DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

Application for Registration, Re-registration or Deregistration of a User Access for the DZHK-IT infrastructure

To apply for a new access or a change to an existing access or to deregister, please fill out this form, have it signed by the coordinating investigator of the study or another authorized person from the project and send it by email to the DZHK.

email: infrastruktur@dzhk.de

Information on the user

last name:		first name:	
phone number:		email-adress:	
enrolling study centre, location:		Project / DZHK-study:	

Trusted Third Party (TTP or THS)

Are there PCs for which existing client certificates are to be used?			
☐ yes (please specify below)		☐ no	
computer name		computer name	
computer name		computer name	

Would you like to have new client certificates issued?	
☐ yes (please specify below)	☐ no
computer name	External IP address (result of the TLS1.2 test https://browser-test.med.uni-greifswald.de/)

I hereby confirm the accuracy of the above information. The client certificates are used exclusively in the context of the specified DZHK study for communication with the DZHK trusted third party.

Clinical Data Management System (CDMS or DH, secuTrial®)

User role in the CDMS system

☐ clinical investigator ☐ study nurse ☐ biomaterial registration

☐ observer ☐ monitor

☐ other _____

☐ inactive

clinical investigator	User may create new patients in the study database. User may create new visits and record and edit patient data. User may sign forms and release them for further quality assurance (Review A).
study nurse	User may create new patients in the study database. Users may create new visits and record and edit patient data. User may completely clarify the data entry of a form and release it for further verification (DEC: Data Entry Complete).
biomaterial registration	User may enter biomaterial data for a patient.
observer	User may open the patient's visit plan and read the patient data.
monitor	User can raise queries, which are then answered and closed after possible queries and new answers.
other	Please only specify defined roles from the rights and role concept of your study.
inactive	User will be deactivated in all centres of which they are members.

Laboratory Information Management System (LIMS, CentraXX)

User role in the LIMS

☐ study nurse ☐ MTLA ☐ monitor

☐ other_____

☐ inactive

study nurse	User may prepare sampling, print labels, process document, provide information on blood collection/urine delivery.
MTLA	User may document sample receipt, centrifugation, aliquoting, storage, retrieval and transfer of samples and create new storage structures for sample storage
monitor	User may view all process steps.
other	Please specify defined role from the rights and role concept of your DZHK study.
inactive	User is inactivated for all DZHK studies.

! If the process steps Study Nurse and MTLA are performed by one person, this person can apply for access for both roles !

Image Data Management System (IDMS aka. BDMS, TrialConnect)

User role in the IDMS

☐ clinical investigator ☐ study nurse ☐ imaging analyst

☐ monitor ☐ coordinating investigator

☐ other _____

☐ inactive

clinical investigator	User may set and cancel signatures for eCRFs. (Study Centre)
study nurse	User completes writeable eCRFs of his institution and uploads DICOM files. (Study Centre)
imaging analyst	User downloads image data and fills and signs eCRFs; sends queries on image data to the study centers if necessary.
monitor	User can raise queries, which are then answered and closed after possible queries and new answers.
coordinating investigator	User receive extensive rights
other	Please specify defined role from the rights and role concept of your DZHK study.
inactive	User will be deactivated in all centres of which they are members

! If a person is to perform the activities of study nurse and clinical investigator, this person may request access for both roles !

We attach great importance to data protection. The collection and handling of your personal data is performed according to the current General Data Protection Regulation (GDPR) in the extent necessary for the execution of the respective project/clinical study. Please find further information on our data protection regulations at dzhk.de at the imprint.

With your signature on this form you confirm that you consent to the processing of your personal data according to the above mentioned conditions

Applicant / user signature:	

Authorization and Confirmation of the Correctness of the Content of the Application

name of authorized person:			
date/location:		Signature of authorized person:	

To be filled in by DZHK System staff!!

Area for Application Processing

date of receipt:		project:	
IT-system:	☐ THS ☐ DH ☐ LIMS ☐ BDMS		
factually correct:	☐ ja ☐ nein		
note:			
processed by:			
date/location:		signature:	

Filling Instructions

Information on the user

First and last name: of the user, who wants to use the client certificates.
Phone number: The user can only request the passwords for installing the client certificates from this telephone connection.
email address: The client certificates are sent to this e-mail address. Please use business addresses only. One client certificate per PC is sent to the user by e-mail.
Enroll site: Address of the enroll site where the computer for which a client certificate is required are located.
Study: Name of the study for which client certificates are to be used.

Trusted Third Party (TTP aka. THS)

Are there computer for which existing client certificates are to be used? If a client certificate already exists for a computer and this should now also be used for the user in the study, then check the box and enter the PC name.
Would you like to have new client certificates issued for PCs? If a client certificate does not yet exist for a computer, but participants are to be created with it, then please mark yes and fill in the following table.
Computer name: name of the computer for which a client certificate is required.
external IP-adress: IP address of the computer that must be activated for communication with the THS in the firewall of the trustee. You can get it by visiting https://browser-test.med.uni-greifswald.de/ from your computer.

Signatures

Date and user signature: Date and signature of the person named under User's details.
Name of the authorized person: Name of an authorized person for the respective study who releases the request. Authorised persons for a study are the respective central study director as well as persons authorised by him/her (see authorization form).