

MEDICAL RESEARCH SUMMIT

APRIL 21, 2004

**David R. Hoffman
Assistant United States Attorney
Eastern District of Pennsylvania**

The views expressed herein are those of the author and do not necessarily reflect the official position of the United States Department of Justice or the U.S. Attorney's Office for the Eastern District of Pennsylvania.

Who Are the Players and What Are Their Issues?

- **Department of Health and Human Services (HHS)**
 - **Office of Human Research Protections (OHRP)**
 - **Informed Consent, Recruitment Issues, Financial Relationships, Conflicts of Interest, Scientific Integrity, Adverse Event Reporting, and Other Issues**
 - **Office of the Inspector General for the Department of Health and Human Services (OIG)**
 - **Enforcement**
 - **Particular Interest in Informed Consent, Institutional Review Board Functions, Financial Relationship, and Recruitment Issues**

Who Are the Players and What Are Their Issues?

- **Department of Health and Human Services (HHS)**
 - **National Institutes of Health (NIH)**
 - **Grant Administration, Cost Reporting, Scientific Integrity, and Multiple Other Issues**
 - **Office of Research Integrity (ORI)**
 - **Scientific Misconduct**
 - **Food and Drug Administration (FDA)**
 - **Grants; Research on Humans**

Fraud in Research Grants

- Major Sources of Obligations
 - 45 CFR Part 46 (protections for human research subjects)
 - OMB Circular A-122
 - OMB Circular A-21
 - 21 CFR Part 56 (IRBs)
 - 42 CFR Part 50 (grantee responsibilities)
 - 21 CFR Part 312 (IND requirements)
 - NIH/PHS Grants Policy Statements

What Potential Illegal Conduct can be Anticipated in Clinical Research?

- **Recruitment**
- **Failure to Meet Qualifying Criteria**
- **Ghost Patients**
- **Secret Payments for Recruitment**
- **Threats to Patients to Induce Participation**

- **False Statements to Induce Consent or Participation**
- **False Statements to Drug Company or CRO**
- **Forged Consent Forms**
- **False Consent Forms**
- **Failure to Disclose Risks of Study to Patients**

- **Failure to Disclose Conflicts of Interest to Patients**
- **Failure to Disclose Research or Information about Research to IRB**
- **Failure to Comply with Terms of IRB Approval**
- **Failure to Contact IRB and Seek Approval for Modification**

What is Expected?

- **Meaningful and full disclosure to Patients**
- **Studies should be designed by Researchers, not by Marketing Departments**
- **Researchers should be expected and permitted to write and publish what is the most accurate and fair conclusions from studies they undertake**
- **Those who do research should tell the truth about the results**

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and provide the required progress reports if a grant is awarded as a result of this application.

Fraud in Research Grants

- **Application Misrepresentations**
 - **Capability, Personnel Responsible, Qualifications of Personnel, Prior Research, Fiscal and Management Controls**
- **Claiming Costs that Are Not Allowable**
 - **Entertainment, Lobbying, Fines and Penalties, etc.**
- **Misrepresenting Percentage of Effort Relating to Researchers**
- **Inconsistent Positions on Direct/Indirect Costs**

Fraud in Research Grants

- **Misallocating Costs**
 - **Personnel/Salaries, Equipment, Supplies, Space, etc.**
 - **Failure to Properly Allocate Costs Where Multiple Financing Sources Are Present**
- **Falsely Certifying Costs that Are Funded or Provided in-Kind by a Third Party (such as a sponsor)**

Fraud in Research Grants

- **Failure to Obtain Pre-Approval (Where Required) of:**
 - **Budget Changes**
 - **Changes in Principal Investigator**
 - **Changes in Scope and Objectives**
- **Periodic Reporting Issues**
 - **Misstating Accomplishments**
 - **Misrepresentations Regarding Findings and Relevant Data**
 - **Research Misconduct**
 - **Falsification of Data**

Research Integrity and Scientific Misconduct

- **Issues:**
 - **Compliance with Protocols**
 - **Compliance with Controls**
 - **Falsification of Data**
 - **Taking Inappropriate Credit or Denying Appropriate Credit**

Recent Cases

- **Johns Hopkins - February 26, 2004**

Proposed Brooner Salary

<u>Source</u>	<u>Percent</u> <u>(\$105,000 base)</u>	<u>Dollars</u>	<u>Percent</u> <u>(\$87,000 base)</u>	<u>Dollars</u>
---------------	---	----------------	--	----------------

SERVICE DELIVERY

ATS D	25%	\$26,250	25%	\$21,750
ATS G	52%	\$55,074	63%	\$55,074
ARCHWAY	15%	\$15,570	15%	\$13,050

Proposed Brooner Salary

<u>Source</u>	<u>Percent</u> <u>(\$105,000 base)</u>	<u>Dollars</u>	<u>Percent</u> <u>(\$87,000 base)</u>	<u>Dollars</u>
<u>RESEARCH GRANTS</u>				
Comparing Behavior Therapies (new 5 yrs)	30%	\$31,500	30%	\$26,100
LAAM Center Study (new 5 yrs)	45%	\$47,250	45%	\$39,150
Behavior Therapy (Stitzer, 2 yrs left)	15%	\$15,750	15%	\$13,050
Cornerstone (Stitzer, 2 yrs left)	10%	\$10,500	10%	\$8,700

Proposed Brooner Salary

	Brooner Costs <u>@ New Base</u>	Brooner Costs <u>@ Existing Base</u>
Salary:	\$105,000	\$87,000
Fringe (16%):	16,800	13,920
D/Travel:	6,500	6,500
G/A (10%):	<u>10,500</u>	<u>8,700</u>
Subtotal Costs:	\$138,800	\$116,120
Total Funds:	\$252,368	\$221,093
Subtotal Costs:	\$138,800	\$116,120
Total Funds:	\$113,568	\$104,973

Proposed Brooner Salary

<u>Source</u>	<u>Percent</u>	<u>Dollars</u>	<u>Percent</u>	<u>Dollars</u>
	<u>(\$105,000 base)</u>		<u>(\$87,000 base)</u>	
Subtotals	***	\$201,894	***	\$176,874
Fringes (est. at 25%)	***	\$50,474	***	\$44,219
Totals	192%	\$252,368	203%	\$221,093

Proposed Brooner Salary

	Brooner Costs <u>@ New Base</u>	Brooner Costs <u>@ Existing Base</u>
<u>SESSIONS</u>		
For Brooner:	\$30,432	\$30,432
For Dept:	\$83,136	\$74,551
TOTAL SALARY:	\$135,432	\$117,432

Chet – as you can see, I would like a new total salary of \$135,432, beginning in September. I also would like a commitment to increase my base 10% upon receiving the promotion to Professor. Lets get together and talk about salary and the other possibilities associated with remaining here.

Recent Cases

- **Northwestern University - January 2003**
- **Nemours Cardiac Center—A.I. DuPont Hospital for Children**
- **US ex rel. Wu v. Thomas Jefferson University, EDPA, No. 00-923**

