec required-if Yes, is InfoSec approval on file?** [ ]  Yes *MUST BE YES*  |

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# **RECRUITMENT**

*If you need additional assistance reviewing the recruitment material use the* [Advertising Approval Checklist](https://research.virginia.edu/sites/vpr/files/2019-08/Advertising_Approval_Checklist.docx)

 *When approved, upload all recruitment material into IRB Pro Enter type of recruitment in IRB Online under Adverts*

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| *Add the following comment to comment field of the determination event.* Approved with this protocol is /are the following recruitment material(s):      . *Insert item as checked below* |
| **Direct Contact by a UVA researcher**[ ]  Recruitment letters/emails[ ]  Telephone Contact Script[ ]  Other direct contact (describe): Information sheet, In person Verbal HIPAA Authorization Script, etc. |
| [ ]  Waiver of HIPAA Authorization is not needed because no health information is accessed or required for this recruitment contact. Recruitment is being distributed via list-serv or other via another individual who has access to emails, or the contact info is publically available.[ ]  The IRB justified the determination that waiver of HIPAA Authorization is appropriate to contact potential subjects because *(all must be checked prior to granting waiver)* [ ]  Contacting subjects involves no more than minimal risk to the subjects because the subjects will be contacted by UVA personnel according to steps outlined in the IRB application.[ ]  The waiver will not adversely affect the rights and welfare of the subjects because the contact will be handled according to the processes outlined in the IRB application and their information will be protected according to the steps outlined in the data security plan. [ ]  Obtaining consent to contact a potential subject before contacting them could not practicably be done without the waiver because it would not be feasible to obtain consent from subjects to contact them prior to contacting them AND[ ]  Whenever appropriate, the subjects will be provided with additional pertinent information after participation. |

# **UNAFFILIATED INVESTIGATOR, ACCESS TO PHI, WAIVER OF CONSENT/HIPAA AUTHORIZATION**

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| ***Does the work to done by the unaffiliated investigator meet the criteria for Waiver of HIPAA authorization?*** [ ]  *Yes* [ ]  *No*1. *The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals, based in, at least, the presence of the following elements:*
* *An adequate plan to protect the identifiers from improper use and disclosure.*
* *An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and*
* *Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.*
1. *The research could not practicably be conducted without the waiver or alteration and*
2. *The research could not practicably be conducted without access to and use of the protected health information*

***IF YES, insert ALL of the following statements into the Comment Field of the Assurance Form.**** *This protocol has been granted a waiver of HIPAA authorization under 45CFR 164.512(i)(2) for the work being done by the unaffiliated investigator.*
	+ *The following HIPAA identifiers will be shared with the unaffiliated investigator:*
	+ *The PHI, deemed to be the minimum necessary to share with the unaffiliated investigator includes*
	+ *Study team must track disclosures to the Unaffiliated Investigator in EPIC.*

***On Regulatory Page mark the following:****HIPAA- Identifiable-External Disclosure- Tracking Required (no consent)*  |

# **Optional Review Checklist**

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| **See AG 3-1 for Additional Information to use during review. All responses should be YES or NA** | **YES** | **NO** | **NA** |
| Application Question 1: Are all items under #1 checked NO? | [ ]  | [ ]  |  |
| Application Question 2: Are all items under #2 checked NO?  | [ ]  | [ ]  |  |
| Application Question 3: Is the Brief Summary complete?* Is the purpose of THIS project clearly stated?
* Are the sources of data/methods of data capture/collection provided and consistent with the Data Security Plan
* Are the data elements/points to be captured/collected provided and is this information consistent with the Data Security Plan?

*(TIP: If no health information/specimens are being collected, the study may qualify for SBS review.)* | [ ]  | [ ]  |  |
| Application Question 4: Is at least one of the EXEMPT CRITERIA checked YES and is it consistent with the information provided per the information in the Application? [ ]  Study will be approved under *Category #2iii, 3(i)(c). A limited IRB Review by a Board Member will be required. Refer to the instructions below under the section entitled Limited IRB Review.** *If Category 3 is chosen, IRB staff should refer to* [*SACHRP Recommendations on Benign Behavioral Intervention*](https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html) *. If Category 3iii is chosen, the study team must submit the agreement provided to the subject for the subject to authorize deception.*
 | [ ]  | [ ]  |  |
| Application Question 5: Is NA OR A, B or C checked and is this response consistent with the information previously provided in the application? | [ ]  | [ ]  |  |
| Application Question 6: If the response was YES, were surveys, interview questions and recruitment materials submitted for review as applicable?  | [ ]  | [ ]  | [ ]  |
| Application Question 7: Is the YES box checked?  | [ ]  | [ ]  |  |
| Application Question 8: Is there a response checked either YES or NO and is this response consistent with the information previously provided in the application and in the Data Security Plan? * If checked YES is question 9 blank, does question 10 have a response and is Appendix D completed and consistent with the information previously provided in the application and in the Data Security Plan?

OR* If checked NO does question 10 have a response?

*If question 8 is NO, then HIPAA does not apply for this study because no health info is collected*  | [ ]  | [ ]  |  |
| Application Question 9: Is there a response either YES OR NO and is the response consistent with the sum of the information in the application and Data Security Plan?* If checked YES, is there a response to question 10 and is Appendix D completed?
* If checked NO, is there a response to question 10?
 | [ ]  | [ ]  |  |
| Application Question 10: Is there a response either YES OR NO and is the response consistent with the sum of the information in the application and Data Security Plan?* IF checked YES, is there a response to question 11 and is Appendix D completed?

If checked NO, is there a response to question 11?  | [ ]  | [ ]  |  |
| Application Question 11: Is there a response either YES OR NO and is the response consistent with the sum of the information in the application and Data Security Plan?* If checked YES, is Appendix D completed?
 | [ ]  | [ ]  |  |
| * Application Question 12: Is there a response YES or no and is this response consistent with the sum of the information in the application? If Checked YES, is Appendix E completed?
 | [ ]  | [ ]  |  |
| Is the Investigator Agreement box is checked?  | [ ]  | [ ]  |  |
| Is Application Appendix A either:* completed because Application Question 5b is checked and the information is consistent with the information in the Brief Summary and the Data Security Plan?
* blank?

*(Tip: Application Appendix A should be blank unless UVA is receiving data from an outside institution)* | [ ]  | [ ]  |  |
| Is Application Appendix B either:* completed because Application Question 5c is checked and the information is consistent with the information in the Brief Summary and the Data Security Plan ?
* blank?

*(Tip: Application Appendix B should be blank unless UVA is sending data outside of UVA.)*  | [ ]  | [ ]  |  |
| Is Application Appendix D:* completed because Application Question 4, Category 4iii is checked?
* completed because Application Question 8 is answered YES?
* blank?

*(Tip: Application Appendix D should be blank unless Application Question 4, Category 4iii is checked or Application Question 8 is answered YES)**If Application Appendix D is required, then use the section of this form entitled Appendix D to review.* | [ ]  | [ ]  |  |
| **APPENDIX D [ ]  NA- Appendix D is not required for this submission** |
| Is Appendix D, Question 1 answered YES?  | [ ]  | [ ]  |  |
| Does Appendix D, Question 2 have a response and is the response consistent with the information previously provided in the Application and in the Data Security Plan?  | [ ]  | [ ]  |  |
| Is Appendix D, Question 3 answered YES?  | [ ]  | [ ]  |  |
| Is Appendix D, Question 4 answered and is this response consistent with the Brief Summary and the Data Security Plan?* If Question 4 is YES, is Table A completed?
* If Question 4 is NO or is NA , is Table A blank?
 | [ ]  | [ ]  |  |
| Is Appendix D, Question 5, Table B completed and are the responses consistent with the information provided in the Application and the Data Security Plan?  | [ ]  | [ ]  |  |
| Is Appendix D, Question 6 answered and consistent with the information provided in Question 5, Table B? * If Question 6 is answered NO and ALL identifiers in Table B are checked NO, is the remainder of Appendix D blank? Is so, the IRB Reviewer should skip to the next REVIEW SECTION of this form.
* If Question 6 is answered YES or NO, and if at least 1 identifier is checked in Table B is a response present in question 7?

IF DATA COLLECTED ARE DEIDENTIFIED THE REST OF APPENDIX D SHOULD BE BLANK  | [ ]  | [ ]  |  |
| Is Appendix D, Question 7 completed and consistent with the information provided in Table B? * If Question 7 is answered YES is question 8 completed?

 If Question 7 is answered NO is question 8 blank and information is present in Question 9? | [ ]  | [ ]  | [ ]  |
| Is Appendix D, Question 8 completed and consistent with information in the Application and Data Security Plan? (*Answer NA if Question 7 is NO)* * If Question 8 is answered YES was a Written HIPAA Authorization Form and Information Sheet submitted?
* If Question 8 is answered NO are Question 9 and Appendix E completed?

*If Application Appendix E is required, then use the section of this form entitled Appendix E to review.* | [ ]  | [ ]  | [ ]  |
| Is Appendix D, Question 9 completed and consistent with the information present in the Application and Data Security Plan?* If Question 9 is answered YES does question 10 list identifiers in the comment field?
* If Question 9 is answered NO is question 10 blank
* If Question 9 is answered NO is the response to question 10 blank?
 | [ ]  | [ ]  | [ ]  |
| Is Appendix D Question 11 completed and consistent with the information in the Application and Data Security Plan?* If Question 11 is answered YES is a reason for sharing provided in the text field?
* If Question 11is answered NO is no reason for sharing provided or checked NA
 | [ ]  | [ ]  | [ ]  |
| Is Appendix D, Question 12 completed and consistent with the information present in the Brief Summary and the Data Security Plan?* Is Question 12 answered YES OR
* Is Question 12 answered NO, Question 8 answered YES and a written HIPAA Authorization and Information Sheet provided?
 | [ ]  | [ ]  | [ ]  |
| **APPENDIX E [ ]  NA- Appendix E is not required for this submission** |
| Is Appendix E All questions are completed and the responses are consistent with information present in the previous sections of the Application?  | [ ]  | [ ]  |  |
| Is Appendix E Question 3 completed and does the response provide adequate explanation as to why the research could no practicably be conducted without access to PHI is also consistent with the information present in previous sections of the Application?  | [ ]  | [ ]  |  |
| **APPENDIX F [ ]  NA- Appendix F is not required for this submission** |
| Appendix F Question 1 and/or 2 are answered YES if Application Question 12 is answered YES and all sub questions are addressed in a manner consistent with sum of the information present in the application.  | [ ]  | [ ]  |  |
| **APPENDIX G [ ]  NA- Appendix G is not required for this submission** |
| Protocol Builder questions indicate there is a support source or sponsor and Exempt application header section indicates YES for support or sponsorship from outside of UVA and Appendix G is completed with information that is consistent with the rest of the information provided in the Application.  | [ ]  | [ ]  |  |