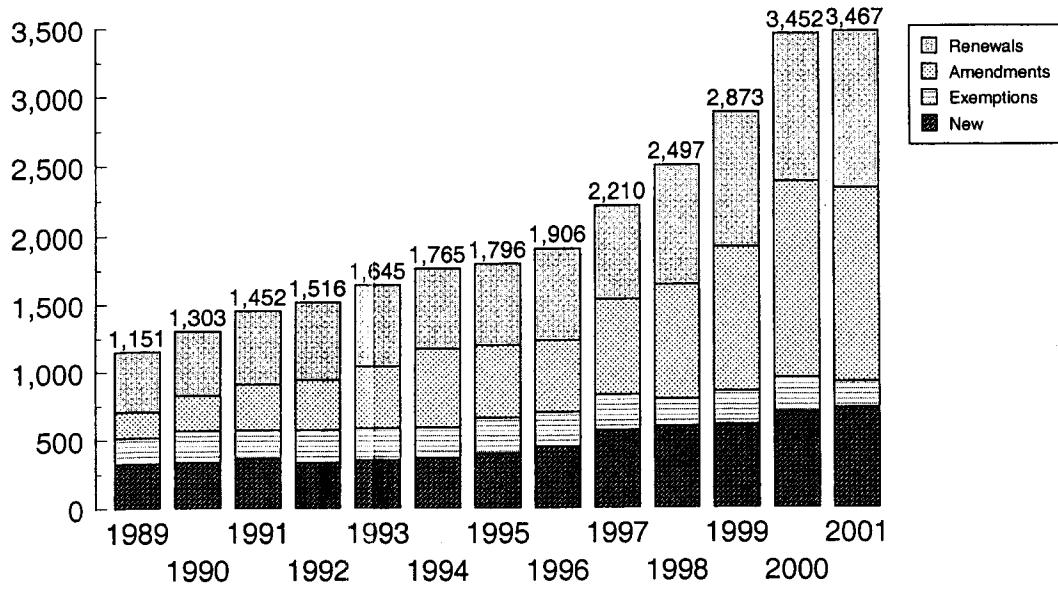
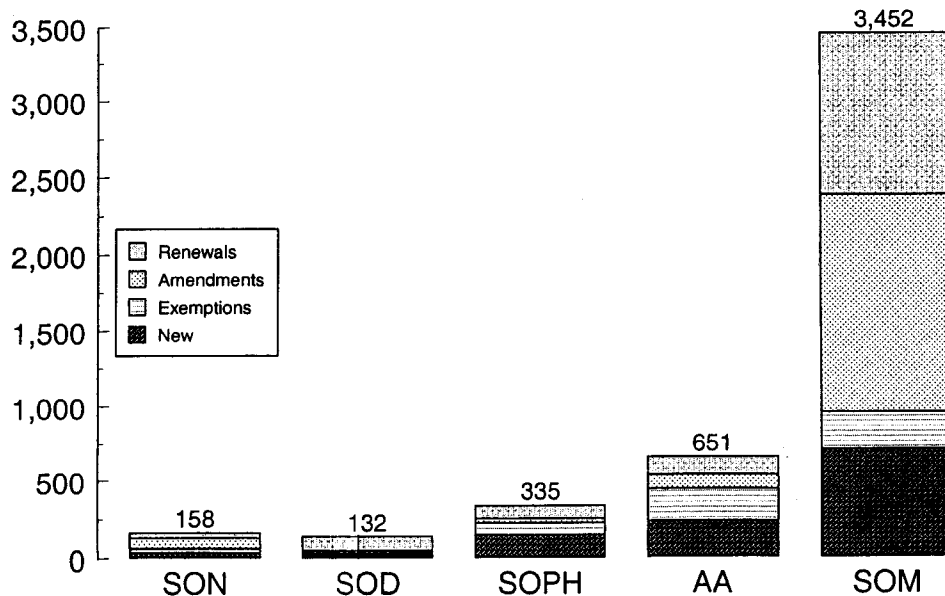


TOTAL SOM-IRB SUBMISSIONS 1989-2001



2000 IRB SUBMISSIONS

Total Actions, By School



PROS & CONS OF CURRENT DECENTRALIZED STRUCTURE

ADVANTAGES

School-based expertise, appropriate to research under review
IRB knowledge of investigators
Access by investigators
Direct reporting lines to those controlling resources (Deans)

DISADVANTAGES

Inefficiencies

- 5 sets of procedures
- 5 websites
- 5 databases
- 5 application forms
- 5 sets of document templates
- 5 business plans
- 5+ people performing basic office routines
- 5 channels to legal counsel, feds, UNC offices, etc
- 5 educational programs
- 5 battles with HR

Variability (= Exposure)

- Minimal sharing of best practices
- Knowledge, interpretation, application of complex regs
- Workload distribution
- Experience
- Documentation
- Support
- Staffing (number, classifications, cross-coverage)
- Inability to support common functions on own (IT, training, etc)

Fragmented reporting lines

Direct lines to multiple points, with minimal knowledge of regulatory requirements or ability to oversee

Indirect lines to regulatory knowledge and responsibility, but without resources or direct authority

"The bucks stops... where?"

Accreditation of the Human Subjects Protection PROGRAM

"The parts are not stronger than the whole"

Federal Assurance

"All for one and one for all"

UNC-CH is the legal entity with ultimate responsibility

-Individual schools are not autonomous legal entities