

# Key Legal Issues Associated with Development, Use, and Management of Biological Databases

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# Law & Biological Databases

- Law affects ability to develop and collect information needed to create databases
- Law influences access to databases
- Law affects use of databases
- Legal issues substantially influence ability to create, maintain, and use databases

# Database Creation Legal Issues

- Rights necessary to collect database content
  - Informed consent
  - Contract rights
  - Privacy limitations
- Ownership of the database and its content
  - Contract rights
  - Property rights (intellectual property and personal property)

# Database Access Legal Issues

- Rights of access by private parties
  - Contract rights
  - Property rights
- Rights of access by government authorities
  - Law enforcement
  - National security
  - Contract rights

# Database Use Legal Issues

- Rights of use by database developer
  - Contract rights
  - Property rights
- Rights of use by private parties
  - Contract rights
  - Property rights
  - Antitrust/competition law rights
  - Non-discrimination
- Rights of use by government

# Impact of Legal Issues on Research and Database Development

- Limit or prohibit specific fields of research, thus restricting data collection
- Restrict collection or sharing of data
- Limit use of research data
- Impose obligations on developers and users of databases

# Impact of Legal Issues on Commercialization of Databases

- Affect potential liability of developers and users
- Influence potential for successful database applications
- Impact on incentives for investment in development and maintenance of databases

# Conclusions

- Database development, access, and use affected by a wide range of laws and regulations
- Laws affect scope of research and database content
- Laws affect funding available for database development and maintenance
- Range of applications for databases substantially influenced by laws