



Authoritative requirements that may be applied depend upon many study parameters, such as location, study activities, study team, participants, data or biospecimen collection and use of regulated products.

- ✓ Federal protection of human subjects law will always apply, and several other federal laws and policies may also apply (e.g., HIPAA Privacy Rule for health information; FERPA for student information; conflicts of interest; FDA for drugs and devices)
- ✓ Local laws and rules that are more stringent than or in addition to federal laws may apply (e.g., parental permission; mandatory reporting; provider licensing)
- ✓ Studies conducted abroad or use of foreign national's information or biospecimens may invoke international laws (e.g., EU's GDPR)
- ✓ Ethics codes, such as the Belmont Report, will always apply
- ✓ FSU polices and SOPs, and those of study sponsors and extramural partners, may also apply