**Welcome! Thank you for choosing to work with the MHealth CRU for your research.**

We know that you are anxious to get started on your research study.  We want to set your study up as efficiently as possible while ensuring the highest quality & integrity in the services we provide.  Our study set-up process is summarized below. We will help guide you through each step.

**What is the Process to Get a Study Set-Up to Use the CRU?**

Understand Your Study

Prepare Study Training and Visit Materials

Training

Schedule and Conduct Visits!

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| --- | --- | --- | --- | --- |
| **What Should I Expect?** | Please send us your source documents once drafted. Templates of the CRU required format are provided for your convenience. | We will work to ensure your study materials are ready for training and visits. This includes: preparing a protocol training summary, re-formatting your study source documents into the CRU template\*, and preparing lab processing documents *(if applicable).* | CRU staff reviews all protocols before working on a study. You will also be asked to present a study in-service as needed to ensure that CRU staff understands your study, source documents and lab processing instructions. | Once training is complete, you can schedule visits!  If you need a facility tour or scheduling system training please let us know! |
| **What is Required?** | * Current Study Protocol * Identification what visits/procedures will occur in the CRU * Draft of Source documents | * Study Source Documents * Study Lab Processing Manuals/Instructions | * IRB supplement (if applicable) * IRB Approval * IRB approved ICF * Completed Source Documents, Lab Processing Instructions * Approval of Protocol Training Summary | * For each visit, you will need to upload the source documents with the appointment. **The PI or designee will be responsible for ensuring that all documents uploaded to the scheduling system are correct.** * Signed Consent Form (for screening visits the ICF can be provided at the time of the visit) * Medical Record Number (MRN) |

\*To ensure the highest quality in services, we require source documents and lab processing manuals be in our CRU standard template. If you need assistance in translating your study source documents and lab processing manuals into the CRU format, our team will be happy to help your get your materials ready.\*

**Studies are responsible for ensuring they have reviewed and comply with all University policies relating to research execution. These can be found at:** [**http://policy.umn.edu/Policies/Research/index.htm**](http://policy.umn.edu/Policies/Research/index.htm)

**Who Do I Contact If I Have Questions?**

Kayla Harrison, RN or Lisa Anderson, RN will be your contact. You can reach them at (612) 624-0104 or [kharriso10@umphysicians.umn.edu](mailto:kharriso10@umphysicians.umn.edu) or [landerso11@umphysicians.umn.edu](mailto:landerso11@umphysicians.umn.edu)

In their absence, you can reach out to: Adi Molvin, CRU Manager (612)-626-9142 or [amolvin10@umphysicians.umn.edu](mailto:amolvin10@umphysicians.umn.edu)

**We look forward to working with you to make your research a success!**