Legal/Ethical Issues in Clinical Research

Joe Clamon
Agenda

- Background
- Legal/Ethical Issues in Clinical Research
- Resources
Background

• Each residency program must provide an opportunity for residents to participate in research or other scholarly activities, and residents must participate actively in such scholarly activities (Accreditation Council for Medical Education).

• Amount of clinical research, in particular industry-funded research, is on the rise

• Amount of clinical research outside the traditional university environment is seeing the most growth
  – Both industry-initiated and investigator-initiated
Why Participate in Clinical Research?

• Regardless of where you practice, clinical research and investigation of latest treatment options will remain a critical component to your future practice

• Some reasons investigators have shared for conducting research:
  – Professional freedom and intellectual curiosity
  – Desire to streamline expedite drug/device development
  – Share in the research dollar
  – Desire for increased treatment flexibility/understanding of treatment options
  – Attract patients with cutting edge care options

• Iowa Health – Des Moines, through its Office of Research, is well-positioned to assist you to begin or continue your work in research – not just to fulfill a requirement, to make it a valuable part of your active practice
Isn’t the IRB Enough?

• Why do I as an investigator need to be concerned about legal/ethical issues – isn’t that what the IRB is for? Isn’t my job to just come up with the idea and/or perform the research?
  – The IRB is not enough!
  – Compliance issues go beyond the IRB and require investigator participation
Examples of Legal/Ethical Issues for Investigators

- Informed Consent
- FDA regulations for devices
- HIPAA/privacy rules
- Conflicts of Interest
- Ethics in Patient Referrals Act (“Stark Law”)/Anti-Kickback Statute
- Adverse Events
- Research Misconduct
Resources to Address Legal Issues

• Do I have to understand/handle all of these issues before I can do research – **NO**.
• It is a team effort and you have many resources:
  - IRB
  - Office of Research
  - Law Dept. & Compliance
  - Sponsor
  - Investigator
Questions?

Contact Information:

Joseph Clamon
1515 Linden Street, Suite 100
Des Moines, Iowa 50309
Phone: (515) 241-4665
Email: clamonjb@ihs.org