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WHO WE ARE

- Oversee implementation of all PHS policies and procedures related scientific misconduct
- Monitors investigations conducted by institutions
- Oversight of inquiries and investigations
- **Division of Investigative Oversight**
 - oversight over inquires and investigations
- **Division of Education and Integrity**
 - compliance, education, whistleblower and institutions policy and procedures
- **Division of Legal Counsel**
 - Prosecutors before Departmental Appeals Board (DAB)

ORI Mission

- Oversight of misconduct cases.
- Assistant Secretary for Health makes final decision subject to appeal.
- ORI conducts education, prevention, and research and activities intended to promote integrity.
- Office of Inspector General conducts misconduct investigations when needed.

Basic Statistics

- ORI reviewed over 2,600 allegations.
- Closed over 500 inquiries and investigations
- Found over 200 confirmed incidents of misconduct (approx. 19% clinical).
- Since 1995, institutions conducted the investigation over 95% of time.
- For past 3 years, institutions have conducted all inquiries and investigations.

Year	Closed	MC (%)	NMC (%)	Adm. Cl
1993	38	15 (43)	20 (57)	3
1994	44	11(28)	29 (72)	4
1995	58	24 (41)	34 (59)	0
1996	49	17 (41)	28 (59)	4
1997	39	14 (39)	22 (61)	3
1998	32	9 (28)	23 (72)	0
1999	33	13 (42)	8 (58)	2
2000	27	7 (26)	20 (74)	0
2001	25	14 (58)	10 (42)	1
2002	32	13 (45)	16 (55)	3
2003	29	12 (41)	17 (59)	0

Scientific Misconduct Vs Protocol Violations in Clinical Cases

- Scientific Misconduct

- Making up lab values
- Fabricating consent form
- Changing data on protocol forms

- Protocol Violation

- Enrolling ineligible patient in trial
- Forging signature on consent form
- changing protocol

Number and Percentage of Misconduct Findings in Clinical vs Non-Clinical Cases: 1995-2004

Clinical Cases			Non-Clinical Cases	
Rank	MC	No MC	MC	No MC
Prof.	2 (50)	2 (50)	10 (10)	90 (90)
Assc. Prof.	3 (75)	1 (25)	26 (29)	65 (71)
Asst. Prof.	1 (50)	1 (50)	16 (33)	33 (67)
Post- Doc.	4(100)	0	30 (45)	36 (55)
Res. Asst.	7 (64)	4 (36)	13 (54)	11 (46)
Student	3 (75)	1 (25)	16(53)	14(47)
Nurse	4 (67)	2(33)	3(33)	6(67)
Others	18 (58)	13(42)	36(38)	60(62)
Total	42(64)	24(36)	150 (32)	315(68)

Environments Conducive to Misconduct in Clinical Cases

- Poor supervision of the research
- Other duties and responsibilities
- Poor or lack of adequate training
- Lack of interest of PI in the project
- Incentive for enrolling subjects in study

ORI Rapid Response Technical Assistance 301 443 5330

- Telephone or on site assistance available
- Allegation assessment
- Advice on policies and procedures
- Sequestration of evidence
- Starting the inquiry or investigation
- Analysis of the evidence
- Investigative strategy and legal problems

ORI: Who To Call

Office of the Director	301-443-3400
Division of Education and Integrity	301-443-5300
Policies and publications	
Workshops and conferences	
Research Program	
RCR Education	
Division of Investigative Oversight	301-443-5330
Allegations	
Oversight of inquiries and investigations	
Technical assistance	
Office of General Counsel	301-443-3466
Legal issues and litigation	

ORI home page: <<http://ori.dhhs.gov>>