	STANDARD OPERATING PROCEDURES			
	WEST JEFFERSON MEDICAL CENTER ANCILLARY REVIEW			
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PURPOSE

This procedure establishes the process for review of an application involving LSU Health Sciences Center (HSC) investigators performing research at West Jefferson Medical Center (WJMC).

1 CONSIDERATIONS

- Initial applications (**protocol types: exempt, expedited, full board, reliance requests**) submitted in Quali Research (KR) that have research activities taking place at WJMC direct users to complete the combined UMCNO/WJMC research application and require UMCNO or WJMC ancillary review approval, as applicable, prior to LSUHSC IRB issuing approval of the study.
- WJMC ancillary review assignment and application display is automated based on performance site and protocol type:
 - o If WJMC is listed as a performance site and UMCNO is NOT, WJMC Research will be added as an Ancillary Reviewer.
 - o If WJMC and UMCNO are BOTH listed as performance sites, ONLY UMCNO will be added as an Ancillary Reviewer (not WJMC Research), as UMCNO will complete the review for both WJMC and UMCNO.
 - o Humanitarian Use Device (HUD) and Expanded Access to a Test Article (EATA) protocols that have WJMC listed as a performance site will not follow the ancillary review process or display the WJMC application; however, the WJMC administrative contact will be added to the permissions tab of the protocol and therefore notified of all activities related to the protocol.
- Post-approval submissions (e.g, amendments, renewals, closures), will not follow the ancillary review process but the permissions tab will be checked during the review process to ensure that the WJMC administrative contact is listed and therefore receives all notifications related to the protocol.


2 PROCEDURES

2.1 LSUHSC IRB Administrative Reviewer Responsibilities

- 2.1.1 Upon receipt of an initial application (all protocol types except NHR), the IRB staff member assigned to review the application will confirm if WJMC is listed as a Performance Site
- 2.1.2 Once WJMC is confirmed as a performance site, IRB Staff will perform the following:
 - 2.1.2.1 Add WJMC Research as the LSUHN administrative contact to the Permissions Tab;
 - 2.1.2.2 Follow the WJMC Ancillary Review Process for Initial Submission Protocol Types: Exempt, Expedited, Full Board, and Reliance Request.

Note: Performance site ancillary reviews are automatically assigned based on the protocol type and performance site conditions stated above:

 - 2.1.2.2.1 If UMCNO is NOT listed as a performance site, WJMC will be assigned as the ancillary reviewer;
 - 2.1.2.2.2 If UMCNO is also listed as a performance site, WJMC will not be added as

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an ancillary reviewer. UMCNO will be added as an ancillary reviewer of the application and their approval will cover both UMCNO and WJMC. Follow the current UMCNO Ancillary Review process.

2.1.2.2.3 *If WJMC was not automatically assigned when applicable, inform IRB Staff KR Administrator of discrepancy and manually assign WJMC as an ancillary reviewer.*

2.1.2.2.4 Post-Approval Submissions are out of scope for the ancillary review process. Instead, when reviewing amendments, renewals, or close requests for any protocol type, IRB Staff will check the permissions tab to ensure that the WJMC administrative contact is listed. If not, add WJMC Research as the administrative contact so WJMC will receive all protocol-related notifications.

ANCILLARY REVIEW PROCESS – EXEMPT, EXPEDITED, FULL BOARD, AND RELIANCE REQUEST PROTOCOLS

2.1.3 If changes and/or more information is requested by WJMC as outlined in the *WJMC Reviewer Responsibilities*, the IRB Staff will create action items within the application requesting these revisions from the study team.

2.1.3.1 Once revisions are submitted back to the IRB, the IRB staff member will change the ancillary review status back to “Pending” to alert WJMC that their requested changes and/or additional information has been provided.

2.1.3.2 This process will repeat itself until all necessary changes have been made and/or all additional information has been provided to WJMC.

2.1.4 Once WJMC provides their ancillary review approval as outlined below, the IRB staff member will approve the research in KR

2.2 WJMC Reviewer Responsibilities

2.2.1 When WJMC Office of Clinical Research receives an email from KR notifying them of assignment as an ancillary reviewer, the WJMC staff member will:

2.2.1.1 Review the combined UMCNO/WJMC application for completion and accuracy, and based on their own internal policies and standards, determine if additional information/changes are required (e.g., data transfer agreement form) or if it is ready for approval.

2.2.1.1.1 If changes and/or more information is needed from the study team, the WJMC reviewer will add a comment to the ancillary review outlining what is needed and change the ancillary review status to “Not Approved Yet.”

2.2.1.1.1.1 *Note: The status must be changed for IRB staff to be alerted of ancillary review update and see what is needed.*

2.2.1.1.2 Once the WJMC Office of Clinical Research approves the research, the WJMC reviewer will change the ancillary review status to “Approved,” alerting the LSUHSC IRB that the research can be approved.