

Regulatory Compliance:

Impact on Patients and Academic Institutions
Conducting Clinical Research

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“Regulatory Compliance”: Multiple forms, agendas and concerns

- **Patient safety** (OHRP; FDA; NIH; Federal/State laws; NCI Central IRB; Institutional IRBs)
- **Billing** (Medicare; multiple 3rd party payers; State laws; FDA; OHRP; institutional policy)
- **Contracts/grants** (NIH/DOD; foundations; *pharmaceutical/biotech companies* – major issues: (a) “ownership” of intellectual property; (b) “research for hire” (IRS-tax law); (c) ownership/use of “biological specimens”)

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- **Conflict-of-interest** [individual/institutional] (NIH; Federal law; OHRP; Institutional IRBs)
- **Publication** [mandated registration of clinical trials and timely reporting of study results] (new Federal law – how will this be implemented and who will have responsibility for reporting data from multi-center or sponsored trials?)

Recent Issues:

- OHRP decision against “verbal consent” related to minor modifications required in IRB-consent forms (e.g., new toxicity) – impact: delay in study accrual
- Mandated Medicare modifiers for submitted bills for patients participating in clinical trials (major effort/cost for all institutions conducting cancer clinical trials in Medicare population)
- Sponsors requiring “institutions” to “hold IND’s” (assume major regulatory responsibility/burden) for investigator initiated/industry-funded trials, including multi-centered studies