This guide is intended for use by any UofL employee or student (1) with dual appointment at the Robley Rex VA Medical Center (VAMC), Louisville, KY and the University of Louisville regardless of full time or part time, or are compensated or uncompensated, or (2) that involves other VA personnel or uses other VA resources, that will be performing research on human subjects.

All human studies being conducted at the VAMC must be approved by the Research and Development Committee (R&D) subcommittee, Human Studies-HSS/IRB. If a subject is at a local facility other than the VAMC (e.g. Jewish Hospital, Norton Healthcare, University Hospital), and the VA is paying for the services they are still considered a VA subject. The subject to be enrolled must be enrolled on an approved VAMC consent form. If the subject is at a local facility, on their own private insurance, then the subject can be enrolled on an approved UofL IRB consent form. For questions regarding their submission process, please call 502-287-5118.

**Chart Review Studies**

- If you will be performing a retrospective and/or a prospective chart review study on subjects that are only seen at the VAMC or VA clinics, you do not need to submit paperwork/documents to the UofL Institutional Review Board (IRB).
- If you will be reviewing charts at both VAMC and UofL clinics, in addition, to other facilities such as Jewish hospital, University Hospital, or Norton Healthcare; please complete a study application in the UofL electronic submission system. Please make sure to include a copy of the VAMC R&D approved documents and letter.

**Specimen Studies**

- If you are collecting specimens on subjects that are only seen at the VAMC or VA clinics and not storing anything at UofL, you do not need to submit paperwork/documents to the UofL Institutional Review Board (IRB).
- If you are collecting specimens on subjects that are only seen at the VAMC or VA clinics and storing and/or analyzing specimens in a UofL facility, please complete a study application in the UofL IRB electronic submission system. Please make sure to include a copy of the VAMC R&D approved documents and letter. The subjects will be consented with the VA approved consent documents.
- If you are collecting specimens on subjects that are seen at the VAMC or VA clinics and UofL clinics, in addition, to other facilities such as Jewish Hospital, University Hospital, or Norton Healthcare and storing/analyzing the specimens in a UofL facility, please complete a study application in the UofL IRB electronic submission system. Please make sure to include a copy of the VAMC R&D approved documents and letter. You will need to use the VA approved consent documents for the VA subjects and the UofL approved consent documents for all other subjects.
- If you are collecting specimens on subjects that are seen at the VAMC or VA clinics and UofL clinics, in addition, to other facilities such as Jewish Hospital, University Hospital, or Norton Healthcare and storing the specimens in a VAMC facility, please complete a study application in the UofL IRB electronic submission system. Please make sure to include a copy of the VAMC R&D approved documents and letter. You will need to use the VA approved consent documents for the VA subjects and the UofL approved consent documents for all other subjects.
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**Any other study**

- If you are enrolling subjects that are only seen at the VAMC or VA clinics and all follow-up procedures will be completed at the VAMC, but you are a UofL employee or student; you do not need to submit paperwork/documents to the UofL Institutional Review Board (IRB). You, however, MUST obtain VA R&D committee approval.
- If you are enrolling subjects that are at the VAMC or VA clinics and UofL clinics, in addition to other facilities such as Jewish Hospital, University Hospital, or Norton Healthcare, please submit a study application in the UofL electronic submission system. You will need to use the VA approved consent documents for the VA subjects and the UofL approved consent documents for all other subjects. (If the study is an industry sponsored study, please note the VA would be considered a separate site, its own site. The VA will require a separate contract via its NPC with the drug company. Contact UL Clinical Contracts Division at 502-852-8359 and/or the VA Clinical Research Foundation at 502-287-6260)

**Study Funded by the VA**

If a study is funded by the VA (i.e. MERIT) and any part is conducted at UofL facilities, using Veterans and/or non-Veterans, you must use the VA consent and HIPAA Authorization forms and must also use the UofL IRB approved consent forms.

**UofL Electronic submission system**

https://iris.louisville.edu