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| **DETERMINATION OF UVA AGENT FORM** |

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| **INFORMATION ABOUT THIS FORM**  Used to determine if UVA personnel are working as an Agent\* for UVA on anticipated project.  ***\*Agent-*** *all individuals (including students) performing institutionally designated activities or exercising institutionally delegated authority or responsibility.*  If it is determined that UVA personnel are working as an Agent\* for UVA, then the study team will be required to provide an additional submission to the IRB-HSR, unless the project is determined to not involve human subject research. See [UVA Non-Human Subject Research Online Tool.](https://redcapsurvey.healthsystem.virginia.edu/surveys/?s=EAFEDMEEFD)  Email completed form to [irbhsr@virginia.edu](mailto:irbhsr@virginia.edu) for IRB review. |

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| Name of Individual to be Working on Project: |  |
| UVA Email: |  |
| Phone: |  |
| Project/Protocol Title if Known: | Unknown or  Title: |
| List your UVA School or Department affiliation *(e.g., Nursing, Medicine, etc.)* |  |
| Name of the Division *(if applicable)*  *(e.g., Anesthesia, Graduate Studies etc.)* |  |
| Explain your role in the project:  (200 words or less) |  |
| Explain the reason for traveling to the outside institution. |  |

**INSTRUCTIONS: Complete the applicable option below:**

**Option A: Typically used by UVA personnel who are asked to assist with a research study after arriving at the non- UVA institution. (e.g., resident doing rotation at another institution)**

**Answer the following questions:**

**Yes No**  I was involved in the design of this research project.

**Yes No**  A UVA IRB has approved this research. IRB-HSR/UVA Study Tracking #

**Yes No** Funding to conduct this research will come from or through UVA.

**Yes No** Working on this research is required for my degree program.

**I confirm that:**

**Yes No**  I am a student, employee, or faculty member of the University of Virginia.

**Yes No**  My work on this project will be overseen by the Principal Investigator and the IRB at the outside institution. This includes completing any training in human subject research protection or other training as required by the outside IRB.

**Yes No**  I will communicate with the UVA IRB and UVA Contracts Office for my school, to determine what approvals may be needed, prior to receiving any data from the outside institution

**Option B: Typically used by graduate students conducting their research outside of UVA.**

**I confirm that:**

Yes No I designed this research.

Yes No I am a student, employee or faculty member of UVA but am employed by another institution.

Yes No All subjects will be enrolled at this outside institution.

Yes No Only de-identified data may be brought to UVA. If data is brought to UVA, it will be protected according to UVA Data Security Policies.

Yes No The research will be overseen by their IRB and, if applicable, their HIPAA Privacy Board. This includes completing any training in human subject research protections or other training as required by the outside IRB.

Yes No There is no funding for this study or if there is funding, it will be handled by the non- UVA institution at which I am employed.

Yes No I have notified the outside IRB that a UVA IRB will not be overseeing my work.

ATTACH COPY OF THE OUTSIDE IRB APPROVAL/DETERMINATION.

**Option C: Typically used by a person who will continue working on their research at their previous institution after transferring to UVA. No research protocol will be opened to enroll additional subjects at UVA.**

**I confirm that:**

Yes NoI am a student, employee, or faculty member of UVA but I was employed by another institution when the research was begun.

Yes NoAll subjects were or will be enrolled at the outside institution & all data will remain there.

Yes NoThe research will be overseen by a non-UVA IRB and, if applicable, the HIPAA Privacy Board of my previous institution. This includes completing training in human subject research protections or other training as required by the outside institution.

Yes NoThere is no funding for this study or if there is funding, it will be handled by my previous institution.

Yes NoI have notified the IRB of Record that I have transferred to UVA and that a UVA IRB will not be overseeing my work on this research protocol.

ATTACH COPY OF THE OUTSIDE IRB APPROVAL/DETERMINATION.

**Option D: Typically used by a UVA Faculty member who has an appointment or clinical privileges at another institution. Research to be conducted at outside institution. Research protocol will not be opened to enroll subjects at UVA facilities.**

**I confirm that:**

Yes No I am a faculty member of UVA and I have an appointment or clinical privileges at another institution.

Yes No All subjects will be enrolled at the other institution and all data will remain there.

Yes No The research will be overseen by a non-UVA IRB and, if applicable, the HIPAA Privacy Board of the other institution. This includes completing any training in human subject research protections or other training as required by the other institution.

Yes No There is no funding for this study or if there is funding, it will be handled by the other institution.

Yes No I have notified the IRB of Record that a UVA IRB will not be overseeing my work on this research protocol.

ATTACH COPY OF THE OUTSIDE IRB APPROVAL/DETERMINATION for this protocol.

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| **FOR IRB-HSR OFFICE USE ONLY** | |
| UVA personnel are not considered to be conducting research as an Agent for UVA on this project.  No approvals from the UVA IRB-HSR are required.  No data may be brought back to UVA for any purpose except as described above.  If you wish to collect and use data from the original study for an additional research project, you must obtain IRB approval from the IRB-HSR before taking data outside of the UVA institution. | |
| UVA personnel are conducting research as an Agent for UVA on this project.  Submit a research application to the UVA IRB-HSR. | |
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| Name of IRB Chair, Director, or Designee | Date |