

	<b>Standard Operating Procedures</b>
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Procedure Category:	Pre-Study Activities
Procedure CLN-02-03:	Identification of Appropriate and Qualified Personnel

**Procedure Overview**

This procedure describes the necessary activities performed by the MICHHR to identify and select appropriate and qualified personnel to assist with a specific study. This procedure covers tasks necessary to ensure adequately educated and experienced staffing are available and meet the requirements defined by federal and local agencies and the study sponsor/CRO.

**Responsible Individuals**

Qualified MICHHR personnel (including, but not limited to, RSC Manager and Project Manager); Primary Investigator; Laboratory Manager; Director, MICHHR

**Procedure**

**Identification of Personnel**

1. Review the various aspects of staffing requirements for the specific protocol (refer to SOP CLN-01-03, Assessing Workload/Staffing Requirements).
2. Review MICHHR files or post a position via Human Resources for candidates that meet key terms and the complexity level for the specific protocol.
3. Obtain additional candidates via referrals from the investigator and institutional staff, if needed.
4. Identify candidates that meet or exceed the minimum requirements, as determined by the study sponsor/CRO.
5. Contact the candidates to assess interest, availability, and any other relevant experience or capability (i.e. experience with special testing such as EKGs or PFTs, blood draws, equipment calibrations and/or special certifications/licensing).
6. Assemble the project team. If appropriate and qualified personnel cannot be identified, assess the potential for specific training based on study-specific needs. Review study sponsor/CRO documentation regarding available budget for recruitment and/or training. If resources are not available for recruitment and/or training, contact the primary investigator and study sponsor/CRO to discuss resource limitations and other possible options. If adequate resources are available for recruitment and/or training, refer to CLN-06-04 for guidance on job description development and posting.

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7. Repeat Steps 1-6, as needed, until the project staffing needs have been met. If appropriate and qualified personnel cannot be assembled based on the specific needs of the study, decline participation in the targeted protocol by contacting the primary investigator or study sponsor/CRO.
8. Initiate project team training, as needed, to meet targeted protocol requirements as defined by the study sponsor/CRO and the MICHIR.

### Documentation

Documentation for this procedure includes any documentation generated in the project staffing process, including documentation regarding the project-specific staffing needs, staff attributes, referrals, job descriptions, and communication with the study sponsor/CRO.

### Deviation Approval

The Director, MICHIR or designee, must approve deviation from this procedure. The Director, MICHIR or designee, must store documentation of the deviation approval.

### Relevant Definitions

Key term(s): essential words that identify experience (i.e. cardiovascular, respiratory, research...)

CV: curriculum vitae

### Procedure Author

Manager, Research Support Core

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