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11. Confidentiality/Security/Privacy

Hide

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 contr over the extent, timing, and circumstances sharing oneself (physically, behaviorally, o intellectually) with others. In the context of research, this primarily pertains to method used to obtain information about subjects 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:

- [ ] Locked office
- [ ] Locked cabinet or storage unit
- [ ] 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
- [x] Encryption of digital data
- [x] 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 conse documents, case report forms or study flo sheets, survey instruments, database or spreadsheet, screening logs or telephone eligibility sheets, web based information gathering tool, audio/video/photo recordin subjects, labeled specimens, data about subjects, subject identifiers, etc.

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

If other please specify:

Exit Save Continue

11.4* Does either statement apply to this research:

Research has NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable sensitive information, identifiable biospecimens, individual human-level genomic data/biospecimens, or any information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

or

Research does NOT have NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable, sensitive information or identifiable biospecimens that, if revealed, might place the subjects at risk for personal safety, criminal or civil liability, or damage to their financial standing, employability, insurability, or reputation.

[Require Section 11-2]

○ Yes ● No Clear

Examples of information that, if disclosed, might pose a risk to subjects include sexu matters, use of alcohol or drugs, stigmatiz or discriminating medical or mental health information. If you are applying for a Certif of Confidentiality, respond yes to this ques

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/specim that are collected, stored and disseminate research purposes. Researchers may be obligated by grant, contract or other agree to submit data/ specimens to a repository. example, see National Human Genome Research Institute (NHGRI) or NIH Genon Wide Association Studies (GWAS) Databa 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:

- ☐ 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:

- ☑ Destroy
- ☑ Retain for study recordkeeping purposes
- ☐ Retain for future research use - requires Section 11-4

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

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.

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

Exit Save Continue

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.