

OnCore Staff Tab Updates and Maintenance: Lead Site & Participating Site Responsibilities

Guidelines

- The staff tab is maintained by the lead site in accordance with the Delegation of Authority log.
- Participating sites communicate with the lead site to request updates.
- Updates to the staff tab must be done in a timely manner to ensure that staff have access to their required protocols.

1. Critical addition of staff:

While it is preferable for the lead site to update the staff tab, there may be emergency cases in which this is not feasible. Each site should have senior staff (e.g. Regulatory Coordinator, RM, CTS, etc.) who are able to add staff to the staff tab for trials in which the site is participating. They would then communicate the addition of the staff to the lead site. Critical additions should be an infrequent occurrence.

2. New trials / routine additions of staff:

When staff are added to the DAL an email should be sent to the lead site coordinator indicating that the staff have been trained and added. At that time the lead site would add them to the staff tab in OnCore. This must be done promptly. A follow-up to the lead coordinator should be done if staff are not added in a timely manner.

3. New staff:

The process outlined for #2 above will be followed for new staff who need to be added to trials. In the rare event that staff must be added to such a large number of trials that it is burdensome for the lead site and/or cannot be done in a timely manner, senior staff from the participating site may assist. This should be done with prior approval from the lead site coordinator.

4. Removal of staff:

When staff are removed from the DAL, an email should be sent to the lead site coordinator indicating that the staff have been removed. At that time the lead site will promptly remove them from the staff tab in OnCore. A follow-up to the lead coordinator should be done if staff are not removed in a timely manner. If the removal is due to staff leaving the institution or moving to a role in which they no longer require OnCore access, the participating site will open a ServiceNow ticket for the OnCore team to remove OnCore access.

5. Preparation for decentralization:

During preparation for OnCore decentralization, to ensure that the staff tab of all trials is up to date, it is acceptable for the senior staff of the participating site to update the staff tabs of the trials that will be decentralized. To ensure all other regulatory documents are in place, the participating site must notify the lead site if they update the staff tab.