



Beth Israel Deaconess
Medical Center



A teaching hospital of
Harvard Medical School

TIME'S TICKING:

**How to Ensure Your Institution Is Complying
With Time and Effort Reporting and
Other Research Requirements
In Light of Recent Qui Tam Settlements**

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Today's Topics

- Settlements Galore!
- BIDMC's Infamous History
- Time & Effort Key Concepts/Special Issues
- One Institution's Approach to Compliance



Recent Settlements

- Northwestern University – November 2003
 - Overstating % effort
 - Overstating Institutional Base Salary
 - Failure to meet 75% effort required on K award
 - \$5.5 Million + repayment of unallowable costs



Recent Settlements, cont.

- Johns Hopkins/Bayview Medical Center
 - February 2004
 - Overstating % effort
 - Overstating Institutional Base Salary
 - Failure to reconcile estimated and actual reported effort
 - \$2.6 Million + repayment of unallowable costs



Recent Settlements, cont.

- University of Alabama, Birmingham – April 2005
 - Charges for personnel not working on grants
 - Increased effort reported to draw down salary and IDC at greater than budgeted
 - Left out time spent at hospital affiliated practice, but included salary in institutional base compensation
 - Billed Medicare for visits that should have gone to grant
 - Failure to reconcile estimated and actual reported effort
 - \$3.4 Million + repayment of unallowable costs + compliance program



Recent Settlements, cont.

- Mayo Foundation – May 2005
 - Re-allocated direct costs from over spent grants to under spent federal awards
 - \$6.5 Million + repayment of unallowable costs



Recent Settlements, cont.

- Weill Medical College of Cornell – June 2005
 - GCRC allowed one researcher and one division to monopolize funds
 - Charged grants for personnel who did not work on grants
 - Charged monies to grant that should have been billed to Medicare.
 - \$4,385,696



Recent Settlements, cont.

- University of Connecticut – January 2006
 - 500 grants from July 1997 – October 2004
 - Improper basis for setting and updating billing rate structure
 - Failure to follow federal law to bill for extra compensation for additional work
 - Failure to cost-share/provide matching
 - \$2.5 million + Compliance Program



BIDMC's History – Settlement #1

- **BIDMC Settles Federal Lawsuit**
 - BIDMC has agreed to pay \$900,000 to settle federal fraud claims that it misused grant money targeted for...research.
 - US Attorney Donald K. Stern said the case "should serve as a wake-up call to all Boston area hospitals and universities. We will not tolerate false statements or misappropriations in connection with federal research grants. Indeed we intend to keep a sharp lookout for any evidence of grant fraud by other institutions."
 - Boston Globe, April 15, 1999



BIDMC's History – Settlement #2

- 4 Grants Awarded to Harvard University and performed primarily at BIDMC
 - K award, T-32, 2 program project awards
 - Applications included incorrect or overstated information
 - Non-citizens on K and T32 awards
 - Required Effort on K award not reached
 - \$3.25 million - \$2,169,639 (HU) + \$1,084,819 (BIDMC)



Time & Effort The Basics

- Institutions can charge salary, wages and benefits to federally funded research projects provided that they are:
 - Reasonable
 - Conform to established payroll policies; and
 - Reflect no more than the percentage of time actually devoted to the project



Time & Effort The Basics, cont.

- What's Your Organization?
 - Hospital
 - Professional Staff – Monthly effort reports
 - Non-professional staff – time and attendance and payroll distribution records
 - Non-Profit Organizations
 - Professional Staff – Monthly effort reports
 - Non professional staff – additional supporting reports



Time & Effort The Basics, cont.

- What's Your Organization?
 - State, Local, and Indian Tribal Governments
 - Time and attendance or equivalent records for all employees
 - Time distribution records if employees paid from more than one grant
 - Educational Institutions
 - Planned effort confirmation system by academic term, but at least every 6 months
 - For-Profit
 - Conform with industry standard – effort reporting



Time & Effort Hospital Effort Reporting

- Must submit monthly after-the-fact reports certifying that the distribution of activity listed on the pre-printed report accurately represents a “reasonable estimate” of actual work performed
- Verifies that work was performed
- Verifies that cost sharing was performed as promised in the proposal



Time and Effort Hospital Effort Reporting, cont.

- Estimates must be broken down for each organized research project
- Estimates of time and effort expended must include an allocation between organized research and the following activities in terms of total effort devoted:
 - Patient Care
 - Instruction and Training
 - Administration



Time and Effort Percentages and Workload

- Effort (organized research + patient care + teaching + administration) CANNOT exceed 100%
 - "...commitment of an individual's effort greater than 100 percent is not permitted..
 - "Commitment overlap occurs when a person's time commitment exceeds 100 percent, whether or not salary support is only requested for key personnel....no individuals on the project may have commitments in excess of 100%"
 - NIH Grants Policy Statement (Dec. 2003)



Time & Effort Percentages and Workload, cont.

- What does this mean?
 - Grant 1 – 25% T&E
 - Grant 2 – 25% T&E
 - Other – 50% T&E
- A report which shows the above distribution means that the investigator spends half his or her time on research grants, and half his or her time on patient care and/or teaching and instruction, and/or administrative responsibilities.



Time & Effort Percentages and Workload, cont.

- **Not based on 40 hour workweek**
 - Person who works 40 hours per week who spends 20 hours of his or her time and effort on organized research, spends 50% of his or her time on organized research and 50% of his or her time on “Other” activities (patient care, teaching, administration)
 - Person who works 80 hours per week who spends 40 hours of his or her time and effort on organized research, spends 50% of his or her time on organized research and 50% of his or her time on “Other” activities (patient care, teaching, administration)
 - Be careful, however – How long can one person keep up an 80 hour plus work week?



Time & Effort Institutional Base Salary

- NIH Definition:
 - The annual compensation paid by an organization for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.
 - NIH GPS, p. 11.



Time & Effort Dual Appointments

- Investigators with both university and clinical practice plan appointments, compensation from both may be considered institutional base salary when clinical practice:
 - Compensation is guaranteed by the university
 - Effort is shown on the university appointment form and is paid through the university
 - Effort is included and accounted for on university's effort report
 - NIH GPS, p. 98.



Time & Effort

Why TEFRA Doesn't Cover It

- TEFRA is only a two-week snap shot in the course of a 3 month reporting period. It only measures clinical time in terms of hours spent during the course of those two weeks.
- The research Time & Effort Report is an estimate of all of the work that an investigator does at the hospital (including research patient care, teaching and administration), but it aggregates all the non-research categories into one lump percentage
- In general, however, the two reports should complement each other. By the nature of the two different accounting mechanisms required (i.e. hours vs. %), etc., it is unlikely that the numbers will exactly match. That is ok. Remember, the research T&E report is only a good faith estimate of the work performed during the previous month.



Time & Effort

Voluntary Effort – Committed or Not

- Voluntary committed effort (said in grant application would dedicate 5%, but did not request salary)
- Voluntary uncommitted effort (committed to 10% effort in grant application, but actually worked 15% while paid for 10% effort)



Time & Effort NIH Salary Cap

- NIH Salary Cap and Cost Sharing
 - Cap is raised each year
 - Currently \$183,500
 - But different caps apply to different years
 - http://grants.nih.gov/grants/policy/salcap_summary.htm
 - If investigator's salary is over the cap, another account must be identified to which the salary above the cap can be transferred or cost-shared.
 - NEVER cost share to another federally funded account.



Time & Effort Changes in Status/Effort

- Change in Status – **Requires prior approval from NIH**
 - Key Personnel Absent from project during any 3 continuous months
 - Key Personnel reduces effort devoted by 25% or more
 - Calculate
 - $(\text{Original Effort \%} - \text{New Effort \%}) / \text{Original Effort} = \text{Change in Effort}$
 - $(40\% - 30\%) / 40\% = 25\%$
 - $\text{Original Effort} \times .25 = \text{Change in Effort Requiring Prior Approval}$
 - $40 \times .25 = 10\%$
 - Any change less than 10% does not require prior approval



Time & Effort F32s and T32s

- Fellows/Trainees on F32s, T32s
 - They are not considered employees and do not have to report their effort
 - But, they are expected to spend full time effort on the grants
 - only group whose full time effort is defined by 40 hours per week
 - They can moonlight, work on other projects unrelated to the research



Time & Effort K Awards

- K Awards (Career Development)
- Intent is to support and protect a significant component of an individual's professional time for research activity
- Institutes manage these awards differently – look to Institute's guidance:
 - 25-75% effort commitment based on total professional effort
 - Limited salary – cost sharing often required
 - 11/03 revisions – can get other award if in last 2 years of mentored award and named PI (K01, K07, K08, K12, K22, K23, K25)



Time & Effort BIDMC's Approach

- Process Flow – A-Z
 - Grant Submission
 - NOGA/Award
 - Submitting Faculty Payroll Spreadsheet to Research Finance
 - Uploading Info. to On-Line System
 - RA Verification
 - Key Personnel Certification
 - Account Close Out



Time & Effort Grant Submission

- RAs remind investigator only to include true "key personnel" on Key Personnel page
- RAs compare Effort Budgeted with what Investigators have already committed
- NIH prohibits "0% effort" or effort "as needed" for key personnel
- If potential conflict in commitment, RAx contact PI/Key Personnel to resolve
 - T-32
 - K awards
 - More than 100% T&E committed



Time & Effort NOGA/Award

- RAs review award notice for changes in dollars awarded versus what was applied for
- Compare Effort Budgeted with what Investigators have already committed
- Contact PI for changes in key personnel or planned effort
- Resolve any conflicts



Time & Effort RA Verification

- Verification tasks:
 - Review effort committed on grant application
 - Review HMFP spreadsheet again
 - Do account allocations and % salary match T&E report?
 - Click “Verify Report Data – Release for Signature” if accurate
 - If inaccurate, follow Instructions for Revising T&E Reports, then complete steps above until verification complete



Verification Page

Key Personnel Time and Effort Reporting - Microsoft Internet Explorer

Address: http://research.bidmc.harvard.edu/Data/TimeEffortAE.asp?Submit=ShowTE&OUName=Anesthes

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Key Personnel Time and Effort Reporting

Sponsored Program Time and Effort Report

Person: [REDACTED]
Dept/Div: Anesthesia
TE Report: May (5/1/2004) Fiscal Year: 2004

Sponsor Award ID / DeptID Title	DeptID	% Effort	% Salary	Cost Sharing	Share DeptID
[REDACTED] nter Fund	37135	7.2%	7.2%	0.0%	
[REDACTED] Research Fund	38117	30.0%	30.0%	0.0%	

Research % Effort: 37.2%
All Other: 62.8%

Date Generated: 5/1/2004 Date Verified: Date Signed/Returned:

[Add/Edit DeptID Data](#) [Remove TE Record from system](#)

[Verify Report Data - Release for Signature](#)

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Time & Effort Instructions for Revising T&E

- RA processes salary change and submits Labor Cost Transfer to credit or debit salary
- RA makes appropriate changes on T&E report and Verifies
- ARC notifies Key Personnel to certify
 - NOTE: If key personnel have already certified, RA must get prior approval from OSP and RFO to make revisions



Time & Effort Key Personnel Certification

- Once Verification complete, ARC sends email to Key Personnel to Certify
- Important: This is a salary distribution only! Key personnel must notify RA to make changes if report does not accurately reflect a reasonable estimate of their effort
 - + or – 5%



Time & Effort Key Personnel Certification, cont.

- Key Personnel must certify as to their own effort. RA's cannot:
 - "...estimates of effort...must be prepared by the individual who performed the services or by a responsible individual such as a department head or supervisor having first-hand knowledge of the services performed on each research agreement."
45 CFR Pt 74, App. E



Certification

Microsoft Word Document1 - Microsoft Word

Time and Effort Reports - Microsoft Internet Explorer

Address: http://research.bidmc.harvard.edu/Data/TimeEffort.asp?Submit=SignTE&ID=59&TE=2/1/2004

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Time and Effort Reports

Sponsored Program Time and Effort Report

Person: [REDACTED]
TE Report Month: February of 2004

Account Name - Number	% Effort	% Salary	Cost Sharing %	Sharing Acct
MECHANISMS & THERAPEUTIC EFFECTS OF RE - 47060	50.0%	50.0%	.0%	

Research % Effort: 50.0%
All Other: 50.0%

Date Generated: 2/1/2004 Date Verified: 4/5/2004 Date Signed:

I certify that I have direct knowledge of all the effort on this report. I certify further that to the best of my knowledge the above effort reasonably reflects the actual effort of this employee. I understand that no changes are allowed once this statement is signed and submitted to OST.

Signature: _____ Date: _____

OR: Print this Page to create a paper form - Sign and date - Return to your Research Admin
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Questions?

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