UNIVERSITÀ DI TORINO

Scuola di Medicina

Medcap Policy

Medcap Service policy for Research Electronic Data Capture - School of Medicine, University of Turin

1. This policy defines the general principles for the protection and use of the Medcap Service for the collection, storage and electronic retention of research data at the School of Medicine of the University of Turin
2. The School of Medicine of the University of Turin recognizes the value of biological and / or clinical data produced during scientific research.
3. The School of Medicine of the University of Turin is aware of the importance of data management for maintaining the quality of research and for this purpose it undertakes to develop, apply and maintain the highest operating standards for the collection, storage and data retention.
4. This Policy applies to all spontaneous (non-profit) research projects of the Departments belonging to the School of Medicine who intend to use the Medcap Service.
5. The activities carried out are aimed at collecting, storing and research data retention in order to make them reliable and easily available, in compliance with the FAIR principles (Findability, Accessibility, Interoperability, Reusability). Therefore the protocols for the collection and data retention on the Medcap Service comply with standardized operation procedures (SOPs) and are subject to periodic internal audit checks.
6. To access the Medcap electronic data collection service, it is mandatory for the principal investigator to acquire the favorable opinion of the research projects from the Ethics Committee of reference.
7. The Principal Investigator is responsible for collecting, archiving and preserving research data relating to his/her research projects
8. The Principal Investigator, on behalf of the Director of the Department, is responsible for the Communications of research data Register relating to his/her research projects
9. Access to the system is allowed only to authorized users, through a mechanism of user and password authentication.
10. The management and maintenance of the Service is administered by the following figures and competence scope:
    a. System Administrators:
        i. create new Medcap Department Internal Staff Contact (DISC) system users
        ii. policy compliance audit
    b. Medcap Department Internal Staff Contact (DISC)
        i. acts as unique interface with System Administrator

ii. enrolls new research projects on the system
iii. supports the PI in the implementation of research projects, giving basic guidelines on the platform
iv. creates and manages PIs and recruiting users accounts
v. manage existing users (modifying and disabling the account)
vi. DISC is the only one allowed to associate/disassociate one or more recruiting users to/from the studies they are part of.

c. Principal Investigator
   i. scientific manager of the spontaneous research projects
   ii. responsible for the collection, storage and research data retention research projects
   iii. defines the roles and responsibilities in the data management process of the projects
   iv. policy monitor of the projects
   v. interface with Medcap Department Internal Staff Contact (DISC)
d. Data Manager
   i. Contributes to the compilation, organization, and production of protocols
   ii. Coordinates eCRF design as per established standards
   iii. Builds, tests and validates clinical database
   iv. Prepares reports, statistical comparisons, data charts and other presentation materials
e. Recruiter user
   i. interface with the principal investigator
   ii. inserts the data into the eCRF

11. Service access must take place on the basis of digital identities, assigned to each user (contacts, recruiters, ...) by the University of Turin.
12. The principal investigator and the recruiting user operate only on the studies they are authorized to.
13. The framework and design of the eCRF cards of each study must be designed ensuring only the insertion of anonymous or pseudonymised data. By example, but not limited to, Surname, Name, Tax Code, complete date of birth, medical record number and any other personal data that allows identification of the interested party other than the identification code of the case internal to the research project (pseudonym).
14. The recruiting user inserts the data in the eCRF forms, created by the DISC, taking care of any anonymization or pseudonymisation principle violation.
15. The eCRF cards framework of each study, included on the Medcap service, must comply with the model of the eCRF card approved by the University or Hospital Ethics Committee. Cards that do not comply with this criterion will be closed by the System Administrator.
16. The System Administrator carries out regular audits on compliance with this policy, closes the non-compliant eCRFs and notifies the DISC concerned.
17. In the event that the spontaneous research project is a clinical project and involves the collection of data relating to the participants, is due of the principal investigator maintaining and preserving confidentiality by the use of the standardized operating procedures (SOPs) as follows:
    a. Potential participants will be identified at the time of the scheduled visit at the reference premises (clinics, departments, ...) associated with the study
    b. Eligible participants will be invited to participate in the study by their specialist or by a member of the clinical and / or research team and will be provided with an information sheet with the study details.

c. Following the acceptance of participation in the study and the signature of the informed consent, a unique "identification code of the study participant" will be created for each participant.
d. pseudonym management is an internal activity of each individual recruiting center and is beyond the treatment carried out with the Medcap Service

18. The collected data will be kept for the duration of the research project and for reporting purposes in compliance with sector regulations and until the research purposes are achieved.
19. This Policy relating to the correct use of the Medcap Service for electronic data collection comes into force from the date of subscription and will be updated at least annually.

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