eResearch M REGULATORY MANAGEMENT SAND

Edit: Application - HUM00009240

Note *(0 Notes Total)*

Hide Help

11. Confidentiality / Security / Privacy

11.1* Will the study team access any data that is linked to a subject's identity by name or other identifier or code? ***[Require Section 11-1]***

(•) Yes ( ) No Clear

NIH guidance on identifiable information

Additional Help

11.2* Explain how the subjects' privacy will be protected.

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Privacy is defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. In the context of research, this primarily pertains to methods used to obtain information about subjects or the setting in which research takes place.

Additional Help

11.3* How will the study team protect research records, data, and / or specimens against inappropriate use or disclosure, or malicious or accidental loss or destruction in order to protect the confidentiality of subject data?

Select all that apply:

- [x] Locked office
- [x] Locked cabinet or storage unit
- [x] Restricted access
- [ ] Destruction of source data immediately after data collection (e.g., to preserve anonymity of a vulnerable population)
- [ ] Restrictions on copying study-related materials
- [ ] Access rights terminated when authorized users leave the project or unit
- [ ] Secure laptop
- [ ] Individual ID plus password protection
- [ ] Routine electronic back up
- [ ] Disaster recovery plan
- [ ] Encryption of digital data
- [ ] Network restrictions
- [ ] No non-UM devices are used to access project data, or any that are used to access project data use secure connections to communicate with U-M services (e.g. VPN – “virtual private network”)
- [ ] Security software (firewall, anti-virus, anti-intrusion) is installed and regularly updated on all servers, workstations, laptops, and other devices used in the project
- [ ] Safe disposition/destruction of data or devices, as appropriate (e.g., shredding paper documents, destroying disks or thumb drives, secure erasure of electronic media)
- [ ] Offsite storage
- [ ] Climate-control environment
- [ ] Other

Records and data include informed consent documents, case report forms or study flow sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordings of subjects, labeled specimens, data about subjects, subject identifiers, etc.

If you are storing data on a laptop or thumb drive, please refer to Guidelines for mobile device security for researchers.

If other please specify:

11.4* Will the research generate information that, if revealed, might place the subjects at risk of personal safety, criminal or civil liability, or damage to their financial standing, employability, or reputation [Require Section 11-2]

( ) Yes (•) No Clear

Examples of information, that if disclosed, might pose a risk to subjects include sexual matters, use of alcohol or drugs, stigmatizing or discriminating medical or mental health information. If you are applying for a

11.5* Will data be provided to a repository as part of a data sharing agreement?

(•) Yes ( ) No Clear

A repository is a collection of data/specimens that are collected, stored and disseminated for research purposes. Researchers may be obligated by grant, contract or other agreement to submit data/ specimens to a repository. For example, see National Human Genome Research Institute (NHGRI) or NIH Genome-Wide Association Studies (GWAS) Database of Genotype and Phenotype (dbGaP). Submission of data/specimens to certain repositories may require additional IRB certifications.

11.5.1* Please indicate the repository:

Select all that apply:

- [x] GWAS/dbGap
- [ ] NHGRI
- [ ] ICPSR
- [ ] Other

If Other, please specify:

11.6* What will happen to the data and/or any specimens at the conclusion of this study?

Select all that apply:

- [x] Destroy
- [x] Retain for study recordkeeping purposes
- [ ] Retain for future research use - requires Section 11-4

For information on retention periods, refer to the record keeping guidelines. Records retained for future use may be retained by the researcher or in a research bank or repository.

11.6.1* If the data and/or specimens will be destroyed, describe the specific plan that will be employed following the required retention period.

THIS QUESTION IS REQUIRED IF YOU ANSWER 11.6 "Destroy."

For information on retention periods, refer to the record keeping guidelines. If the data/specimens will be destroyed after the required retention period, describe the plan for destruction.

11.6.2* If the data and/or specimens will be retained for study recordkeeping purposes, provide the following information (if covered in the attached protocol, please indicate section):

- expected duration of the retention period,
- any changes in the conditions or arrangements for storage of research data/specimens during the retention period, if different from those listed above in question 11.3.

THIS QUESTION IS REQUIRED IF YOU ANSWER 11.6 "Retain for study recordkeeping purposes"

For information on retention periods, refer to the record keeping guidelines.