Confidentiality Concerns & Pitfalls

- Define “Confidential Information”
- Label information “Confidential”
- Include all 6 exceptions
- Very often the following exceptions are missing:
  - “…disclosed in writing or reduced to writing …”
  - ‘… independently developed …’
  - ‘…is required to be disclosed by law or regulation…’
- Include additional paragraph re: ‘make disclosure as required by law or regulation’ (“In the event that information is required to be disclosed pursuant to law or regulation …”)
- Make provision ‘mutual’
- Include that each party will use reasonable efforts to keep the information ‘confidential’
- Limit confidentiality obligations to a reasonable number of years
- If Sponsor’s clause makes the results confidential:
  - EITHER delete the reference in the confidentiality clause
  - OR cross-reference our right to publish the results
- If Sponsor wants to own the data:
  - Cross-reference our right to publish the results
- Delete any restriction requiring us to obtain written agreements regarding confidentiality from everyone (eegad!) who may work on the Study
- Be careful not to let the existence of the Agreement or the existence of the relationship become confidential (Open Records Act)
- Replace vague and ambiguous references with ‘real’ words:
  - Replace ‘necessary’ with ‘reasonable’
  - Replace ‘immediately’ with ‘prompt’
  - Replace ‘all information that Sponsor provides to Institution’ with ‘Sponsor Confidential Information’
- Beware of cross-reference in confidentiality section (“subject to our rights to publish …”) and cross-reference in publication section ~ okay to publish, provided that ‘such publication does not violate Section 4.c [= to the confidentiality section] ⇒ they knock each other out.