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Description automatically generated

**Research Protections Office**

**External Study Team Member Information**

Definition: External study team member – is an individual, not employed by UVM, conducting research activities on a research protocol in collaboration with a current UVM researcher as the lead. Information about adding an external study team member to your project can be found in Section [13.7](https://www.uvm.edu/rpo/irb-policies-and-procedures?_gl=1%2A4bmol0%2A_gcl_aw%2AR0NMLjE3MTgzMDc5NzUuQ2owS0NRandzYXF6QmhEZEFSSXNBSzJncW5mSHE3Sk1BWjJaV1MzZHZfVnE0VkVwVzBOVzlOb3pwX2FGX21lTlVUWEtFMnFSS29VTm5ROGFBbjFXRUFMd193Y0I.%2A_gcl_au%2AMTY4NDg1NDI2My4xNzEzMjkyMDgz%2A_ga%2AMTY1MDgyNzkzMi4xNzEzMjkyMDg0%2A_ga_G3S3K4BJ32%2AMTcxODY0MzM0Ny44OS4xLjE3MTg2NDM0OTguNTMuMC43MzcyMDUzNjE.%2A_ga_4JTET9KDVF%2AMTcxODY0MzM0Ny43Ny4xLjE3MTg2NDM0OTguNTMuMC4w&_ga=2.51167017.1472132751.1718627701-1650827932.1713292084#13p7) of the IRB Policies and Procedures manual.

Complete the form and upload it to question #2 on the Study Team Member page in UVMClick.

|  |  |
| --- | --- |
| Name of UVM PI |  |
| Protocol Study Number & Title |  |
| Date Form Completed |  |

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| 1. **External investigator information** | | | | | | | | | | | | | | | | | | | | | |
| Name: | |  | | | | Phone: | | | |  | | | | | | | | |
| Email: | |  | | | |  | | | | | | | | | | | | |
| 1. **Is the individual engaged by the regulatory definition** | | | | | | | | | | | | | | | | | | | | |
| Is the external team member relationship with this UVM project contractual or collaborative in nature? | | | | |  | Contractual | | | | | | | |  | | Collaborative | | | |
|  |  | |
| If contractual, explain what services are being provided and whether there is research participant or data interaction. | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | |
| Is this external member/institution receiving a subaward from UVM? | | | | | | | | | | | | |  | | Yes | | |  | No |
| Describe this person’s assigned research activities. | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | |
| Will this person need access to UVMHN hospital resources? | | | | | | | | | |  | | Yes | | | | |  | No | |
| Will this person need access to medical records (PHI)? | | | | | | | | | |  | | Yes | | | | |  | No | |
| Will this person have access to individual direct identifiers? | | | | | | | | | |  | | Yes | | | | |  | No | |
| If any of the above are answered “yes,” explain below. | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | |
| 1. **Determining who will provide IRB oversight for this individual’s research activities** | | | | | | | | | | | | | | | | | | | | | |
| Is this person acting as an individual or as an agent of their institution? | | | | | | | |  | Individual | | | | | | | |  | Institution | |
|  |  |
| Does the institution have an IRB? | | | | | | | |  | Yes | | | | | | | |  | No | |
| Provide the name of the institution and, if applicable, contact information for the IRB. | | | | | | | | | | | | | | | | | |
| Institution: | |  | | | | | | | | | | | | | | | |
| IRB Contact Information: | |  | | | | | | | | | | | | | | | |
| 1. **Required Training** | | | | | | | | | | | | | | | | | | | | | |
| Human subjects, good clinical practice training and UVMHN hospital credentialing, as applicable, is required prior to approval of the external team member. The required training for researchers is outlined in [Section 5.4 CITI Training Requirements](https://www.uvm.edu/rpo/irb-policies-and-procedures?_gl=1%2A4bmol0%2A_gcl_aw%2AR0NMLjE3MTgzMDc5NzUuQ2owS0NRandzYXF6QmhEZEFSSXNBSzJncW5mSHE3Sk1BWjJaV1MzZHZfVnE0VkVwVzBOVzlOb3pwX2FGX21lTlVUWEtFMnFSS29VTm5ROGFBbjFXRUFMd193Y0I.%2A_gcl_au%2AMTY4NDg1NDI2My4xNzEzMjkyMDgz%2A_ga%2AMTY1MDgyNzkzMi4xNzEzMjkyMDg0%2A_ga_G3S3K4BJ32%2AMTcxODY0MzM0Ny44OS4xLjE3MTg2NDM0OTguNTMuMC43MzcyMDUzNjE.%2A_ga_4JTET9KDVF%2AMTcxODY0MzM0Ny43Ny4xLjE3MTg2NDM0OTguNTMuMC4w&_ga=2.51167017.1472132751.1718627701-1650827932.1713292084#5p4). The UVM IRB will consider other forms of education in the protection of human subjects on a case-by-case basis.  If the external team member must access data or resources from UVMMC, they must complete hospital credentialing found at [Office of Clinical Trials Research](https://www.med.uvm.edu/clinicaltrials/credentialing). | | | | | | | | | | | | | | | | | | |