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Award Number: DAMD17-00-1-0193

TITLE: Outcomes of Screening Mammography in Elderly Women

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REPORT DATE: April 2004

TYPE OF REPORT: Annual Summary

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	April 2004	Annual Summary (13 Mar 2000 - 12 Mar 2004)

4. TITLE AND SUBTITLE
Outcomes of Screening Mammography in Elderly Women

5. FUNDING NUMBERS
DAMD17-00-1-0193

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

There is uncertainty about whether women older than age 65 should undergo screening mammography. Although screening mammography may benefit some elderly women through the detection of early breast cancers, it may harm other women through false positive diagnoses and the detection of clinically insignificant lesions. This research study involves the design and implementation of a data analysis of HCFA Medicare billing claims linked with National tumor registry data from the Surveillance Epidemiology and End Results (SEER) program. The analysis will first determine if Medicare billing claims are accurate, and second, evaluate differences in breast cancer at diagnosis, tumor attributes, and treatment between women who are screened with mammograms and those who are not. The PI will focus on validating that the Medicare claims are accurate for determining screening mammography prior to completing any analysis.

14. SUBJECT TERMS
Breast cancer

15. NUMBER OF PAGES
38

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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INTRODUCTION

There is uncertainty about whether women older than age 65 should undergo screening mammography. The SEER-Medicare data, created through a collaborative effort of the NCI and CMS, is a population-based dataset and provides an ideal data set to study mammography screening among elderly women. Using prospectively collected data from the San Francisco-Oakland, New Mexico, and Washington State Breast Cancer Surveillance Consortium (BCSC) registries (an NCI sponsored collaboration of mammography registries) linked with data from Medicare for the same geographical regions from 1992–1996, we assessed whether Medicare physician claims can be used to determine the use of screening mammography.

STUDIES and RESULTS

SOW #1: Obtain Health Care Financing Administration/SEER Tumor Registry Data
The linked Medicare HCFA/SEER database describing Medicare claims through 1998 and breast cancer cases through 1996 was obtained, and data cleaning of this complex administrative database was completed in Year 1.

SOW #2:
a) Develop Algorithm for determining the predictor variable of screening mammography utilization
1. Medicare claims were found to be an accurate tool for measuring mammography screening. Our manuscript entitled "Can Medicare billing claims data be used to assess mammography utilization among women age 65 and older" has been submitted to *Health Services Research* and we have also submitted a revised manuscript.

2. Our secondary goal of determining how well Medicare claims distinguish screening from diagnostic mammograms is currently complete. Overall, 11.5% of exams are misclassified with respect to whether they are screening or diagnostic. Manuscript is currently being written.

b) Develop a plan to approximate SES using census tract and zip code information
We had previously described a method to combine census tract and zip code level information on median income to approximate SES levels in SEER-Medicare. In "Can Medicare billing claims data be used to assess mammography utilization among women age 65 and older", under review at *Health Services Research,* we used this method to adjust risk estimates of the probability of a mammogram having a matching claim in Medicare. Proper SES adjustment was important for this analysis so that we could interpret any potential differences in match probability by race.

c) Develop a survival analysis plan
We are currently finalizing working definitions of the variables that will be included in the survival analysis, including measures of screening mammography utilization, timeliness of breast cancer diagnosis, and breast cancer treatments. Manuscripts describing mammography utilization and breast cancer treatments have been submitted for publication.

KEY RESEARCH ACCOMPLISHMENTS

1. Smith-Bindman R, Quale C, **Chu P**, Rosenberg R, Kerlikowske K. "Can Medicare billing claims data be used to assess mammography utilization among women age 65 and older" was submitted to *Health Services Research*, and a revision was requested and resubmitted. (Manuscript attached.)

2. Kagay C, Quale C, **Chu P**, Smith-Bindman R. "Mammography use among the American elderly" was submitted to *Annals of Internal Medicine.* (Abstract in appendices.)

3. Haagstrom D, Quale C, **Chu P**, Smith-Bindman R. "Racial differences in breast cancer treatment" is near complete and will be submitted for publication.

4. Smith-Bindman R, Quale C, **Chu P**, Rosenberg R, Kerlikowske K. "Differentiating screening from diagnostic mammography using Medicare billing claims." Manuscript under preparation.

REPORTABLE OUTCOMES

None

CONCLUSION

We found Medicare data are accurate for determining use of mammography. Therefore, these data can be used for Health Services Research to determine outcomes associated with breast cancer screening. Additionally, we found substantial persistent racial and ethnic disparities in using mammography and receipt of appropriate breast cancer treatment. Additional research should target diminishing these disparities.

APPENDICES

SCREENING MAMMOGRAPHY IN THE AMERICAN ELDERLY

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Sponsorship: This work was supported in part by the Mt. Zion Health Care Fund Dean's Account, the California Breast Cancer Research Fund, the Department of Defense (DAMD179919112) and the National Cancer Institute (K07 CA86032).

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Running Head: Screening mammography in the American elderly

Key words: Mammography, Utilization, Medicare, Aged, Women, Health Services for Aged, Mass Screening, Breast Neoplasms

Word Count: 2,675

Abstract Word Count: 292

ABSTRACT

Background: Substantial differences exist in estimates of the proportion of elderly women who undergo screening mammography and the impact of race and ethnicity on mammography usage.

Methods: A representative 5% sample of elderly women living in 11 Surveillance, Epidemiology and End Results (SEER) areas in 1991-2001 was constructed using Medicare data. Biennial rates of screening mammography were calculated for overlapping two-year periods, adjusting to a 2000-01 age and race distribution and for the proportion of mammograms not captured by Medicare. Multivariable repeated measures logistic regression was used to examine predictors of screening usage.

Results: 146,669 women were included. Between 1991 and 2001 the proportion of women age 65 and older who underwent at least biennial screening mammography increased from 38.3% to 51.4%. Mammography screening increased for all racial and ethnic groups, but remained significantly higher for non-Hispanic White women as compare with all other groups. There was no decline in this disparity in screening rates during the years of the study. The biennial screening rate in 2000-01 was 53.7% for non-Hispanic White, 43.0% for African-American, 36.8% for Asian-American, 38.5% for Hispanic and 13.2% for Native-American women. After controlling for age, site, physician access, comorbidities, education and income, African-Americans [OR 0.80

(95% CI 0.78 - 0.83)], Asian-Americans [OR 0.53 (0.51 - 0.55)], Hispanics [OR 0.70 (0.67 - 0.74)] and Native Americans [OR 0.37 (0.29 - 0.46)] were all less likely to undergo screening than were non-Hispanic White women.

Conclusion: Elderly women undergo significantly less mammography screening than suggested by self-reported surveys, and a substantial number are inadequately screened. This is particularly true for women in ethnic and racial minority groups. The low screening rates found for African-American and Hispanic women potentially help to explain the later stages at breast cancer presentation of those groups.

CAN MEDICARE BILLING CLAIMS DATA BE USED TO ASSESS MAMMOGRAPHY UTILIZATION AMONG WOMEN AGE 65 AND OLDER

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This work was supported in by the NCI (K07 CA86032), Breast Cancer Surveillance Consortium co-operative agreement U01CA63740, and The Department of Defense (DAMD179919112 and DAMD 170010193).

Key words: Screening Mammography, Utilization of Mammography, Medicare, Elderly Women

Word Count: 2,842

Abstract Word Count: 267

ACKNOWLEDGEMENT

This study used the linked SEER-Medicare database. The interpretation and reporting of these data are the sole responsibilities of the authors. We acknowledge the efforts of the Applied Research Branch, Division of Cancer Prevention and Population Science, National Cancer Institute; The office of Information Services and the Office of Strategic Planning, HCFA; Information Management Services, Inc; and the SEER program tumor registries in the creation of the SEER-Medicare database.

ABSTRACT

Objective: Medicare data may be a useful source for determining the utilization of mammography among elderly women. We determined whether Medicare physician billing claims are an accurate reflection of mammography utilization among women age 65 and older.

Data Sources: Mammography use was assessed by comparing Medicare administrative billing claims with radiology reports from mammography registries that participate in the NCI-funded Breast Cancer Surveillance Consortium (BCSC). Data were included from three geographic areas by linking information for each patient and each mammogram from Medicare and the BCSC mammography registries.

Subjects: Women age 65 and older, diagnosed with breast cancer between 1991-1996, who had at least one mammogram between 1992 - 1998.

Methods: Completeness of the Medicare data were assessed by comparing mammography usage based on Medicare claims alone with data from the radiology reports.

Results: There were 5,842 mammograms obtained by 1,676 women between 1992 and 1998 included in this analysis. Overall, 82% of mammograms obtained by women age 65 and older had a corresponding billing claim in Medicare, and this increased from 70.8% in 1992 to 91.3% in 1998. In multivariable analysis, age, race, ethnicity, and socioeconomic status did not affect the likelihood that a mammogram would be associated with a billing claim. A total of 94.3% of women were accurately classified by Medicare claims as having undergone at least biennial mammography (at least one mammogram in a two year period.)

Conclusion: Medicare administrative claims are reliable for assessment of mammography utilization, and have become more accurate over time. Population trends in the use of mammography can be assessed using these data, in particular starting in 1998.

INTRODUCTION

Several national efforts have encouraged mammography use among elderly women over the last decade, including the expansion of Medicare coverage to reimburse for screening mammography in 1991. As a result, overall utilization rates of screening mammography among elderly women are believed to have increased substantially. [1, 2] However, there remain substantial differences in the published estimates of the proportion of elderly women who undergo mammography and how close elderly women come to meeting national guidelines for screening frequency. The most widely cited estimates of mammography use are based on self-report data collected as part of the Behavior Risk Surveillance System [3] and the National Health Interview Study [1], and these suggest elderly women in aggregate are close to reaching national recommended for biennial screening. However, recent analyses have raised doubts about the reliability of these data. [4-8] Thus there are few accurate estimates of the utilization rates of mammography among elderly women, or data that can be used to study whether mammography is being used appropriately and by whom.

The ideal database to assess mammography utilization among elderly women would be population-based and readily available to allow the rapid and reliable assessment of mammography utilization. If found reliable, Medicare data would be an ideal source with which to study screening among the elderly, as the vast majority of elderly women in the U.S are covered by this government-sponsored insurance policy and it would give an unbiased estimate of mammography utilization. However, Medicare claims have not yet been shown to be reliable for determination of mammography utilization. [9] Specifically, because beneficiaries may pay out of pocket for mammograms, pay for them through private health insurance, or have them paid for through other programs, using Medicare billing claims data to assess mammography utilization could lead to an underestimation of actual utilization. [8]

The purpose of this analysis is determine whether Medicare physician billing claims data can be used to accurately determine the use of mammography among elderly women. Specifically, among a group of elderly women in whom we know mammography was obtained based on radiology

physician reports, we determined the percentage of mammograms that had an associated Medicare billing claim.

METHODS

Mammography use among elderly women was assessed in three geographic areas using data from two sources: (1) Medicare administrative billing claims and enrollment information provided by the Center for Medicare and Medicaid Services (this information was obtained as part of the linked SEER-Medicare dataset [10]); and (2) information from mammography registries that have participated in the Breast Cancer Surveillance Consortium (BCSC), an NCI-funded consortium in the U.S. [11-13] The Medicare and BCSC data cannot be readily linked for all women as both datasets have been anonymized. [10] However, each dataset has been linked with their regional SEER (Surveillance, Epidemiology and End Results) tumor registry data, and thus we were able to link Medicare data (SEER-Medicare) with the BCSC data (SEER-BCSC) using SEER Registry identification codes. The study was limited to women diagnosed with breast cancer, as we only were able to link information for these women. The UCSF institutional review board, and each of the SEER and mammography registries approved the study.

Data Sources

SEER-Medicare

The SEER-Medicare dataset provided a convenient source to evaluate the Medicare claims information. The SEER-Medicare database is a collaborative effort of the National Cancer Institute, the SEER program, and the Center for Medicare and Medicaid Services to create a large population-based source of information for cancer related epidemiologic and health services research. [10] SEER-Medicare data combines cancer information from population based cancer registries, including approximately 12-14% of cancers diagnosed annually in the U.S., with clinical information derived from the Medicare data, which includes billing claims for physician services including mammography.

Breast Cancer Surveillance Consortium

Data were obtained from mammography registries that have participated in the Breast Cancer Surveillance Consortium (BCSC). [11-13] The BCSC is a National Cancer Institute (NCI)-funded consortium of registries that collect patient demographic and clinical information, [14] mammographic interpretation from radiology reports and cancer diagnoses for participating facilities in seven states. The registries were initially funded in 1995, which allowed them to expand existing mammography facility based data collection in their areas. Each registry has tried to capture all mammograms in their region, limited primarily by practical concerns. None of the registries is entirely population-based, but they have become increasingly population based over time. These data provided a way to assess mammography use among elderly women based on detailed medical records. Three registries (New Mexico, San Francisco and Washington State) were included in this study because each of these registries links their mammography data with their regional SEER tumor registry. Each registry includes both screening and diagnostic examinations that were performed on women living in their defined catchment areas.

Data Linkage

Information from the SEER-Medicare and SEER-BCSC data sources were linked for women who resided in the same geographic areas. We were able to find matches among women since the tumor ID variable in the BCSC was a subset of the identifying variable in the SEER-Medicare data. We considered mammograms from the two different sources to match if the ID variables matched and the dates from the two datasets were within one week from each other, although the majority (over 92%) of the matches were on the same day.

Assessment of Mammography Utilization and Other Variables

SEER-Medicare

Mammography claims were taken from the outpatient facility file (OUTSAF) and the physician's claim file (NCH.) We searched for all claims with one of three CPT codes: 76090 (Mammography, unilateral), 76091 (Mammography, bilateral) or 76092 (screening Mammography, bilateral). [15-21] We included both screening and diagnostic mammograms because Medicare claims do not reliably distinguish between these two procedures [9, 17], because our referent standard based on the BCSC registries included both screening and diagnostic examinations, and because mammograms are considered diagnostic for five years following a diagnosis of cancer. [12, 13] When we encountered duplicate claims (more than one mammogram for the same woman occurring on the same day but from the different claim sources, i.e. one from the physician's claim file and one from the facility claim file), we only counted one of those mammograms to avoid over-estimating Medicare mammography usage. Thus at most a single mammogram was counted and compared between the data sets for any given day in the study period. Overall, 59.8% of the mammography claims occurred in the physician's claim file (NCH), but not in the outpatient facility file (OUTSF), while 3.5% of the claims were in the outpatient file but not in the physician claims. Overall, 36% of claims were in both files.

Age was stratified within 5-year age groups, race/ethnicity was grouped as Hispanic and non-Hispanic white, African American, and Asian/Pacific Islander using the SEER race "recode B. [22] SES was determined using a combination of median neighborhood income based on census tract and zip-code level variables. [22]

SEER-BCSC

The BCSC records include the date of all mammographic examinations, and radiologist mammographic interpretation. We considered a mammogram to have occurred if there was a record of a mammographic examination with a corresponding physician interpretation.

Subjects

The BCSC began in different years for each of the three sites, and we included all mammograms obtained inclusively between 1992-1998. We used information from both the SEER-Medicare and SEER-BCSC data to assemble our cohort of study subjects. We began with all of the women aged 65 and older (eligible for Medicare), at diagnosis of breast cancer (between 1991 and 1996), who had at least one mammogram in the BCSC, present in the SEER-Medicare data, and who live in one of the three geographic areas (n=2,244.) As part of Medicare, women may be enrolled in risk-based HMO plans. Since Medicare does not receive billing claims for physician services for these women, and thus mammography utilization cannot be assessed, we did not include the mammograms during the months when a woman had HMO coverage. Additionally, as Medicare does not receive billing claims during periods where a woman is not Part B eligible, we excluded mammograms that occurred during months where the woman was not Part B eligible. From the original 2,244 eligible women from the BCSC, 558 (25.3%) women had all of their mammographic history excluded for either HMO enrollment or non Part B eligibility. Of those 568, most 501 (89.3%) were removed because of mammograms during months of HMO enrollment, 60 (10.5%) because of mammograms excluded during months of non-Part B enrollment, and 74 (1.2%) had mammograms excluded for both HMO enrollment or non-Part B enrollment. This yielded a population of 1,676 (74.7%) women who had one or more eligible mammograms, and who received those mammograms during years of study. For this group of women, we included all mammograms obtained from 1992 to 1998, including all mammograms obtained both before and after their diagnosis of cancer.

Analysis

The referent standard included all mammograms that were documented in a BCSC mammography registry, and using this referent standard, we determined the percentage of mammograms that were documented in Medicare (Medicare capture rates). We calculated unadjusted Medicare capture rates by age, race, ethnicity, geographic site, income, and timing of mammogram in relation to cancer diagnosis (before/after). In order to estimate what patient variables predict the likelihood of a mammogram being billed to Medicare, all of the above variables were included in a multivariable generalized estimating equation (GEE) logistic model [23] that accounted for within-woman correlation. All analyses were done using the SAS System version 8.2. [23] Fitting the multivariable model allowed us to examine the differential effects of age, race, ethnicity and SES on the probability of capturing a mammogram in Medicare data.

For the preceding analysis, we calculated Medicare capture rates at the mammogram level. From a health care policy perspective, it is important to understand what proportion of women are undergoing at least biennial mammography (at least one mammogram within a two-year period.) In order to assess whether women are correctly classified as having undergone at least biennial mammography, for each two year period (1992-199; 1993-1994; 1995-1996; 1997-1998) we calculated the percentage of women who were classified as having undergone mammography based on the Medicare data, and compared this to the classification based on BCSC data.

The BCSC data may be valuable to measure cancer screening practices, and it is unknown the degree to which these data are population based. In order to assess the degree to which the BCSC registry data were population-based, for each mammogram identified in the Medicare data, we assessed whether there was an associated record in the BCSC.

RESULTS

There were 5,842 mammograms obtained by 1,676 women between 1992 and 1998 included in this analysis, including 1,859 (31.8%) obtained prior to breast cancer diagnosis, and 3,983 (68.2%) following a breast cancer diagnosis, Table 1. Overall, 82.0% of the mammograms reported in the registries had a corresponding billing claim in Medicare, and this increased from 70.8% in 1992 to 91.3% in 1998, Table 2. There were no significant differences in the crude capture rates by age, race, ethnicity, or income. The capture rate prior to cancer diagnosis was lower than after breast cancer diagnosis.

In a multivariable model, we found significant differences in the percentage of mammograms with an associated billing claim by site, year and timing of mammogram with respect to breast cancer diagnosis, Table 2. A mammogram was more likely to be associated with a billing claim in the most recent years of the study (with a fairly consistent increase), and mammograms that occurred following a diagnosis of cancer were more likely to be associated with a billing claim than mammograms obtained prior to a diagnosis of cancer. We did not find a significant difference in the Medicare capture rates based on the median community income, race, ethnicity or age.

To evaluate whether women are classified correctly as having undergone at least biennial mammography, we compared the characterization of women based on Medicare data with the characterization based on the BCSC data. A total of 94.3% of women were accurately classified by Medicare claims as having undergone biennial mammography (at least one mammogram in a two year period.) This ranged from 93.8% in 1992 to 94.6% in 1997.

In order to assess the degree to which the BCSC registry data were population-based, for each mammogram identified in the Medicare data, we assessed whether there was an associated record in the BCSC. Overall we were able to find a radiology report in the BCSC for 83% of the mammograms that occurred in Medicare, and this increased over time. By 1998, the BCSC was

nearly population-based, as it captured greater than 90% of mammograms obtained in Medicare-aged women.

DISCUSSION

Medicare physician claims can be used to determine whether women with breast cancer have undergone mammography as most mammograms (82%) obtained among women diagnosed with breast cancer have a corresponding Medicare billing claim. Medicare capture-rates have increased over time, suggesting that Medicare data have become more reliable in recent years. By 1998, greater than 91% of mammograms had an associated billing claim. Similarly, Medicare data can be used to determine whether women have undergone at least biennial mammography, as over 94% of women were correctly classified as having undergone at least biennial mammography. We did not find a large percentage of missing mammography claims, nor differences by age, race, ethnicity, or median community income. We found differences in the capture rates among the different sites and speculate that geographic differences in billing practices, as well as the availability of alternate payment sources for mammography might explain this result.

The BCSC data may be useful to study cancer-screening practices. By 1998, we found the BCSC was nearly population-based and that it captured greater than 90% of mammograms obtained in Medicare-aged women. We are unable to assess if the registries are equally population based for women younger than age 65 as they were not included in our study.

We included mammography billing claims from both the physician claims file (NCH) and output (OUTSF) files. Most of the mammography claims were present in the NCH file and including the OUTSF contributed only 3.5% additional mammograms. Thus there was relatively little additional value from searching for mammograms in the OUTSF file.

The major strength of this report is that it is the first to compare mammography use as assessed by Medicare administrative billing claims, with patient specific medical records, and we found the administrative claims reliable. Medicare records provide a readily available and timely method to

measure mammography screening rates that are free of recall bias, and thus we have shown they can be used to assess screening.

There are several limitations of this study. We did not include women enrolled in HMO plans. Unfortunately the use of physician services cannot be ascertained in Medicare beneficiaries enrolled in HMO-types of plans, and thus mammography usage among women enrolled in these types of plans cannot be assessed. However, the majority of elderly women (>70%) are enrolled in FFS plans, and thus Medicare data remain an important tool that can be used to assess the use of mammography among most elderly women. This analysis did not evaluate the utility of Medicare claims to measure the use of screening as opposed to diagnostic mammography or the utility of screening for the diagnosis of cancer. We assessed the capture rate of all mammograms obtained by women age 65 and older, and did not separately determine the capture rates of screening versus diagnostic examinations. Approximately 90% of mammograms are obtained for screening purposes [24] Therefore if the total number of mammograms among elderly women is assessed using Medicare data (including the billing codes we have used), than this number will need to be adjusted downward in order to determine the number of mammograms obtained for screening. We looked at billing claims only in women who were diagnosed with breast cancer and these may not be generalizeable to the majority of women who undergo mammography who do not have breast cancer. However, the overall capture rates were relatively high even in the years prior to breast cancer diagnosis. We only looked at three geographic areas, and even within those areas there was variability in the capture rates. Lastly, we did not find differences in capture rates between non-Hispanic white, African American and Asian women, or by socio-economic variables, however, our sample size may have been too small to conclude that capture rates are the same across these different groups.

What are the implications of this study? Mammography use as assessed by self-report has been found to be very high, as 70-80% of women older than age 65 have reported biennial screening mammography use. [1, 3] However, these rates have not been confirmed with administrative claims.

The results of this study suggest administrative billings claims capture a large percentage of examinations, and that patient self-report data may substantially overestimate the use of mammography. This analysis suggests that Medicare data are a fairly reliable method for assessment of mammography utilization among elderly women. These findings support the use of Medicare claims to assess population trends in the use of mammography, in particular, in particular after 1998.

TABLE AND FIGURE LEGENDS

Table 1

Characteristics of women included in this report

Table 2

The percentage of mammograms among women age 65 and older with an associated Medicare billing claim, by registry, age, race, ethnicity, SES, and timing in relation to breast cancer diagnosis. The odds ratios are from the multivariable logistic regression results.

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Pdf Excel

Expenditure Summary By DPA, Fund, NCA Group for 05/2004 (CLOSED)

Row(s) 1 - 9 of 9

Grouping	Budget	Financial	Lien	Balance	Pct
DPA - 444951 MED RES-RADIOLOGY					
Fund/FY - 23020- DAMD17 00 1 0193 04/03					
- DIRECT					
- SALARY					
ACADEMIC	0.00	35,595.48	0.00	35,595.48	N/A
Total:	0.00	35,595.48	0.00	35,595.48	N/A
- BENEFITS					
ACADEMIC	28,417.00-	8,573.63	0.00	19,843.37-	30.17%
Total:	28,417.00-	8,573.63	0.00	19,843.37-	30.17%
- NONPAYROLL					
OTHER SERVICES	0.00	300.00	0.00	300.00	N/A
TRAVEL	1,047.00-	2,174.92	0.00	1,127.92	207.73%
OTHER EXPENSES	0.00	365.00	0.00	365.00	N/A
CAMPUS UNALLOCATED	32,520.00-	0.00	0.00	32,520.00-	0.00%
CAPITAL EQUIPMENT	0.00	3,249.58	0.00	3,249.58	N/A
Total:	33,567.00-	6,089.50	0.00	27,477.50-	18.14%
Total:	61,984.00-	50,258.61	0.00	11,725.39-	81.08%
- INDIRECT					
- OVERHEAD					
OVERHEAD	497.00-	12,222.39	0.00	11,725.39	N/A
Total:	497.00-	12,222.39	0.00	11,725.39	N/A
Total:	497.00-	12,222.39	0.00	11,725.39	N/A
Total:	62,481.00-	62,481.00	0.00	0.00	100.00%
Total:	62,481.00-	62,481.00	0.00	0.00	100.00%
DPA - 784351 MISC STDT AID-GRAD-RADIOLOGY					
Fund/FY - 23020- DAMD17 00 1 0193 04/03					
- DIRECT					
- NONPAYROLL					
OTHER EXPENSES	3,348.00-	3,348.00	0.00	0.00	100.00%
Total:	3,348.00-	3,348.00	0.00	0.00	100.00%
Total:	3,348.00-	3,348.00	0.00	0.00	100.00%
Total:	3,348.00-	3,348.00	0.00	0.00	100.00%
Total:	3,348.00-	3,348.00	0.00	0.00	100.00%
Totals:	65,829.00-	65,829.00	0.00	0.00	100.00%

Row(s) 1 - 9 of 9

Selected Report Criteria
Business Unit: UCSF
Fund Type: Current
Department Code: 497616 - RADIOLOGY-MT ZION HOSPITAL
DPA: 444951
Fund: 23020
Date: 05/2004

Pdf Excel

Distribution of Payroll Expense by DPA, Fund, Sub for 01/2001 (CLOSED)

Row(s) 1 - 30 of 30

ET Mo	Page Line	Employee Name	Employee ID	Title	Period End Date	DOS	Toe	Time		Pay Rate		A J	Gross Earnings	Total Benefits	GSTR/ IAPOF	OASDI MEDC
Dpa - 444951 MED RES-RADIOLOGY																
Fund - 23020 DAMD17 00 1 0193			**04/03**													
Sub - 0 Academic Salary																
0207	1357601	CHU,PHILIP W.	027692797	3300	01/31/2002	REG		.2200	%	5335.00			1,173.70	282.54	0.00	87.94
0208	1369501	CHU,PHILIP W.	027692797	3300	02/28/2002	REG		.2200	%	5335.00			1,173.70	282.54	0.00	87.94
0210	1377801	CHU,PHILIP W.	027692797	3300	04/30/2002	REG		.2200	%	5335.00			1,173.70	404.66	0.00	86.09
0211	1334901	CHU,PHILIP W.	027692797	3300	05/31/2002	REG		.2200	%	5335.00			1,173.70	404.66	0.00	86.09
0212	1411201	CHU,PHILIP W.	027692797	3300	06/30/2002	REG		.2200	%	5335.00			1,173.70	282.54	0.00	87.94
0301	1265601	CHU,PHILIP W.	027692797	3300	07/31/2002	REG		.2200	%	5966.00			1,312.52	180.46	0.00	100.41
0302	1540001	CHU,PHILIP W.	027692797	3300	08/31/2002	REG		.2200	%	5966.00			1,312.52	302.58	0.00	98.56
0303	1376701	CHU,PHILIP W.	027692797	3300	09/30/2002	REG		.2200	%	5966.00			1,312.52	302.58	0.00	98.56
0304	1388401	CHU,PHILIP W.	027692797	3300	10/31/2002	REG		.2200	%	5966.00			1,312.52	302.58	0.00	98.56
0305	1428801	CHU,PHILIP W.	027692797	3300	11/30/2002	REG		.2200	%	5966.00			1,312.52	302.58	0.00	98.56
0306	1439101	CHU,PHILIP W.	027692797	3300	12/31/2002	REG		.2200	%	5966.00			1,312.52	315.47	0.00	99.55
0307	1385601	CHU,PHILIP W.	027692797	3300	01/31/2003	REG		.2200	%	5966.00			1,312.52	315.47	0.00	99.55
0308	1408301	CHU,PHILIP W.	027692797	3300	02/28/2003	REG		.2200	%	5966.00			1,312.52	315.47	0.00	99.55
0309	1482101	CHU,PHILIP W.	027692797	3300	03/31/2003	REG		.2200	%	5966.00			1,312.52	315.47	0.00	99.55
0310	1411401	CHU,PHILIP W.	027692797	3300	04/30/2003	REG		.2200	%	5966.00			1,312.52	315.47	0.00	99.55
0311	1411301	CHU,PHILIP W.	027692797	3300	05/31/2003	REG		.4200	%	5966.00			2,505.72	602.25	0.00	190.04
0312	1454601	CHU,PHILIP W.	027692797	3300	06/30/2003	REG		.4200	%	5966.00			2,505.72	700.33	0.00	189.53
0401	1460301	CHU,PHILIP W.	027692797	3300	07/31/2003	REG		.4200	%	5966.00			2,505.72	596.76	0.00	190.05
0402	1516301	CHU,PHILIP W.	027692797	3300	08/31/2003	REG		.4200	%	5966.00			2,505.72	596.75	0.00	190.04
0403	1438001	CHU,PHILIP W.	027692797	3300	09/30/2003	REG		.4200	%	5966.00			2,505.72	596.75	0.00	190.04
0404	1576101	CHU,PHILIP W.	027692797	3300	10/31/2003	REG		.4200	%	5966.00			2,505.72	596.75	0.00	190.04
0405	1448001	CHU,PHILIP W.	027692797	3300	11/30/2003	REG		.4200	%	5966.00			2,505.72	596.75	0.00	190.04
0406	1462201	CHU,PHILIP W.	027692797	3300	12/31/2003	REG		.4200	%	5966.00			2,505.72	620.16	0.00	188.91
0409	1448601	CHU,PHILIP W.	027692797	3300	12/31/2003	REG		-.3870	%	5966.00		E	2,308.84-	571.41-	0.00	174.06-
0409	1448602	CHU,PHILIP W.	027692797	3300	11/30/2003	REG		-.3870	%	5966.00		E	2,308.84-	549.84-	0.00	175.10-
Total:													34,421.78	8,410.32	0.00	2,597.93
Sub - 2 General Assistance																
0209	1511001	CHU,PHILIP W.	027692797	3300	03/31/2002	REG		.2200	%	5335.00			1,173.70	160.76	0.00	89.79
0312	0257001	CHU,PHILIP W.	027692797	3300	06/30/2003	REG		.4200	%	5966.00			2,505.72	291.65	0.00	191.68
0312	0257002	CHU,PHILIP W.	027692797	3300	06/30/2003	REG		-.4200	%	-5966.00			2,505.72-	291.65-	0.00	191.68-
0305	1428802	ZHAO;JIE	023479751	3220	10/31/2002	REG		.9500	%	4300.00			4,085.00	475.49	0.00	312.50
0306	1439102	ZHAO,JIE	023479751	3220	10/31/2002	REG		-.9500	%	-4300.00			4,085.00-	472.94-	0.00	309.95-
Total:													1,173.70	163.31	0.00	92.34
Total:													35,595.48	8,573.63	0.00	2,690.27
Total:													35,595.48	8,573.63	0.00	2,690.27
Totals:													35,595.48	8,573.63	0.00	2,690.27

Row(s) 1 - 30 of 30

Selected Report Criteria
Department Code: 497616 - RADIOLOGY-MT ZION HOSPITAL
DPA: 444951
Fund: 23020
Adjustment Code: ALL
TOE Date: 01/2001 **To:** 06/2004

UCSF CONTRACTS AND GRANTS APPROVAL FORM

OFFICE OF SPONSORED RESEARCH, CONTRACTS & GRANTS (C&G) DIVISION AND INDUSTRY DIVISION

SUBMIT ORIGINAL OF THIS APPROVAL FORM WITH PROPOSAL TO
C&G – Suite 315, 3333 California St (Laurel Heights) OR Industry Div. – Suite 4603, 185 Berry St. (China Basin)
PROPOSALS ARE DUE BY 9 A.M. FOUR WORKING DAYS BEFORE AGENCY DEADLINE

ATTACHED ARE AN ORIGINAL + COPIES OF PROPOSAL
(Includes a Copy for C&G or Industry Division)

P.I./Fellow: **Philip W. Chu** Sponsor: **Rebecca Smith-Bindman, MD** P.I. Mail Stop: **1667** P.I. Phone: **885-3842** P.I. Fax: **885-7876** P.I. E-mail: **Bill.Chu@Radiology.ucsf.edu**	P.I./Fellow Academic Title: Current Title Eligible for P.I. Status? ☒ Yes ☐ No If NO, attach Principal Investigator Status Form. Form available at http://www.research.ucsf.edu/cg/ucsfform.htm)
Funding Agency: **DOD**	Agency Deadline: **4/12/2004** ☐ Postmark or ☒ Receipt Date
Address Proposal To: (street & room number required for overnight delivery) **U.S. Army Medical Research Acquisition Activity, Attn: MCMR-AAA-B, 820 Chandler St., Fort Detrick, MD 21702-5014**	( ) Additional Copies To: (street & room number required for overnight delivery)
Agency Contact (if known): **Judy Pawlus** Phone: **301-619-7322** Fax:	E-mail: **judy.pawlus@det.amedd.army.mil**
Administering Dept. / ORU: **Radiology** Administrative Contact (AC) Person: **Travis Seawards**	AC Phone: **353-7983** AC Fax: **885-7876** AC E-mail: **Travis.Seawards@Radiology.ucsf.edu**
Initial Budget Period (mm-dd-yyyy): **8/1/2001** to **8/1/2002** Initial Budget Period Amount: **$16,273.00** (Direct costs) **$7,648.31** (F&A costs) **$23,921.31** (Total)	Total Project Period (mm-dd-yyyy): **8/1/2001** to **8/1/2004** Total Project Period Amount: **$65,829.00** Total including F&A costs
Indirect Cost Rate: **47.00 %**	Does this proposal include mandatory cost sharing? ☐ Yes ☒ No If yes, mark amount: **$0.00** Source:

RFP#, RFA#, Program Title (if any):
(Attach Copy of RFP, RFA, or Program Announcement)

Project Title (200 characters maximum): **Outcomes Of Screening Mammography in Elderly Women**

Check One Box In Each Column:

Type of Action:	Type of Agreement:	Type of Project:
☐ New ☒ Renewal of No. **DAMD17-00-1-0193** ☐ Continuation of No. ☐ Revision of No. ☐ Supplement of No.	☒ Grant ☐ Contract ☐ Cooperative Agreement ☐ Subcontract Prime Funding Agency ☐ Fellowship	☒ Research ☐ Instruction ☐ Public Service ☐ Clinical Trial ☐ Other Clinical Service ☐ Equipment ☐ Other Sponsored Activity

Check 'Yes', 'No', or 'Pending/Just-in-Time' for each item below:

Yes	No	Pending or JIT	
☐	☒	☐	Committee on Animal Research. If yes, attach approval
☒	☐	☐	Committee on Human Research. If yes, attach approval
☐	☒		Radiation Safety Committee
☐	☒		Biosafety Committee
☐	☒		Use of human stem cells. If yes, attach CHR approval
			Federal applications only - Are the following costs budgeted for:
☐	☒		Clerical or other administrative salaries *
☐	☒		Local telephone costs, postage, or memberships/subscriptions *
			* If yes, these charges must comply with the UCSF Charging Practices (see http://recfin.ucsf.edu/Docs/Cpolicy.Htm)
			NIH applications only:
☐	☒		MOU – Does this project involve faculty with a joint VAMC/UCSF Appointment? (If yes, attach one copy of the signed memorandum of understanding (MOU) See http://www.research.ucsf.edu/os/jointform.htm)

DISCLOSURE OF FINANCIAL INTEREST*

Yes	No	
☒	☐	Is the Sponsor PHS or NSF, or a sponsor that follows PHS/NSF disclosure requirements? If yes, attach PI Declaration Form plus all Participant Disclosure of Financial Interest Forms. For a list of PHS agencies, see http://www.research.ucsf.edu/colsc/colsc_federal.htm
☐	☒	Is the Sponsor a non-governmental agency? If yes, attach FPPC 700-U Form (Statement of Economic Interest) unless exempt. For a list of exempt agencies see http://www.ucop.edu/research/exempt.htm

* Disclosure forms are available at http://www.research.ucsf.edu/colsc/colsc_forms.htm

Space commitment: By approving this proposal submission the administering department chairperson/ORU director assures that adequate space will be available for the duration of the project.

Project is on campus at: (check site(s))	Project is off campus at: (check site(s))
☐ Parnassus ☐ Laurel Hts. ☐ MCB ☒ Mt. Zion ☐ SFGH ☐ Mission Bay ☐ Other: (provide address):	☐ VAMC ☐ 74 New Montgomery St. ☐ 3180 18th St. ☐ Fresno, ☐ UC Richmond Field Stn. ☐ Other: (provide address):
Department(s) to which space is assigned: Radiology	

Certification: the information provided is accurate and complete to the best of my knowledge. In the event this proposal is funded, I shall accept responsibility for the design, execution and management of the project.

Philip W. Chu — 4/11/2004

Additional Review Signatures: (see http://www.research.ucsf.edu/ag/deptsig.htm for a list of required signatures)

Rebecca Smith-Bindman, MD — 4/11/2004

Ryo Aragon, MD

Pat Byrd — 4/19/04

Electronic version for Research Grant Application Forms

DISCLOSURE OF FINANCIAL INTERESTS

University of California, San Francisco

Provision of the information on this form is mandatory for the Principal Investigator and any Participant identified by the PI as someone who has responsibility for the design, conduct or reporting of research on a sponsored project (i.e. any individual who can direct the research or research results), in accordance with Public Health Service (PHS) or National Science Foundation (NSF) regulations and the *University Policy on Disclosure of Financial Interests Related to Sponsored Projects.* Failure to disclose may result in loss of federal funding. This information may, under the California Public Records Act, be released to sponsoring agency personnel or members of the public. Submit the original of this form with the proposal that is sent to Contracts and Grants.

Principal Investigator's Name: Philip W. Chu

Title of Proposal or Award: Outcomes of Screening Mammography in Elderly Women

Agency Name and Award Number (if known): DAMD17-00-1-0193 DOD

(THIS FORM MUST BE COMPLETED AND SIGNED BY SIGNATORY. FALSE DISCLOSURES CAN RESULT IN LOSS OF FUNDING AND OTHER DISCIPLINARY ACTION.)

Name of Participant Making This Disclosure: Philip W. Chu

Mailing Address: 1667 **Department:** Radiology **Phone:** 885-3842

Email Address: Bill.Chu@Radiology.ucsf.edu

☒ I DO NOT have a financial interest in a single entity, which exceeds $10,000 income, or 5% ownership interest related to the research to be conducted as part of the above-referenced project.

☐ I DO have a financial interest in a single entity, which exceeds $10,000 income, or 5% ownership interest related to the research to be conducted as part of the above-referenced project.

CERTIFICATION

I certify that this a complete and accurate disclosure of any financial interest, which would reasonably appear to be related to this sponsored project.

Signature: Philip W. Chu *Date:* Apr 15, 2004

WHAT IS A "RELATED" INTEREST? Whenever it could reasonably appear that the research to be undertaken could be affected by, or have an effect on an investigator's financial interest, the financial interest is "related" to the sponsored project. The following examples are financial interests that are "related" to the sponsored project:

- The Investigator is conducting a project where the results could be relevant to the development, manufacturing, or improvement of the products or services of the entity in which the Investigator has a financial interest.
- The Investigator has a financial interest in an entity which might manufacture or commercialize a drug, device, procedure or any other product used in the project or that will predictably result from the project.
- The Investigator receives income exceeding $10,000 (including payments to the Compensation Plan) from a single entity for consulting activities that would reasonably appear to be related to the research.
- The Investigator has a financial interest in an entity and the sponsored project will subcontract a portion of the work, or lease property, or make purchases from the entity.
- The sponsored project will involve referral of patients/subjects to organizations in which the Investigator has a financial interest.

WHAT IS A "FINANCIAL" INTEREST?

- Income from a single entity including salary, consulting fees, honoraria, royalties, dividends, or any other payments or consideration with value, including payments made to the Compensation Plan.
- Equity in any one enterprise in the form of stock, stock options, real estate, or any other investment or ownership interest.
- Income from a management position, such as board member, director, officer, partner, or trustee in any business entity.
- Income from a position as employee in any business entity.

Where financial interests exceed federal thresholds, the Participant must complete a supplemental questionnaire, and the Conflict of Interest Advisory Committee will conduct a complete review. For auditing purposes, the principal investigator and participants in the project may be asked to provide verification of actual financial interests during the term of the sponsored project.

(Retention: Three (3) years after termination of sponsored project or until resolution of any action by the sponsor, whichever is longer.)

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
COMMITTEE ON HUMAN RESEARCH
EXEMPT CERTIFICATION FORM

☐ New ☒ Re-certification

SECTION 1 – General Information

Principal Investigator (Must be an eligible faculty member):		
Name and degree **Rebecca Smith-Bindman, MD**	University Title **Asst. Professor**	Department **Radiology, Epi., & Biostatstatistics**
Campus Mailing Address (Box No.) **Box 1667**	Phone Number **415-885-7511**	E-mail Address **Rebecca.Smith-**
Co-Principal Investigator:		
Name and degree	University Title	Department
Campus Mailing Address (Box No.)	Phone Number	E-mail Address
Administrative Contact Person (optional):		
Name **Travis Seawards**	University Title **AAIII**	Department **Radiology**
Campus Mailing Address (Box No.) **Box 1667**	Phone Number **415-353-7983**	E-mail Address **Travis.Seawards@Radiology.ucsf.edu**
Study Title (may not exceed 300 characters):		
Validation of Medicare Screening Algorithm		

Other Investigators:	**Site(s) (check all that apply):**	
Name and Degree/Department/Site	☒UCSF ☐SFGH ☐VAMC ☐Stanford ☐UC Berkeley ☐ Foreign Country ☐Other(s): _____	☐GCRC (Parnassus)☐ GCRC (SFGH) ☐PCRC ☐Cancer Center

The following information should be completed for each source of funding related to this study. If there is more than one source of funding, please complete and attach the CHR Funding Addendum Form

How will study be funded?		
Type of funding: ☒ Contract/Grant ☐ Subcontract (identify primary funding source): ___ ☐ Gift ☐ Drug/device donation ☐ Student project Have funds been awarded? ☐ Yes ☐ Pending ☐ No	**Source of funding:** ☒ Federal Government ☐ Other Gov't. (e.g., State, local) ☐ Industry (e.g., pharmaceutical co.) ☐ Other Private ☐ Campus/UC-Wide program ☐ Departmental Funds ☐ Other (identify): _____	**Funds will be awarded to:** ☒ UCSF ☐ Gallo Institute ☐ Gladstone Institute ☐ Goldman Institute on Aging ☐ NCIRE ☐ S.F. Dept. of Public Health ☐ UC Berkeley ☐ VA Research Office ☐ Other: _____

Additional details:

- Sponsor Name: NIH
- Award No. (if known):
- Which Department/ORU is administering the contract/grant?
- Principal Investigator on contract/grant (if different from above):
- Study title on contract/grant (if different from above):

Principal Investigator's Certification:

- I certify that the information provided in this application is complete and correct.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all UCSF policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research.
- I will ensure that the personnel performing this study are qualified and adhere to the provisions of this CHR-certified protocol.
- I will not modify this CHR-certified protocol or any attached materials without first submitting an amendment to the previously approved protocol.

Principal Investigator's Signature

Aug. 2 - 2002
Date

Exempt Category Number

EXEMPT CATEGORY NUMBER: 4

********** **CHR Office Use Only** **********

Certification of Exempt Status

On the basis of the information presented here, this research activity qualifies as exempt from review by the Committee on Human Research. Certifications are valid for three years from the date of certification.

Lori M. Yon
CHR Authorized Signature

8/15/02
Certification Date

8/15/05
Expiration Date

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
COMMITTEE ON HUMAN RESEARCH
EXEMPT CERTIFICATION FORM

☐ New ☒ Re-certification

RECEIVED

SECTION I – General Information

Principal Investigator (Must be an eligible faculty member):		
Name and degree **Rebecca Smith-Bindman, MD**	University Title **Asst. Professor**	Department **Radiology, Epi., & Biostatstatistics**
Campus Mailing Address (Box No.) **Box 1667**	Phone Number **415-885-7511**	E-mail Address **Rebecca.Smith-**
Co-Principal Investigator:		
Name and degree	University Title	Department
Campus Mailing Address (Box No.)	Phone Number	E-mail Address
Administrative Contact Person (optional):		
Name **Travis Seawards**	University Title **AAIII**	Department **Radiology**
Campus Mailing Address (Box No.) **Box 1667**	Phone Number **415-353-7983**	E-mail Address **Travis.Seawards@Radiology.ucsf.edu**
Study Title (may not exceed 300 characters):		
Outcomes of Screening Mammography in Elderly Women		

Other Investigators:	**Site(s) (check all that apply):**	
Name and Degree/Department/Site	☒UCSF ☐SFGH ☐VAMC ☐Stanford ☐UC Berkeley ☐ Foreign Country ☐Other(s): _____	☐GCRC (Parnassus) ☐ GCRC (SFGH) ☐PCRC ☐Cancer Center

The following information should be completed for each source of funding related to this study. If there is more than one source of funding, please complete and attach the CHR Funding Addendum Form

How will study be funded?		
Type of funding: ☒ Contract/Grant ☐ Subcontract (identify primary funding source): ___ ☐ Gift ☐ Drug/device donation ☐ Student project Have funds been awarded? ☐ Yes ☐ Pending ☐ No	**Source of funding:** ☒ Federal Government ☐ Other Gov't. (e.g., State, local) ☐ Industry (e.g., pharmaceutical co.) ☐ Other Private ☐ Campus/UC-Wide program ☐ Departmental Funds ☐ Other (identify): _____	**Funds will be awarded to:** ☒ UCSF ☐ Gallo Institute ☐ Gladstone Institute ☐ Goldman Institute on Aging ☐ NCIRE ☐ S.F. Dept. of Public Health ☐ UC Berkeley ☐ VA Research Office ☐ Other: _____

Additional details:

- Sponsor Name: NIH
- Award No. (if known):
- Which Department/ORU is administering the contract/grant?
- Principal Investigator on contract/grant (if different from above):
- Study title on contract/grant (if different from above):

ncipal Investigator's Certification:

I certify that the information provided in this application is complete and correct.

I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.

- I will comply with all UCSF policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research.
- I will ensure that the personnel performing this study are qualified and adhere to the provisions of this CHR-certified protocol.
- I will not modify this CHR-certified protocol or any attached materials without first submitting an amendment to the previously approved protocol.

R Smith — Principal Investigator's Signature

OCT 2, 2002 — Date

Exempt Category Number

EXEMPT CATEGORY NUMBER: 4

********** **CHR Office Use Only** **********

Certification of Exempt Status

On the basis of the information presented here, this research activity qualifies as exempt from review by the Committee on Human Research. Certifications are valid for three years from the date of certification.

Lisa M. Von — CHR Authorized Signature

Oct. 11, 2002 — Certification Date

Oct. 11, 2005 — Expiration Date

SECTION 2 – Study Specific Information

omplete part 1 and/or 2 below for research eligible under Exempt Category #4:

Category #4 The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

A. Biological Specimens- complete the following if you are requesting permission to study biological specimens

1. **In non-technical language briefly describe the study purpose and activities:**

2. **Will there be any contact with the subjects?** ☐ Yes ☐ No

   If "Yes", this research does not qualify as exempt. Please fill out and submit a subcommittee or full committee application for CHR review.

3. **What is (are) the type(s) of biological specimens?**

   *Please note that if you are working with cell lines you may not need CHR approval. However, you will have to review the *CHR Requirements for Human Tissue Research in the CHR Guidelines* to make a determination.*

4. **Are these from a nationally recognized or an established UCSF Tissue Bank?** ☐ Yes ☐ No

   If "Yes" please answer the following questions.
   Owner/Person in charge of the tissue bank:
   Name of Tissue Bank:
   Location:

   If "No" identify the specific source:
   ☐ **UCSF on-site**
   ☐ **Off-site**
   Specific Location of source:
   Owner/Name of person providing specimens:

5. **Are these pre-existing specimens? Pre-existing means the specimens are collected prior to this research use for a purpose other than the proposed research.** ☐ Yes ☐ No

6. **Are the specimens originally collected for:** ☐ Research Purposes ☐ Clinical Purposes

   Attach a copy of the IRB Approval Notice and Consent Form for the research responsible for the original collection of the data/specimens. If the original collection came from a UCSF IRB Approved study you can just provide the CHR approval number in the space below. If you do not have this documentation, provide a written justification for not having it:

7. **How are the specimens identified when they are made available to the study team?**

   ☐ No Identifier (i.e., no one can identify a subject from *any* information recorded for the research)
   ☐ Indirect Identifier (i.e., a code which could be used by the *source* to identify a subject)
   - Does a written agreement or policy ensure that the source will not identify subjects to the researcher? ☐ Yes ☐ No
   - If there is no agreement or policy, the study does not qualify as exempt.

   ☐ Direct Identifier (i.e., subject name, address, social security number, medical record number, or telephone number)

   Please note: If the researcher can connect the specimen with subjects the study will not qualify for exempt certification. If indirect identifiers are used, a written agreement or policy must specify that the source will not identify subjects to the researcher. If the researcher may receive identifying information, please fill out a subcommittee or full committee application.

8. **Please attach a list with all the data points (e.g. characteristics that are associated with the specimen i.e. gender, age, disease).** ***(Note- your study cannot be reviewed without this information) If this is not applicable, please explain:***

9. **Other approvals needed if using biological specimens:**

You must also have or apply for Biosafety Committee (BSC) approval through the Biological Use Authorization (BUA) process. BUA Applications and assistance may be obtained from your Departmental Safety Advisor (DSA), the Biosafety Officer at 476-2097, or the BSC Office at 476-2198. Forms may also be obtained from the Campus Library or the Environmental Health and Safety (EH&S) web site

BUA number, if known:

2) Will human biological specimens in this study be used in animal studies? ☐ Yes ☐ No

If "Yes," you must also apply for Committee on Animal Research (CAR). CAR Applications may be obtained from the CAR website. For assistance you may call the CAR Office at 476-219

CAR approval number, if known:
Date submitted to the CAR:

B. Records Review and/or Data Analysis- complete the following if you are requesting permission to review records or do data analysis.

1. **In non-technical language briefly describe the study purpose and activities**: Using prospectively collected data from the San Francisco, New Mexico, and Washington State Breast Cancer Surveillance Consortium (BCSC) registries, linked with data from Seer-Medicare for the same geographical regions from 1992-1996, we have assessed whether Medicare physician claims can be used to accurately distinguish screening from diagnostic mammography among 4,140 elderly women with breast cancer. Specifically, we have 1) compared the accuracy of an algorithm developed from Medicare claims for distinguishing whether mammography is obtained for screening or diagnostic purposes by comparing the algorithm's classification of type of examination with the corresponding information from three BCSC mammography registries; 2) if the algorithm for differentiating type of mammographic examination based on the SEER_Medicare data is valid, i.e. at least 90% accurate, the SEER-Medicare database will be used to evaluate screening utilization among Medicare recipients, and will evaluate how utilization varies by age and racial/ethnic group, and 3) if the algorithm for differentiating type of mammographic screening examination based on the SEER_Medicare data is valid, i.e. at least 90% accurate, the SEER-Medicare database will be used to evaluate differences in breast cancer tumor attributes including size and stage, and differences in breast cancer treatment rates including masectomy, lumpectomy, and radiation between women who undergo routine screening mammography and women who do not.

   (This may be the same as in B.1.a. if you are also working with biological specimens.)

2. **Will there be any contact with the subjects?** ☐ Yes ☒ No

   If "Yes", this research does not qualify as exempt. Please fill out a subcommittee or full committee application for CHR review.

3. **What types of records will be reviewed? (Check all that apply)**

   ☐ Medical Records (i.e. STOR, clinic records, UCSF Medical Records)
   Identify type:
   ☐ Cancer Center
   ☒ Publicly available (i.e. DMV, library, newspapers)
   ☒ Data Sets
   ☐ Other:

4. **Do you have clinical privileges to access these records or data sets?** ☒ Yes ☐ No

   If "No" provide a letter of support from clinic or department or IRB approval if from another institution, or explain how you access to the records or data sets:

5. **Will any records or data sets that contain identifiable private information be used? (e.g., medical, accounting, research databases)**

   ☐ Yes ☒ No a code which could be used by the investigator to identify a subject

6. **How will data be recorded from the source records?**

☒ No Identifier (i.e., no one can identify a subject from *any* information recorded for the research)
☐ Indirect Identifier (i.e., a code which could be used by the *source* to identify a subject)
- Does a written agreement or policy ensure that the source will not identify subjects to the researcher? ☐ Yes ☐ No
- If there is no agreement or policy, the study does not qualify as exempt.

☐ Direct Identifier (e.g., subject name, address, social security number, medical record number, or telephone number)

Please note: If there is any way you can connect the research record with subjects identifiers in the source record the study will not qualify for exempt certification. Please fill out a subcommittee or full committee application for CHR review

g. **Please attach a list with all the data points (e.g. characteristics that are associated with the specimen i.e. gender, age, disease).** ***(Note- your study cannot be reviewed without this information) If this is not applicable, please explain:*** All subjects are women – patient age, race, information on inpatient and outpatient hospital admissions, diagnoses, comorbidities, use of physician screening and diagnostic testing, cancer diagnosis including size, stage and maturity.