

Sample repository plan SEA050 (Sepsis study): Thailand and Viet Nam

What samples will be stored in the repository:

All samples collected from the SEA050 sepsis study subjects in Thailand and Viet Nam that are remaining in storage at the Vietnam and Thailand reference laboratories used for the sepsis study. These remaining samples include whole blood, serum, plasma, stool, sputum, respiratory tract swab, and CSF. We will also maintain the blood samples collected from adult study subjects that have signed a separate consent form for their blood to be stored for future genetic testing.

How many samples will be stored:

There are approximately 20,100 vials of these samples from Thailand and Viet Nam contained in 250 cryo-boxes. These will be stored in the study at the repository services (see below). Detailed information about the type and amount of the stored samples is attached to this plan.

Where the samples will be stored:

After the Sepsis contract ends on April 30, 2016, the three reference laboratories that supported the Sepsis study, as detailed below, have agreed to serve as the repository sites for all the remaining study samples which may be used for future testing in Thailand and Viet Nam.. They have agreed to store these samples for the next 3 years:

- MORU laboratory will be the repository site for the samples from the Chiang Rai site and the Ubon site. Those samples are currently held in the MORU laboratory in Bangkok and in the SMRU laboratory in Mae Sot, Thailand. MORU laboratory will also store the remaining and blood samples for genetic testing from all the sepsis sites in Bangkok. Those samples are currently held in the NHL reference laboratory in Bangkok.
- OUCRU laboratory in Hanoi will be the repository site for the remaining and blood samples for genetic testing from all the sepsis sites in Hanoi.
- OUCRU laboratory in HCMC will be the repository site for the remaining and blood samples for genetic testing from all the sepsis sites in HCMC.

When the samples will be placed into the repository sites and how long the samples will be stored there:

We will place all the samples into the designated repository sites as soon as possible but no later than April 30, 2016. The samples will be stored there for three years unless used before that date.

How will the samples be stored?

The samples will be stored under the required controlled temperature and access restrictions during the period of storage. Only authorized staff will have access to the samples (see below). During the period of storage the samples will continue to be tracked using the Freezerworks sample storage system or any other sample tracking system present in all three repositories.

How the network researchers locate and access the samples:

Network investigators who are interested to access the stored sepsis specimens need to send a request email with their study concept to the SEAICRN sepsis protocol committee members listed below. The submitted concept will be shared with all the committee members for their review and approval within a specific timeline notified to the investigator. Access to the stored samples can be granted to the investigator if the proposed study concept is approved by at least 75% of the committee members. If the concept approved, the investigator will be linked to an authorized person from Network repository laboratories for sample sorting and collection. Any costs related with sorting and collection of the required samples will be responsibility of the recipient investigator. The investigator shall submit material transfer agreements (MTAs) or IRB notifications to each relevant study sites if applicable.

The SEAICRN Protocol Committee:

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