

Institutional Conflicts of Interest

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Definition of Conflict of Interest

Competing interests
conflict or compete with
one another

Bayh-Dole Act 1984

- Encouraged Technology Transfer
- Allowed, for the first time, investigators and institutions to be compensated for tech transfer activities

General Presumptions

- Financial conflicts of interest will result in misconduct or lack of impartiality in research
- Human subjects protection might be jeopardized by potential for financial gain

Range of Conflicts/ Financial Remuneration

- Institution receives royalties from a license
- Institution receives equity in a company
- Institution receives equity in a start-up company
- Institution receives equity and royalties in a start-up company

Central Question

- Should an institution carry out clinical trials/research if there are any financial conflicts of interest?
- Can these ever be managed?

Institutional Conflicts of Interest Clinical Research

AAMC Report recommendation

- Rebuttable presumption against institutional financial interest in human subjects research
- If taken literally, there are serious ramifications

Potential Ramifications

If institutions are restricted from receiving intellectual property income resulting from sponsored research, what incentive will they have to support PIs?

Potential Ramifications

If PIs in academe are restricted from receiving this income will clinical research and technology transfer activities begin to migrate to private industry?

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- Range of management depends on magnitude of the conflict of interest
- Argument most often advanced – and rejected – that only PI can carry out the trial

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- Absolute prohibition of Phase III clinical trials if institution holds a patent on drug or device being tested
- Clinical trials may be carried out when the institution holds equity or royalties in a company which holds the patent with appropriate management strategy

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- Multi-center trials carry substantially less risk than single site
- Publication and quality control reside with a committee of non-Washington University PIs
- Oversight committee
- Blind trust