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The Delegation of Authorities (DoA) Log documents the Investigator of Record (IoR) delegation of roles and responsibilities that will be carried out by staff members for the protocol. This operational guidance serves to document the revision of the Delegation of Authorities Log and rationale for this change.

IoR/designee column:

In prior MTN protocols the DoA Log has commonly included a column to indicate whether each staff member is a designee of the IoR. There is not a clear definition of what it means to be an 'IoR designee' and interpretation of this term has varied across clinical research sites. Given the general nature and breadth of use of this term in our study documents, and lack of a clear definition, it has been determined that this designation will no longer be specified in the DoA Log for ASPIRE. All delegated responsibilities will continue to be clearly outlined in the log via the responsibility codes assigned to staff.

Note that no staff member should fulfill the IoR role in the IoR's absence. Full responsibility and authority over the protocol by anyone other than the IoR may only take place if an additional 1572 is completed and submitted to DAIDS.

The instructions on the DoA Log template have been updated accordingly:

All personnel performing protocol procedures with ASPIRE must be listed on this log. Start and end dates refer to the period during which staff is directly involved with conduct of ASPIRE procedures. ~~'IoR Designee' indicates staff capable of performing IoR duties in absence of IoR.~~ Maintain this roster with study Essential Documents and update as staffing changes occur. This log serves as a legal delegation of trial responsibilities, however delegation assignment does not absolve the site IoR of any regulatory or contractual responsibilities for protocol management and oversight. When staff roles and/or responsibilities change, add an end date to the current line listing, and add the staff member to a new line and list all responsibilities with the new start date.

ECI-1 CRF and corresponding responsibilities on DoA:

The ECI-1 CRF requires signature of the 'Principal Investigator or designee' in item 1a, and a second staff member in item 1b, to indicate that s/he has reviewed all eligibility documentation and agrees that the participant is eligible per protocol. 'Principal Investigator' as referenced in the ECI-1 CRF refers to the IoR at the site. These eligibility determination responsibilities must be outlined in site Eligibility SOPs, and specific staff designated through responsibility codes on the DoA. It is recommended that sites revise responsibility codes to clearly document who is responsible for 'primary determination of eligibility (sign ECI-1 item 1a)' and 'secondary determination of eligibility (sign ECI-1 item 1b)'. The study management team considers eligibility determination to be a critical trial responsibility and recommends that any staff member assigned to one of these roles be clearly listed on the DoA and also included on the FDA 1572 form.

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Other DoA clarifications:

Additionally, sites are requested to review role codes for clinical staff, and use the more specific role of “medical doctor” (also referred to as “medical officer” or “study doctor”) in place of “research clinician” where appropriate. In the ASPIRE protocol, the term ‘clinician’ may refer to any clinical role, including that of nurses in settings where nursing training, scope of practice, and delegation, under doctor supervision, permit nurses to perform clinician activities. Please ensure that country guidelines for nursing scope of practice are reviewed and on file in site regulatory documents.

In the case where the DoA includes a list of staff from multiple clinical research sites (CRSs) as members of a single clinical trials unit (CTU), staff who are primary to the site should be distinguished from staff who are listed in ‘back-up/coverage’ roles.

‘Start Date’ on the DoA must be on or before the first date that any study activities were completed by the staff member. The start date indicates that the IoR has determined the staff member to be delegated and trained to perform the responsibilities listed.

Sites are requested to update their DoA logs upon receipt of this guidance and submit to FHI 360 for review.

All Operational Guidance documents must be printed and filed with regulatory documentation.