

Appendix 6 – LEGAL COUNSEL TO THE IRB

1. How do IRB members get legal advice?
2. Are there any state laws that the IRB has to take note of in addition to the federal regulations?
3. What is the age of consent in Texas?
4. Does your office advise the IRB on the definitions of guardian and legally authorized representative?
5. Are there any laws for including subjects who are cognitively impaired and cannot give their own consent in research?
6. Who advises researchers and the IRB when the researchers are conducting research outside the state of Texas or outside the country?
7. How do you advise researchers / IRB with the differences in law if it is a multi-centre trial led by the University researcher?
8. How do you deal when there are legal questions on the federal regulations concerning IRBs?
9. Do you have any message you would like us to convey to the University officials?