

Submission Guidance for studies in Collaboration with TJU

Action	LVHN is Reviewing IRB	TJU is Reviewing IRB
Start Up of a New Study	<p>Step 1: Submit a request to Karla Glagola, Director of the Office of Research Integrity (ORI), for LVHN to serve as the IRB of Record via email at Karla.Glagola@lvhn.org .</p> <ul style="list-style-type: none"> • Include the Statement of Work (Completed by the TJU PI in collaboration with the LVHN PI) <p>After submission, you will receive communication from the Director of the ORI via email.</p> <p>Step 2: Departmental Scientific Review</p> <p>Step 3: NORI Feasibility</p> <ul style="list-style-type: none"> • Include the following documents: <ul style="list-style-type: none"> ○ Statement of Work (Completed in Step 1 above) ○ *TJU Authorization to Submit to LVHN (signed version provided by TJU) <p>* This form will be signed by a representative from TJU's JOHRP Office.</p> <p>Step 4: IRB Review</p> <ul style="list-style-type: none"> • Create a New Study in eIRB <ul style="list-style-type: none"> ○ Indicate "Multi-Site or 	<p>Step 1: Submit a request to Karla Glagola, Director of the Office of Research Integrity (ORI), to cede authority via email at Karla.Glagola@lvhn.org .</p> <ul style="list-style-type: none"> • Include the Statement of Work (Completed by the LVHN PI in collaboration with the TJU PI) <p>After submission, you will receive communication from the Director of the ORI via email.</p> <p>Step 2: Departmental Scientific Review</p> <p>Step 3: NORI Feasibility</p> <ul style="list-style-type: none"> • Include the following documents: <ul style="list-style-type: none"> • Statement of Work (Completed in Step 1 above) • *TJU Certification of Local Context • *LVHN Authorization to Submit to TJU <p>* These forms will be reviewed and signed by a representative from the ORI during the NORI Feasibility Review. The signed documents will be provided along with the NORI Feasibility Approval.</p> <p>Next Step:</p> <ul style="list-style-type: none"> • LVHN Investigator will provide the TJU Investigator the signed forms referenced above. • The TJU Investigator will complete TJU required action. • The TJU investigator will provide the LVHN investigator with the TJU IRB Approval. <p>Step 4: LVHN IRB Review</p> <ul style="list-style-type: none"> • Create a New Study in eIRB

	<p>Collaborative Study” in Question #4- What kind of study is this?</p> <ul style="list-style-type: none"> ○ Indicate “No” in Question #5- “Will an external IRB act as the IRB of record for this study.” ○ Indicate “Yes” in Question #6- “Will your IRB act as a single IRB of record for other participating sites?” ○ Add “TJU” as a Research Location under the “Local Research Locations Page”. <ul style="list-style-type: none"> • Upload the Statement of Work & TJU Authorization to Submit to LVHN under Local Study Team Members > External team member information:. <p>Next Step:</p> <ul style="list-style-type: none"> • The LVHN PI and study team are responsible for providing the TJU investigator with all IRB-approved materials. • The TJU Investigator will complete TJU required action in iRIS. 	<ul style="list-style-type: none"> • Indicate “Yes” in Question #5- Will an external IRB act as the IRB of record for this study? • On the “External IRB” page, indicate TJU will serve as External IRB <ul style="list-style-type: none"> • Upload the TJU IRB Approval • Statement of Work (Completed by the LVHN PI)
Addition or removal of staff	<p>Follow the standard LVHN process for Adding Study Team Members in the eIRB system.</p> <ul style="list-style-type: none"> • Upload the Statement of Work & *TJU Authorization to Submit to LVHN (signed version provided by TJU) under Local Study Team Members > External team member information:. <p>* This form will be signed by a representative from JOHRP.</p>	<p>Email the following forms to IRB_Office@lvhn.org:</p> <ul style="list-style-type: none"> • (Completed by the LVHN PI in collaboration with the TJU PI) • *TJU Certification of Local Context • *LVHN Authorization to Submit to TJU <p>* These forms will be reviewed and signed by a representative from the ORI.</p> <p>Provide signed forms to TJU Investigator.</p> <p>TJU Investigator to follow the standard TJU process for Adding Study Team Members.</p>

