National Human Adipose Tissue Survey

OPERATIONS MANUAL



Exposure Evaluation Division
Office of Toxic Substances
U.S. Environmental Protection Agency

National Human Adipose Tissue Survey

Operations Manual

For National Human Monitoring Program
Office of Toxic Substances
U.S. Environmental Protection Agency

EPA Prime Contract No.68-02-4252 MRI Project No. 8863-20

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PREFACE

This is a revision of the National Human Adipose Tissue Survey (NHATS) Operations Manual and replaces all previous versions. This operations manual was prepared as a guide for personnel involved in the conduct of the NHATS and to assist in maintaining consistency and thoroughness in the ongoing activities. The manual describes in detail the activities involved in the recruitment of cooperators, maintenance of the cooperator network, processing of specimens, and reporting.

Examples of forms, labels, correspondence, and other items used by NHATS personnel are included in the appendices. This manual was prepared by Lori Bailey and Kay Turman for Work Assignment No. 20 of EPA Contract No. 68-02-4252. The NHATS operates under the direction of Ms. Janet Remmers, Work Assignment Manager, and Dr. Joseph Breen, Project Officer, Field Studies Branch (TS-798), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Sincerely,

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I. INTRODUCTION

The National Human Adipose Tissue Survey (NHATS) is responsible for the collection of human adipose tissue based on demographic characteristics (age, sex, and race) reflective of the population distribution in specific areas of the United States. Researchers use the adipose tissue to monitor the prevalence of selected toxic substances and to estimate the level of exposure experienced by the general population. The results are used in evaluating various factors and conditions pertaining to human health and effective environmental regulations.

The EPA, through EPA Contract No. 68-02-4252, Work Assignment 20, directs MRI to operate the collection network in support of the program goals. Operation of the network includes recruitment of the cooperators, maintenance of the cooperator network, processing of specimens, and reporting to EPA. These activities are described in detail in this manual in order to provide a guide for personnel involved in the operation of the NHATS.

Information needed for operation of the NHATS is contained in the following sections:

- II. Reference Information
- III. Recruitment of Cooperators
- IV. Maintenance of Cooperator Network
- V. Processing of Specimens
- VI. Reporting

Examples of letters, forms, tables, and other items used in the operation of the NHATS are included in the following appendices:

Appendix A Recruitment of Cooperators

Appendix B Maintenance of Cooperator Network

Appendix C Processing of Specimens

Appendix D Reporting

II. REFERENCE INFORMATION

To understand the sections on operation of the NHATS, reference information is necessary. This section provides a glossary of terms used throughout the manual, a list of the NHATS files, and a description of the NHATS status boards.

A. Glossary

Table 1 is a glossary of terms used throughout this manual and in the day-to-day operation of the NHATS.

B. Files

Several files are maintained and used routinely in the operation of the NHATS.

- 1. <u>Cooperator File</u>—a separate file for each cooperator which contains records of all contacts with the cooperator.
- 2. Quota Sheet File—an accordion file containing quota sheets for the current fiscal year, alphabetically filed by cooperator name.
- 3. <u>Cooperator List Files</u>—files containing the following lists:
 - a. All Cooperator List--database list of all cooperators who have ever participated in NHATS (p. A-2).*
 - b. Current Cooperator List--database list of all cooperators currently participating in NHATS (p. A-16).
 - c. Cooperator Recruitment List--database list of all cooperators recruited for NHATS since 1983 (p. A-3).

4. Recruitment Files

- a. Current Recruitment File--file containing information on recruitment in progress.
- b. "Finished" File--file containing information on previously completed recruitments.
- c. Possible Cooperator File--file containing information on facilities which might be interested in future participation in NHATS.
- 5. <u>Shipping File</u>—an accordion file containing documentation of shipments of supplies to cooperators.

^{*} Reference to page in an appendix.

Table 1. Glossary of Terms

| Term | Definition | | |
|--------------------|--|--|--|
| Cooperator | Facility at which collection of specimens takes place | | |
| Cooperator Network | The more than 90 cooperators currently collecting specimens | | |
| Contact Person | Person (pathologist, pathology assistant, diener, secretary, etc.) who is contacted by telephone to obtain information on collection | | |
| Specimen | Adipose tissue collected by the cooperator | | |
| Fiscal Year (FY) | Period of collection which runs from October 1 through September 30 | | |

6. Patient Summary Report (PSR) Files

- a. "To Be Checked In" File--file of PSRs which corresponded to specimens not yet checked in.
- b. "Missing Information" File--file of incomplete or questionable PSRs which correspond to specimens which have been checked in.
- c. "To Be Batched" File--file of completed PSRs which correspond to specimens which have been checked in.
- d. PSR File--file of PSR copies retained at MRI after originals are mailed.

C. Status Boards

White, erasable boards (3 ft by 4 ft) are maintained with the current status of collection for each cooperator, each region, and nationwide. Each of three boards contains the following information for a portion of the cooperator network:

- 1. Cooperator name
- 2. Geographic location
- 3. Cooperator quota
- 4. Number of design specimens received at MRI
- 5. Number of specimens collected but not shipped
- 6. Date of last contact by NHATS staff
- 7. Response rate for the previous FY
- 8. Percentages of quota achieved for each region
- 9. Comments on each cooperator

The boards provide an up-to-date summary of the status of the collection in an easily readable, graphic manner. A diagram of the information included on the status boards is shown on p. A-17.

III. RECRUITMENT OF COOPERATORS

Recruitment activities are summarized in Figure 1. Described in this section are identification of potential cooperators, recruitment activities, and post-recruitment activities. Appendix A contains examples of letters, forms, and other materials used in recruiting activities.

A. Identification of Prospective Cooperators

Prospective cooperators fall into two categories. Steps are listed describing activities followed to recruit each of the two categories of cooperators: New MSA and Current or Previous MSA. For all steps, documentation of the activity and its outcome is essential for future reference.

1. New MSA

- a. Consult the MSA list to identify cities and counties included in the MSA.
- b. Identify the city or county with the largest population.
- c. Call directory assistance to get the phone number, if any, for the county coroner or medical examiner. Get the numbers for all counties included in the MSA. Try the largest city in the county or the county seat.
- d. Call the medical examiner's or coroner's office to get the name of the medical examiner or coroner and the mailing address.
- e. If there is only one medical examiner's or coroner's office to contact, continue with step g. If there are at least two medical examiner's or coroner's offices to contact, do not contact any hospitals unless the medical examiner's or coroner's offices decline to participate.
- f. If there is no listing for a medical examiner or coroner, call the county offices or sheriff to determine who performs the county autopsies. If autopsies are performed at a hospital, see step g.
- g. Consult the American Hospital Association (AHA) Guide for cities/counties included in the MSA. Within the county, look at general hospitals and children's hospitals. The hospital should have a histopathology laboratory, and the number of beds is preferred to be ≥ 200. (Generally, the larger the number of beds, the better.) If there is no children's hospital, the hospital should have a pediatrics unit and a newborn nursery. Select the three best choices (if possible). If a hospital performs the coroner's autopsies, include it in the "three best" category.

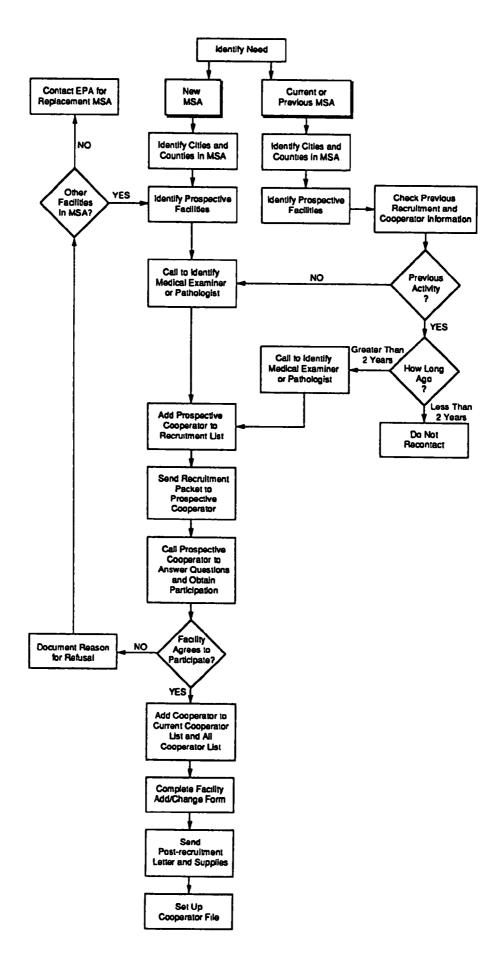


Figure 1. Recruitment of cooperators.

h. Call the selected hospitals (the phone number is in the AHA Guide). Ask for anatomic pathology or the laboratory. Introduce yourself and ask for the name of the chief pathologist or the lab director. Ask for the direct phone number and verify the hospital address. Thank them. If necessary, explain that you want to send information regarding a research program to the pathologist.

2. Current or Previous MSA

a. Replicate or Replacement Cooperators

When it has been decided that a replicate cooperator is needed for a MSA (the current cooperator is performing poorly or is not able to collect certain age groups, or the current cooperator drops out and must be replaced):

- (1) Consult the MSA list to identify the counties and cities included in the MSA.
- (2) Consult the "All Cooperators List" (p. A-2) to determine previous cooperators in the MSA.
- (3) Check the recruitment list data bases (p. A-3) to determine if any other recruitment activities have occurred in the MSA during the last 3 to 4 years.
- (4) If there are no previous cooperators with previous recruitment activities, treat as a new MSA.
- (5) For previous cooperators or cooperators with previous recruitment activities, recontact if:
 - It has been more than 3 years since they participated.
 - It has been more than 2 years since any recruitment activities occurred.

Many times a cooperator which previously declined to participate, when recontacted, may have new staff willing to participate, or other changes in circumstance which now allow them to participate.

b. Reinstated MSA

When a MSA which previously was dropped from the design is reinstated, treat it like replicate or replacement cooperators, but ignore the criteria in Step 5. Previous performance should be considered, especially if the former contact person is still working for a prospective cooperator.

B. Recruitment

Activities are described which occur subsequent to identification of prospective cooperators.

1. Recruitment Packet

- Add the prospective cooperator's name to the recruitment list (p. A-3) and request a recruitment letter (p. A-4).
- b. Assemble remainder of packet:
 - Copy of quota sheet for that MSA (p. A-5)
 - NHATS info flyer (p. A-6)
 - Guidelines for collection (p. A-8)

 - Patient summary report (PSR) (p. Á-12) Reprint of journal article of analysis results
- Proofread the letter and recruitment list. list, sign and photocopy the letter, add to the packet, and ship.
- Send the packet Federal Express Standard Overnight (delivery by next business afternoon).

2. Recruitment Documentation

- Make a call sheet (p. A-13) for each MSA and complete said a. form. Use this sheet to document all phone calls to and from the prospective cooperator. Document with date, time, person contacted, and notes on conversation.
- Put photocopy of letter, original quota sheet, delivery notice, and call sheet in current recruitment file.

3. Phone Calls

After the prospective cooperator has had 2 to 3 days to read the contents of the recruitment packet:

- Call the prospective cooperator. a.
- b. If he/she is not available, leave a message for them to return the call collect. Try to find out when they will be available.
- If they are available and will speak to you, introduce yourself and explain that you are calling in reference to the information that was sent about the National Human Adipose Tissue Survey.

- d. Ask if they received the information.
 - (1) If they have not received it, offer to send them a duplicate recruitment packet and explain the program briefly.
 - (2) If they have received it, ask if they have any questions. If they have questions, answer them--most of the time they missed something in the guidelines or they have concerns about confidentiality.

e. Obtain participation.

- (1) If the prospective cooperator declines to participate, document the reason for refusal and go to step g.
- (2) If the prospective cooperator agrees to participate, determine the contact person and go to post-recruitment activities (Section C).
- (3) If the prospective cooperator has to get department or hospital approval, has to see if anyone on staff is interested, needs more information, etc., find out how long it should take to obtain a decision. State that you will call back on a specified date. They may say they will call; then give them a "deadline." If they don't call back by that date, call them.
- f. Be persistent and make follow-up calls. Leave messages if necessary. Continue until you get a final decision.
- g. If the prospective cooperator declines to participate, staple all recruitment materials (photocopy of letter, call sheet, shipping order, quota sheet, and any correspondence) together and put in the "finished" file for current fiscal year. If they might be interested in the future, put photocopy of call sheet in Possible Cooperator file.
- h. If all prospective cooperators in a MSA have been contacted and all declined to participate, document the reasons and request a replacement MSA from the OTS Work Assignment Manager.

C. Post-recruitment

Activities are described which occur subsequent to obtaining an agreement to participate by a facility.

1. Post-recruitment Letter and Supplies

- a. Pull the post-recruitment letter (p. A-15) and the Current Cooperators List (p. A-16). Request a letter, label, and envelope for each new cooperator. The new cooperator will be added to the Current Cooperator List when the letter is printed.
- b. Assemble supplies (Appendix B) for the new cooperator:
 - Shipping container (Styrofoam in aluminum or Styrofoam in cardboard)
 - Collection bottles (quota and 3 to 6 extra)
 - Bottle labels (quota and 3 to 6 extra)
 - Dry ice labels (2 large, 2 small)
 - Return label
 - Federal Express airbill--put facility name in block with MRI charge number, record airbill number and retain for future reference
 - Patient Summary Reports (PSRs)—make master by typing facility name, city, and state on PSR, photocopy it (make extras), and file master with other PSR masters
 - Instructions for completing PSR flyer
 - Helpful hints flyer
 - Guidelines for collection
 - Copy of latest newsletter
 - Quota sheet copy (fill in facility name, photocopy, send one copy in box, one with letter)

Put all paperwork in a zip-lock plastic bag and place bottles and paperwork in the shipping box.

Unless situation is urgent, send supplies UPS. If time is critical, send supplies Federal Express Economy Service.

c. Proofread the post-recruitment letter and Current Cooperator List and sign and photocopy the letter. Send the letter and a copy of the quota sheet U.S. Mail (unless time is critical, then add to the supplies in the shipping box). Retain the copy of the post-recruitment letter in the cooperator file.

2. File Setup

- a. Photocopy the call sheet and staple a copy to the inside cover of the cooperator file.
- b. Add recruitment correspondence to file.
- c. Type up red file label with facility name, city, and state and label the file.

d. All correspondence in file should be in sequential order, by date, with the most recent on top.

3. Paperwork

- a. Put original quota sheet in the quota sheet file.
- b. When shipping papers are received, put in shipping file.
- c. Put original call sheet in "finished" recruitment file.
- d. Add facility to NHATS status board (p. A-17).
- e. Complete facility add/change form (p. A-14). If a previous cooperator, use the old ID number and mark "rejoin survey." If a new cooperator, assign an ID number from the "All Cooperator List." Mail the original to Battelle Columbus Laboratories (the statistical contractor) and a copy to OTS.

IV. MAINTENANCE OF COOPERATOR NETWORK

Figure 2 summarizes activities necessary to maintain the cooperator network. Details are described in Sections IV.A and IV.B. Examples of forms, letters, and other materials used for maintenance of the cooperator network are shown in Appendix B.

A. New Fiscal Year Activities

Approximately one month prior to the beginning of a new fiscal year (FY), each cooperator is asked during a regular contact whether they will continue to participate during the new year. If they decline, recruitment activities are followed (Section III). For all continuing cooperators and any newly recruited cooperators, the following new FY activities take place:

1. Design Plan Review

The design plan is supplied prior to the beginning of the fiscal year. The plan consists of a list of the metropolitan statistical areas (MSAs) and their collection quotas by number, age, sex, and race categories. The plan is compared to the previous design plan to determine differences. If any MSAs have been replaced, send the cooperators in the dropped MSA a letter informing them of that fact and requesting the return of their supplies (primarily the shipping box). Begin recruitment in the replacement MSA.

2. Purchase of Supplies

a. Collection Bottles

Bottles should be chemically clean, 1-oz glass containers with Teflon-lined metal screw caps. Several suppliers such as I-Chem and Scientific Specialities offer this type of bottle, cleaned by a specified protocol (p. B-2).

b. Bar Code Labels

Bar code labels (p. B-3) are ordered from a local supplier (Graphic Technology, Inc.) and include the bar code and the seven-digit number. Six replicates of each label are ordered (one for inventory notebook, one for bottle label, one for bottle cap, one for the Patient Summary Report, two extras).

The labels are cold-resistant, durable, self-adhesive, white laminated paper, applied at MRI as the specimens are processed. The first two digits of the number are the FY, the next three digits are sequential numbers from 0001 to 1900, and the seventh is a check digit. The procedure for generating the check digit is included in Appendix B (p. B-4). The computer program to generate the sequential numbers is also included (p. B-5). Prior to final printing of the labels, a proof copy is received from the printer and is verified against the computer-generated numbers printed at MRI. Approximately 10% of the numbers are verified manually. After the proof copy of numbers is verified as being correct, enough labels for the FY are ordered (total quota plus 400 to 500 extra).

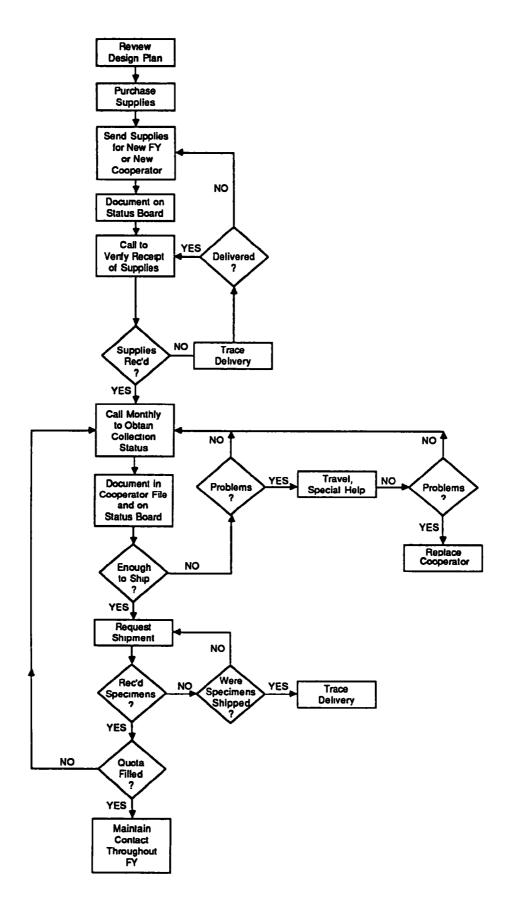


Figure 2. Maintenance of cooperator network.

c. Shipping Containers

There are two types of containers: an aluminum shipping container with a Styrofoam insert and a "Freeze Safe" Styrofoam box contained in an outer cardboard box. Each of these boxes is approximately $10 \text{ in } \times 10 \text{ in}$ in a large enough to hold up to 30 specimens on dry ice. The aluminum shipping containers can be manufactured at MRI, and the "Freeze Safe" Styrofoam shipping containers are available from local scientific supplies (such as Baxter Scientific).

d. Bottle Labels

Bottle labels (p. B-6) are prepared and ordered through MRI's graphic arts department. They are cold-resistant, self-adhesive labels which are attached to the bottles at the collection site and include facility information, patient ID number, and date of collection.

e. Other Supplies

Other supplies (dry ice labels, baggies, PSRs, etc.) are ordered on an as-needed basis from local suppliers. No special order instructions are necessary for these supplies.

3. Shipment of Supplies

Collection supplies are shipped to each cooperator at the beginning of the fiscal year. The following supplies (p. B-6 to B-13) are included in the shipping container:

- Collection bottles (quota and 3 to 6 extra)
- Bottle labels (quota and 3 to 6 extra)
- Dry ice labels (2 large, 2 small)
- Return label
- Federal Express airbill—put facility name in block with MRI charge number, record airbill number, and retain for future reference.
- Patient Summary Reports (PSRs)--personalized with facility name and location
- Instructions for completing PSR flyer
- Helpful hints flyer
- Guidelines (p. A-8)
- Ouota sheet copy

On the outside of the shipping container, apply a label which reads "Open Immediately--Important Instructions are inside for the National Human Adipose Tissue Survey" (p. B-14).

B. Ongoing Activities

Many activities occur regularly throughout the fiscal year. These enable NHATS staff to maintain regular contact with the cooperators and stay informed about collection status.

1. Status Calls

Calls to each cooperator are completed at least once a month. The calls are to obtain a status report on collection, answer questions, uncover potential problems, and otherwise maintain a personal relationship with the cooperator. Documentation of all calls is recorded in the cooperator file.

2. Shipment Request

If during status calls, a cooperator says they have several specimens collected, shipment may be requested. At that time, an expected shipment date is recorded on the status board. If the shipment is not received, a follow-up phone call or a "please ship" written reminder may be used to encourage shipment.

3. <u>Cooperator Withdrawal</u>

During status calls, the contact person may inform us that they no longer wish to participate in the survey. After documenting their reason for withdrawal, ask them to return their supplies, especially the shipping box. Complete a facility add/change form and send one copy to Battelle Columbus Laboratories and one copy to OTS.

If there are other cooperators in the MSA who are performing adequately, it may not be necessary to begin recruitment of a replacement cooperator. If there are no other cooperators in the MSA or the other(s) are performing poorly, decisions must be made to either begin recruitment or request a replacement MSA, if there are no other possible cooperators in the MSA.

4. Travel

Travel, meaning a personal visit with a cooperator, may occur for various reasons during the year.

a. New Cooperator

A cooperator may be visited shortly after being recruited, especially if there are no other cooperators in the MSA or if the other cooperators are not performing well. The purpose of this visit is to make sure that the cooperator understands the requirements of the program, to train the cooperator, and to ensure that the cooperator will collect specimens correctly. Specific questions and/or problems that the cooperator may have can be answered during the visit.

b. Problem Cooperator

A cooperator may be visited if he is not collecting and/or shipping specimens as expected. The purpose of the visit is to determine the problem areas and to help remedy them. Specimens and PSRs will be picked up, and missing PSR information will be gathered during the visit.

c. Other

Cooperators may be visited in the course of a trip to see other cooperators. These "piggy back" visits are advantageous both to save cost dollars and to maintain personal contact for the enhancement of the program.

Cooperator response generally increases after a personal visit. Also, the visits usually give MRI staff insight into how cooperators perceive the program and what areas of the program need to be stressed or explained further.

5. Additional Communication

In addition to status calls and visits, additional contact is planned to encourage cooperation and teamwork among the participants in the program.

- NHATS newsletter—once a year.
- Status reports--usually halfway through FY.
- "End of year" reminder--a letter sent near the end of the FY to encourage collection and shipment.
- Analysis results--copies are sent to the cooperators when available, to promote a sense of purpose to the collection.

V. PROCESSING OF SPECIMENS

The steps in processing specimens are described in the following section. Included are receipt, check-in, payment, transfer of information, follow-up activities, and analysis. Appendix C contains examples of forms, letters, and other materials used to process the NHATS specimens.

A. Receipt of Specimens

This section describes activities associated with the receipt of specimens. Figure 3 summarizes activities which occur after samples are delivered to the laboratory by shipping personnel.

- 1. Pull forms--shipment log (p. C-2), bag insert (p. C-3), PSR cover sheet (p. C-4).
- 2. Determine originating facility of shipment.
- 3. Record the number of the airbill that was used.
- 4. Open box and remove PSRs and specimens. Count number; they should match.
- 5. Determine fiscal year(s) of specimens; use appropriate shipment log(s).
- 6. Enter appropriate information into shipment log and assign shipment number.
- 7. Inspect specimens (wear gloves).
 - a. Complete bag insert.
 - b. Visually inspect specimens for quality and condition.
 - (1) It should be > 1 g of good quality adipose tissue.
 - (2) Lids should be tight.
 - (3) Specimens should be frozen or at least cool (make note in shipment log if they are warm and no dry ice is visible in box).
 - (4) If any bottles are cracked or broken, transfer specimen to a new bottle and label appropriately. (If specimens are out of the bottles, reject and dispose.)
 - (5) Dispose of broken bottles by rinsing them with a 1:1 solution of household bleach in water and then dispose.

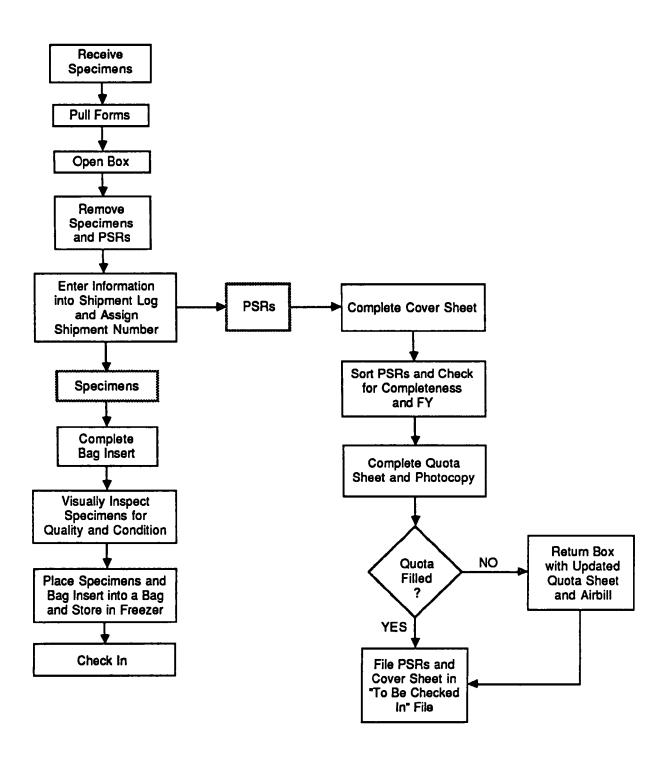


Figure 3. Receipt of specimens.

(6) Place specimens and bag insert in a bag and store in the freezer until check-in.

8. Inspect PSRs.

- a. Complete cover sheet.
- b. Sort PSRs into the categories on the quota sheet.
- c. Check for completeness and appropriateness of information.
 Use colored clip to mark any PSRs that are incomplete or have information that needs to be checked.
- d. Clip any PSR for which there was an insufficient quantity of specimen.
- e. If any age, sex, or race is missing, make a note and attach it on the cover sheet.
- f. If any specimens have infectious diseases such as AIDS or hepatitis, reject specimen, mark PSR, and put specimen in labeled biohazard bag. Place bag in freezer for later disposal.
- g. Complete quota sheet for facility.
- h. Attach a note to quota sheet with information regarding missing age, sex, or race.
- i. If the cooperator's quota has not been filled, return the shipping box to the cooperator with a copy of the quota sheet, return airbill, dry ice labels, and a return label.
- j. Place PSRs and cover sheet (clipped together) in "To Be Checked-in" file.
- 9. Update status boards.

B. Check-in of Specimens

Step-by-step instructions for check-in of specimens are shown in Figure 4. The steps are described in this section.

- 1. Gather check-in supplies: (a) FY stamps and ink pad; (b) extra bottle labels and PSRs; (c) top loader balance; (d) FY specimen inventory notebook (p. C-5); and (e) bar code labels.
- 2. Remove PSRs and Quota sheet from "To Be Checked-in" file, stamp PSRs with date received and correct FY, and write shipment number on each PSR.

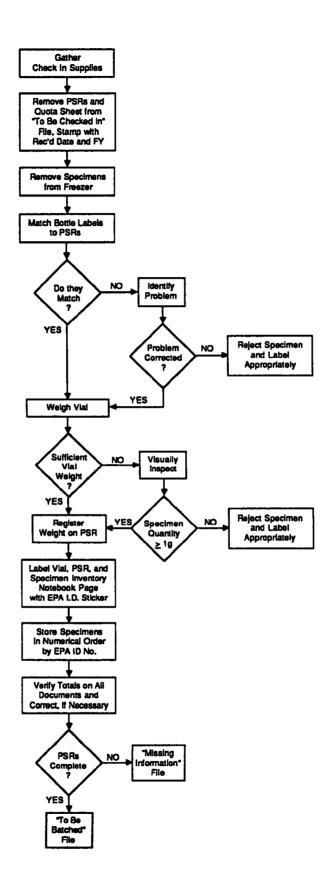


Figure 4. Check-in of specimens.

- 3. Remove specimens from freezer.
- 4. Match bottle labels to PSRs and place bottles in same order as PSRs.
- 5. Do all match?

If not, identify problem and correct it, if possible, by consulting cooperator and/or work assignment leader. If problem is not correctable, reject the specimen and label PSR and specimen bottle appropriately.

6. Weigh vial on top-loading balance.

Sufficient vial weight (> 2 g over bottle weight)

a. No--visually inspect, using standards in freezer.

If < 1 g of tissue, reject specimen, label PSR and bottle appropriately.

If ≥ 1 g of tissue, accept specimen, write total weight (rounded to nearest gram) on PSR and estimated tissue weight with your initials and date.

- b. Yes--write weight (rounded to nearest gram) on PSR.
- 7. Label vial (side and lid), PSR, and inventory notebook page with EPA ID number. Continue until all specimens in shipment have been checked in.
- 8. Store specimens in freezer at -4°C in numerical order by EPA ID number.
- 9. Verify totals on all documents (cover sheet, quota sheet, and inventory page) and correct, if necessary.
- 10. Are the PSRs complete?
 - a. No--put in "Missing Information" file.
 - b. Yes--put in "To Be Batched" file.

C. Storage of Specimens

Specimens are stored at 0°F in the NHATS storage facility (p. C-6). The facility consists of 11 manual defrost freezers equipped with audible and visual alarms in case of freezer failure. All specimens are stored upright in racks in numerical order by EPA ID Number or Sample Number. The temperature of each freezer is manually checked once a week and recorded on a temperature log attached to the door of the freezer. Freezers are defrosted periodically as needed.

D. Payment to Cooperator

The cooperators are remunerated at the rate of \$25 per acceptable specimen for their collection services. Payment activities are described in this section and shown in Figure 5.

- 1. Pull the quota sheet for the cooperator.
- Complete two forms for payment.
 - a. Request for payment form (p. C-6)--includes payee, amount, and hours (0.45 h/specimen).
 - b. Authorization for payment form (p. C-7)--includes date of shipment, detail on number of design and surplus samples, amounts, and reference number from the current cooperator list database.
- Photocopy both completed forms.
- 4. Request check.
- 5. Request a payment letter (p. C-8).
- 6. When the check and the payment letter have been received, photocopy both.
- 7. Assemble the check, payment letter, and a copy of the cooperator's quota sheet for mailing.
- 8. Prior to mailing, check the PSRs associated with the payment for missing information.
 - a. If there is missing information, copy the PSRs and send a request for the information along with the check and payment letter. Be sure to include a postage-paid return envelope.
 - b. If the PSRs are complete, mail the check, payment letter, and copy of the quota sheet.
- 9. Mark "pd" in the shipment log next to the appropriate shipment information.

E. Transfer of Information

Information on specimens received is transferred to the statistical contractor and EPA via the patient summary reports. Steps in the transfer of this information are given in this section and shown in Figure 6.

1. PSRs are removed from the "To be batched" file and grouped in batches of 40 or less, by order of the shipment number. Do not divide a shipment into separate batches.

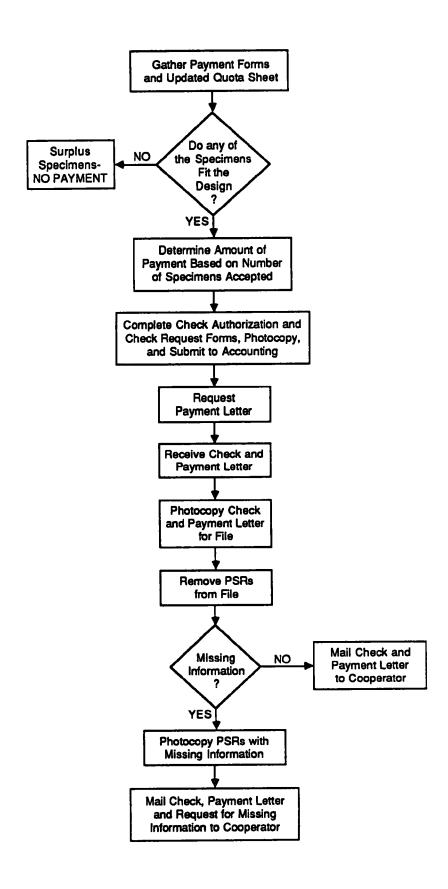


Figure 5. Payment to cooperator.

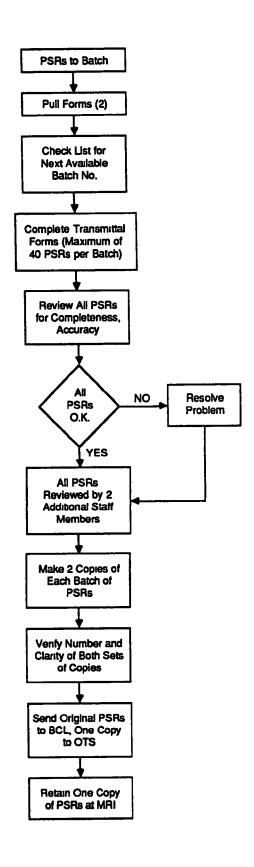


Figure 6. Transfer of information.

- 2. The log sheet of batch information transfer form (p. C-9) and the PSR transmittal form (p. C-10) are pulled from the file and completed.
- 3. Each batch of PSRs is reviewed by three separate NHATS staff members for completeness and appropriateness.
- 4. Two copies are made of each transmittal form and corresponding PSRs--all copies are counted and checked for readability.
- 5. The batches containing the original PSRs are sent to Battelle Columbus Laboratories, one copy is sent to the OTS Design and Development Branch, and the other copy is retained at MRI.

F. Follow-up Activities

Missing information or answers to questions on patient summary reports must be obtained from the cooperator. Original requests (sent with payments) may not be answered. A follow-up phone call to the cooperator approximately 2 weeks following the original request should be made. Written requests for the information should continue approximately once a month until the information is received. If the necessary information cannot be obtained, the corresponding specimen is rejected.

G. Analysis of Specimens

By request from OTS, specimens may need to be retrieved from the repository for chemical analysis. If such a request is received, the specimens will be pulled from the repository by EPA identification numbers (or sample identification number if no EPA ID exists). The ID numbers will be verified against the hardcopy inventory list. The specimens will be retrieved from the freezer and shipped on dry ice to the analysis laboratory. Documentation for all specimen ID numbers (such as date removed, new location, etc.), will be made on the inventory list. Following analysis, any remaining specimens will be returned to the repository and documentation of date returned, location, etc., will be made on the inventory list. Any depleted specimens will be removed from the inventory list.

VI. REPORTING

This section describes reporting activities performed by NHATS staff. Requested required reports are submitted to OTS. Additional reports or information about the program are submitted or presented to current and potential cooperators. Examples of these reports are in Appendix D.

A. Monthly Progress Report

A report on the current NHATS activities is included in the Monthly Periodic Progress Report (p. D-2), submitted by the 15th of each month to OTS. The report contains sections describing progress, QA/QC activity, and problems which occurred during the reporting period. A copy of the current Collection Quota Status Report is included in the monthly report of current activity. Plans for the coming month are also given.

B. Collection Quota Status Report

The current fiscal year collection status is reported to OTS each month. Two Collection Quota Status Reports (CQSRs) are prepared and submitted. One includes collection status for each cooperator, each MSA, each region, and overall; the second omits information regarding each individual cooperator's status. The shorter version (p. D-3) is included in the Monthly Periodic Progress Report. The longer version is submitted directly to the OTS Work Assignment Manager by the 5th of each month.

Both CQSRs are generated on a PC using Multiplan spreadsheet software.

C. Recruitment Reports

Recruitment reports (p. D-7) are submitted to OTS twice a month (by the 5th and 20th) to summarize recruitment activity for the reporting period. Information is included on the MSA and facility being recruited, current activity, future activity, and any pertinent comments on specific recruitments.

D. Trip Reports

A cooperator visit is summarized in a trip report (p. D-10). The report includes who was visited, date of visit, person making the visit, details of the visit, problem areas, conclusions, and future action items. A copy is sent to OTS, and the original is placed in the cooperator file.

E. Additional Reports

Periodically, additional reports are prepared to present NHATS information to the current cooperators. Examples are the NHATS newsletter (p. D-11) and status reports (p. D-12) halfway through or at the end of the fiscal year. All these reports are reviewed and approved by the OTS Work Assignment Manager.

F. Presentations

Two NHATS exhibits are available for presentation at professional meetings for the purpose of promoting the program to current and potential cooperators.

APPENDIX A

RECRUITMENT OF COOPERATORS

| 1. | "All Cooperators List" Database | A-2 |
|-----|------------------------------------|------|
| 2. | Cooperator Recruitment Database | A-3 |
| 3. | Recruitment Letter | A-4 |
| 4. | Collection Quota Sheet | A-5 |
| 5. | Information Flyer | A-6 |
| 6. | Brochure | A-7 |
| 7. | Guidelines for Collection | 8-A |
| 8. | Patient Summary Report | A-12 |
| 9. | Recruitment Call Sheet | A-13 |
| 10. | Add/Change Form | A-14 |
| 11. | Post-recruitment Letter | A-15 |
| 12. | "Current Cooperator List" Database | A-16 |
| 13. | Diagram of Status Board | A-17 |

ALL COOPERATORS LIST DATABASE

| Cooperator Codes | - Numerical Order | Cooperators - Alphabetical Order | | |
|----------------------------------|-------------------|----------------------------------|-------------------|----------|
| <u>Format</u> | | Format | | |
| 001 Facility E 002 Facility L | Name, City, State | | | Code No. |
| 003 Facility P | | Facility A | Name, City, State | 002 |
| 004 Facility B | | Facility B | | 004 |
| 005 Facility I | | Facility C | | 009 |
| 006 Facility R | | Facility D | | 800 |
| 007 Facility Q | | Facility E | | 001 |
| 008 Facility D | | Facility F | | 017 |
| 009 Facility C | | Facility G | | 013 |
| 010 Facility K | | Facility H | | 015 |
| 011 Facility M | | Facility I | | 005 |
| 012 Facility A | | Facility J | | 014 |
| 013 Facility G | | Facility K | | 010 |
| 014 Facility J | | Facility L | | 002 |
| 015 Facility H | | Facility M | | 011 |
| 016 Facility N | | Facility N | | 016 |
| 017 Facility F | | Facility 0 | | 018 |
| 018 Facility 0 | | Facility P | | 003 |
| nnn Facility | | Facility Q | | 007 |
| · - | | Facility R | | 006 |
| | | Facility _ | | nnn |

COOPERATOR RECRUITMENT DATABASE*

Format

Pathologist Name
Title
Organizational Name
Street Address
City, State Zip Code
Telephone Number
(1)

Pathologist Name
Title
Organizational Name
Street Address
City, State Zip Code
Telephone Number
(2)

Pathologist Name Title Organizational Name Street Address City, State Zip Code Telephone Number (n)

^{*} This list contains all contacts made since MRI assumed responsibility for NHATS in 1983. The list is chronological (as indicated by the number following each contact); however, it can be sorted by pathologist, organization, etc.

RECRUITMENT LETTER

November 14, 1988

NO ITEM TO INSERT

Dear NO ITEM TO INSERT:

Midwest Research Institute operates the National Human Monitoring Program for the Environmental Protection Agency. Through this program EPA is working to determine incidences, levels, and trends of pesticide and other toxic residues in the U.S. population. The program, which began in 1967, depends on the cooperation and commitment of pathologists, medical examiners, and coroners who agree to furnish the specimens for study.

NO ITEM TO INSERT

, has been selected as one of 47 cities representative of the general populace. This letter is our invitation to you to participate in this important program.

One activity conducted by the National Human Monitoring Program concerns the analysis of human adipose tissue for residues of selected organic compounds such as organochlorine insecticides and polychlorinated biphenyls (PCBs). These samples are secured from previously excised surgical specimens and/or postmortem examinations. Since the study is conducted in accord with statistically based design, cooperators are requested to submit only specimens conforming to the assigned demographic (age, sex, and race) quota reflective of the population distribution in that area.

We have enclosed some background material, reprints, and guidelines for collecting specimens. Note that the enclosed collection protocol discusses some of the legal issues of tissue collections which are of concern to us all. We will furnish all supplies (shipping containers, forms, bottles, etc.) and will remunerate you or your designee at the rate of \$25.00 per acceptable specimen.

We hope that you will assist our continuing study by providing selected adipose tissues obtained during routine pathological examination. I will telephone you in a few days to answer any questions you may have and to further discuss the project. If you prefer, you may contact us by calling (collect) 816/753-7600.

Sincerely yours,

Kay Turman Midwest Research Institute Program Coordinator National Human Adipose Tissue Survey

KT/1m

Enclosures

COLLECTION QUOTA

National Human Adipose Tissue Survey National Human Monitoring Program Fiscal Year 1990 Survey (Oct. 1, 1989 to Sept. 30, 1990)

| Cooperator: | |
|-------------|--------------|
| Location: | Total Quota: |

| ANNUAL | | | DATE | NUMBER | NUMBER | *NON- | BALANCE |
|--------------|-------|-----------|-------------|----------|----------------|--|-----------|
| QUOTA | AGE | SEX | RECEIVED | ACCEPTED | SURPLUS | CAUCASIAN | REMAINING |
| | 0-14 | Male | | | | | |
| | | | | | <u> </u> | ļ | |
| | | | | | | | |
| | | | | | | | <u> </u> |
| | | L <u></u> | | | | | |
| | 0-14 | Female | | | <u> </u> | | |
| | | | | | <u> </u> | | |
| | |] | | <u> </u> | <u> </u> | <u>. </u> | |
| | | | | | | | |
| | | <u> </u> | | | | | |
| | 15-44 | Male | | | | | |
| ł | | | | | | | |
| | | 1 | | | | | |
| ļ | | | | | | | |
| | 15-44 | Female | | | - | l | - |
| | 13-44 | remale | | | <u> </u> | | |
| | | | | | | | |
| | | | | | | | |
| ļ | | | | | | | |
| - | 45 + | Male | | | - | | |
| [| 40 1 | | | | | | |
| | | Ì | | | | | |
| | | | | | | | |
| | | | | <u> </u> | | | |
| | 45+ | Female | | | | | |
| | | | | | | | |
| | | | | | | | |
| 1 | | | | | | | |
| 1 | | | | | | | |
| | | Totals | 1 | | | | |

| *NON-CAUCASIAN: | to be distributed | i among the | Total Quota |
|-----------------|-------------------|-------------|-------------|
|-----------------|-------------------|-------------|-------------|

National Human Adipose Tissue Survey

The National Human Adipose Tissue Survey (NHATS), established in 1967, has been operated by the U.S. Environmental Protection Agency (USEPA) on an annual basis since 1970. The purpose of the NHATS, the main operative program of the National Human Monitoring Program (NHMP), is to monitor on a national scale the prevalence of selected pesticides and toxic substances and the level of exposure experienced by the general U.S. population. The data collected are used to identify trends in this exposure and to assess the effects of regulatory actions.

Pathologists and medical examiners throughout the conterminous United States are cooperating in the collection of specimens for NHATS. The nine geographic regions and 52 collection sites are shown in Figure 1.



AN IMPORTANT STEP IN VALUABLE HEALTH RESEARCH

What is NHATS?

The National Human Adipose Tissue Survey (NHATS) is a statistically designed national survey to collect human adipose tissue for research purposes.

What is the purpose of NHATS?

The purpose is to collect human adipose tissue based on demographic characteristics (age, sex, and race) reflective of the population distribution in specific areas of the U.S. Researchers use the adipose tissue to monitor the prevalence of selected toxic substances and the level of exposure experienced by the general U.S. population.

What toxic substances have been investigated?

Baseline levels for pesticides, polychlorinated biphenyls (PCBs), polychlorinated dibenzo-p-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs), volatile organic compounds, and trace metals have been determined for the U.S. population.

Who participates in NHATS?

Three groups participate in NHATS: a management team, a collection team, and an analysis team.

- The U.S. Environmental Protection Agency Office of Toxic Substances, Washington, D.C. manages NHATS. Midwest Research Institute, Kansas City, Mo., operates NHATS and maintains the repository of adipose specimens.
- Approximately 90 pathologists and medical examiners from 47 cities across the U.S. are currently collecting human adipose tissue from post-mortem examinations and previously excised surgical specimens. Current and past participants have collected more than 10,000 adipose specimens since NHATS was established in 1967.
- Researchers composite, extract, and analyze the adipose tissue for specific toxic substances based on environmental concerns determined by the U.S. EPA. The data collected are statistically examined to identify trends in exposure to toxic substances and to assess the effects of regulatory actions.

How can I learn more about NHATS?

If you are interested in participation, or if you desire copies of analysis results, please contact one of the persons listed on the attached card.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Guidelines and General Information Regarding the Collection of Adipose Tissue for the National Human Adipose Tissue Survey

The National Human Adipose Tissue Survey is responsible for determining, on a national basis, the prevalences, levels, and other evidence of exposure to pesticides in the general population of the United States. At present, the program collects adipose tissue and analyzes for selected pesticides and their metabolites and other toxic chemicals stored in the lipid portion of these tissues. The results are used in evaluating various factors and conditions pertaining to human health and effective pesticide regulations.

The adipose tissue for this program is secured through the cooperation of participating pathologists and medical examiners located throughout the continental United States. The tissue is obtained from surgical specimens previously excised for therapeutic or elective purposes and from postmortem examinations. The specimens are sent to our laboratories in Kansas City, Missouri for analysis. We will send periodic reports of results to participating physicians. Summaries that compare results among regions of the country will also be provided as they become available.

In order to develop statistically valid information on a national basis, collections must be made according to a survey design that dictates the number of specimens required. The quotas of specimens reflect the demographic distribution of the population in the appropriate census division. As a participant, you should have a copy of the annual quota of specimens expected to be collected from your location on a fiscal year basis. All collections should be made according to this age/sex/race distribution. You should have no difficulty collecting the number of specimens required in each category. Since our total sample is relatively small and the validity of the results depends on a high response rate, your participation is particularly important. If you feel that you will be unable to collect the number of specimens required, please let us know.

Criteria for Selection of Patients to Be Sampled

Since the program objective is to reflect the prevalence and level of exposure to selected pesticides experienced by the general (person-on-the-street) population, a few suggestions are listed here for your guidance:

• The highest priority should be given to satisfying the number and demographic distribution of your annual quota. This quota should be completed as soon after the start of the fiscal year as possible.

- Patients with known or suspected pesticide poisoning should not be sampled, but if you are involved with a potential pesticide poisoning, we would like to know about it. To repeat, specimens should not be taken from such individuals for the National Human Adipose Tissue Survey.
- Patients who exhibit cachexia or who have been institutionalized for long periods should not be sampled.
- Patients with AIDS, hepatitis, or other infectious blood diseases should not be sampled.

Legal Considerations

The National Human Adipose Tissue Survey staff is both interested in and concerned about the legal ramifications of this human research project. Since the program operates in about 40 states, it is not feasible for us to handle the variety of local and state legal interpretations that may arise. Therefore, as a matter of EPA policy, legal requirements, such as informed consent, confidentiality, etc., are matters for your consideration and resolution. We will, however, assist you in any way possible.

We have completed several studies on these matters and do not believe that they present major obstacles to your participation. In most documents authorizing postmortem examinations, there is a clause granting the examining physician permission to remove tissues for research purposes. We consider this project to be in that category. In the case of specimens recovered from your surgical practice, the use of a small amount of tissue from a previously excised specimen certainly does not place the patient at risk in any way whatsoever.

As you will notice in the discussion that follows regarding data needed for each patient sampled, we do have mechanisms to assure confidentiality. In fact, the disclosure or release of certain data is protected by several Federal statutes, including the Privacy Act and the Freedom of Information Act.

The fees paid to you by our program are intended solely to remunerate you or your designee for professional services rendered.

Collection of Adipose Tissue

At least five grams (approximately equal to a rounded tablespoon) of good quality, high lipid-containing adipose tissue, such as subcutaneous, perirenal, or mesenteric adipose tissue, should be collected each time. Avoid fibrous or connective tissue and fascia (i.e., omentum). Such specimens will not yield a satisfactory analysis.

Adipose tissue should be taken dry and should not be rinsed before being placed into the sample bottles. Many water supplies contain materials that would interfere with chemical analysis. Instruments should be well-rinsed with distilled water and dried before the adipose specimen is taken. Contact with other chemicals, such as paraffin, disinfectants, preservatives, or plastics, should be avoided. Take special care to keep specimens from different patients separate. Make certain that the specimens are correctly and securely labeled.

Specimens of adipose tissue may be collected from unfixed surgical specimens that have been excised for therapeutic or elective purposes. Avoid cutting the tissue on paraffin.

Specimens of adipose tissue may also be collected during postmortem examinations. These specimens must be obtained from <u>unembalmed</u> cadavers only. The interval between death and the collection of tissue should be as short as possible and in any case must not exceed 24 hours, assuming refrigeration during that interval.

The specimen of adipose tissue taken should be placed in the chemically clean container provided, without any fixatives or preservatives. Complete the self-adhesive bottle label legibly in ballpoint pen. Securely affix the bottle label, wrap each bottle in gauze to prevent breakage, and freeze. Specimens should be stored upright in the freezer at $14^{\circ}F$ (- $10^{\circ}C$) until shipment.

Completion of the Patient Summary Report

A Patient Summary Report should be completed for each patient from whom a specimen was taken. Special attention should be given to the completeness of the data. First and last initials, in that order, should be used instead of the complete name to ensure that confidentiality is maintained.

Confirmed diagnoses should be detailed in the spaces provided. Only the major ones should be supplied. Other required information should be completed as accurately as possible. The completed forms should be held and placed under the outer lid of the insulated container when specimens are shipped.

Packing and Shipping

Tighten all lids on the specimen bottles carefully. This is important, since we are required to use special aluminum foil cap liners that make tightening somewhat difficult. Be certain that a completed bottle label is firmly attached to each specimen bottle. Wrap each bottle in gauze or paper to prevent breakage during shipment and to keep the label on the container. Place the specimen bottles in a plastic bag in the insulated mailer. Add ~ 5 pounds dry ice to keep specimens frozen in transit.

New transport regulations require any materials shipped in dry ice to be specially labeled. Since frozen medical and/or diagnostic specimens are exempt from some of these requirements, be sure that the contents of the shipping containers are clearly indicated by <u>ORM-A: FROZEN MEDICAL SPECIMENS</u>. We have provided a special label for this purpose. If, for some reason, you do not have these labels, please attach a card or piece of wide adhesive tape with ORM-A: FROZEN MEDICAL SPECIMENS indicated in indelible ink.

A Federal Express airbill and the local number for pickup is provided. There is no cost to you because of the preaddressed airbill. All insulated mailers should have a <u>PERISHABLE - PACKED IN DRY ICE</u> label, visible from all sides, on the outside.

Specimens should be shipped on Monday, Tuesday, or Wednesday. This ensures that they will arrive on or before Friday.

Patient Summary Reports should be sent in the carton with the specimens whenever possible. They can be folded and placed on the top of the polyfoam lid.

Only specimens which meet our criteria and are handled according to the guidelines can be accepted. No substitute vials will be accepted.

For Further Information

If you have questions, problems, or comments, please contact either of us by calling (collect):

Kay Turman Midwest Research Institute 425 Volker Boulevard Kansas City, MO 64110 (816) 753-7600 Janet C. Remmers
National Human Monitoring Program
Exposure Evaluation Division (TS-798)
U.S. Environmental Protection Agency
Washington, DC 20460
(202) 382-3583

October 1988

MEDICAL RECORD: This form contains medical information the disclosure or release of which is restricted by U.S.C. 552, (b)(6); 45 CFR Part 5.

Form Approved
OMB No. 2000-0392
Approval expires 11-30-91

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF TOXIC SUBSTANCES EXPOSURE EVALUATION DIVISION (TS-798) FIELD STUDIES BRANCH WASHINGTON DC 20460

NATIONAL HUMAN ADIPOSE TISSUE SURVEY PATIENT SUMMARY REPORT (PSR)

| FIELD STUDIES BRANG WASHINGTON DC 2040 | | PANERT | |
|--|--|--------------------------------|--|
| INSTRU 1. All unshaded questions for which inf 2. Date should be in the form of Month, | | DO NOT WRITE IN SHADED AREA | |
| Public reporting burden for this collection of information if for reviswing instructions, searching existing data sources, and reviswing the collection of information. Send comment collection of information, including suggestions for reducing U.S. Environmental Protection Agency, 401 M St., S.W., Wa Regulatory Affairs, Office of Management and Budget, West | 8 9 1011 12 13 14 15 16 17 18 19 20 | | |
| HOSPITAL (Name, City and State) | | | 21 22 23 |
| PATIENT'S LD. NO. (Hospital, Accession, or SSN) | PATIENT'S INITIALS (First of | nd Last) | 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 |
| DATE COLLECTED (Month, Day and Year) | BIRTH DATE OR AGE | | 39 40 41 42 43 44 45 46 |
| PATHOLOGIST | SEX MALE | FEMALE | 47 48 49 50 51 52 53 54 55 56 57 |
| HEIGHT (Complete one) | ☐ NEG | ER (Specify) | |
| OCCUPATION RETIRED UNKNOWN | SPECIMEN COLLECTED (CA | AT POSTMORTEM | 59 60 61 62 63: 64-65 66 67 6B 89 |
| | WAS PATIENT HOSPITALIZE BEFORE SAMPLE TAKEN? YES | □ NO | 70 75 72 73 74 75 76 77 78 79 |
| MAJOR DIAGNOSES | OR CAUSES OF DEATH | | |
| 1. | 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 85 | | |
| 2. | ·· · · · · · · · · · · · · · · · · · · | | |
| 3. | 112 127 | | |
| 4. | | | |
| 5. | 144 | | |
| 6. | 180 | | |
| REMARKS | | | |
| PKG. NO | | | |

EPA Form 8510-10 (Rev. 10/88)

PREVIOUS EDITIONS ARE OBSOLETE

RECRUITMENT CALL SHEET

| | MSA: |
|--|---------------------|
| Facility: | First contact date: |
| Address:(department) | Date received: |
| (street or box #) | |
| (city, state, zip code) Phone: () Other: () Contact person: | - |

Date called and result of call:

NATIONAL HUMAN AIPOSE TISSUE SURVEY (NHATS) FACILITY ADD/CHANGE FORM

To be filled in by MRI

| Date completed | Facility ID |
|--|---------------------------------------|
| Ву | |
| | |
| Facility Name | |
| Street | |
| City | State Zip |
| County | |
| | |
| $\hfill\square$ 1. New Cooperator: date joined | survey |
| | |
| ☐ 2. Change of address: | |
| | |
| ☐ 3. Change in status: date | |
| - | rejoin survey |
| <u> </u> | · · · · · · · · · · · · · · · · · · · |
| | |
| · | |
| To be fil | lled in by Battelle |
| MSA | Date added/changed |
| State FIPS Abbreviation | Ву |

June 1990

POST-RECRUITMENT LETTER

//S// January 23, 1990

NO ITEM TO INSERT

Dear NO ITEM TO INSERT

It was a pleasure talking with you about the National Human Adipose Tissue Survey. I appreciate your willingness to cooperate in this survey.

Under separate cover I have sent you the following supplies:

Guidelines for specimen collection (extra copy)
Helpful Hints Flyer
Patient summary reports
"Instructions for Completing PSR" flyer
Collection bottles
Bottle labels
"Dry Ice" labels
Federal Express Airbill
Shipping container

Enclosed with this letter is the Collection Quota form that gives the number of specimens required for each sex and age group. After collection, please keep the specimens frozen until there is a sufficient number (about 10) for shipment. Please be sure to add sufficient dry ice to keep the specimens frozen during transit. We will return the shipping container to you as soon as possible.

An updated Collection Quota form reflecting the number of acceptable specimens received will be sent to you along with a check.

Thank you again for your participation. If you have any questions, please do not hesitate to call me (collect) at (816) 753-7600, ext. 552.

Sincerely.

Lori Bailey Regional Coordinator National Human Adipose Tissue Survey

LB:1m

Enclosure

CURRENT COOPERATOR LIST

Format

- (1) Cooperator Name
 Organizational Name
 Street Address
 City, State Zip Code
 Payment Information
 Contact Person
 Payee
 Phone Number of Cooperator and/or Contact Person
 Organizational Name
 City, State
- (2) Cooperator Name
 Organizational Name
 Street Address
 City, State Zip Code
 Payment Information
 Contact Person
 Payee
 Phone Number of Cooperator and/or Contact Person
 Organizational Name
 City, State
- (3) Cooperator Name
 Organizational Name
 Street Address
 City, State Zip Code
 Payment Information
 Contact Person
 Payee
 Phone Number of Cooperator and/or Contact Person
 Organizational Name
 City, State

| | Location Cooperator | | Qı | iota | FY | '90 Rec'd | Expected Shipment Date | # | Misc. | Last | Comments | | FY | 89 Rec'd |
|------------------------------|---|---|----------------------|----------------------------|---------------------------------|---|------------------------------|-------------------------------------|-------|------------------------------------|---|------------|--------------------------------|---------------------------------|
| | | - Coporation | MSA | Соор | Design | Surplus (dup) | Date | Collected | | Contact | | | Design | Surplus (dup) |
| East South Central Region | Lexington, KY Memphis, TN Nashville, TN | Coop Coop 1 Coop 2 Coop 1 Coop 2 Totals % Rec'd | 27 27 27 81 | 27 27 27 21 21 | 27 10 16 0 27 80 | 11 ——————————————————————————————————— | | ★ 0 4(s) 3(s) ★ 7(s) | | 6-6 6-18 5-15 5-8 3-30 | DONE Muliple Facilitites Slow DONE | No Dry Ice | 27 7 20 2 25 81 | 15 7 14 <u>2</u> 48 |
| West North Central Region | | | | | · | | | | | | | | | |
| Mountain Region | | | | | | | | | | | | | | |
| Pacific Region | | | | | | | | | | | | | | |

APPENDIX B

MAINTENANCE OF COOPERATOR NETWORK

| 1. | Cleaning Protocol for Bottles | B-2 |
|-----|---|------|
| 2. | Bar Code Labels | B-3 |
| 3. | Procedure for Generation of Check Digit | B-4 |
| 4. | Computer Program for Generation of | |
| | EPA ID Numbers | B-5 |
| 5. | Bottle Label | B-6 |
| 6. | Dry Ice Labels | B-7 |
| 7. | Return Label | B-8 |
| 8. | Federal Express Airbill | B-9 |
| 9. | Patient Summary Report | B-10 |
| 0. | Instructions for Completing PSR Flyer | B-11 |
| 11. | Helpful Hints Flyer | B-12 |
| 12. | Quota Sheet Copy | B-13 |
| l3. | Outer Label for Shipping Container | B-14 |

CLEANING PROTOCOL FOR BOTTLES

- Protocol A™-

Amber Glass Bottles

■ Clear Glass Bottles

■ Wide Mouth Amber Glass Jars

■ Wide Mouth Clear Glass Jars*

* Also available cleaned according to Protocol B™ - see below

Cleaning Protocol A™ specifications:

1. Laboratory Grade Detergent Wash and Rinse

2. Acid, Deionized Water, and Solvent Rinses

3. Oven Drying, Capping and Packing under quality controlled conditions

Sample Containers Prepared According to Protocol A[™] Are Recommended For Use In The Analysis Of:

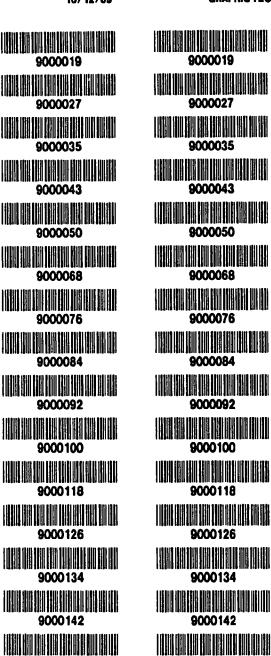
Acidity/Alkalinity Hardness Settleable Residue/Suspended Solids BOD (Biological Oxygen Demand) Mercury Silica Chlorida Metals Sulfate Oil & Grease **COD (Chemical Oxygen Demand)** Sulfide Sulfite Color pН Conductivity Phenois TOC (Total Organic Carbon)

Cyanide Phosphate Turbidity

Extractable Organics

TM Protocol is a trademark of I-Chem Research

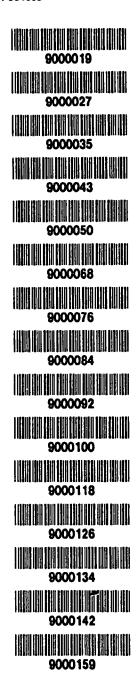




B-3







PROCEDURE FOR GENERATION OF CHECK DIGIT FOR EPA ID NUMBER

- 1. Multiply the EPA number by the special check number.
 - a. The EPA number is the six-digit number generated previously (860001 861500).
 - b. The special check number is also a six-digit number which is 121212.
 - c. The multiplication takes place along each digit.
 - d. Examples:

| <u>1</u> | 2 | <u>3</u> |
|----------|--------|----------|
| 860001 | 860750 | 861500 |
| 121212 | 121212 | 121212 |
| 830002 | 830550 | 831100 |

Note: if the number generated from the multiplication is two digits, subtract 9 from the two-digit number and write down the result.

Example: $7 \times 2 = 14$, 14 - 9 = 5; so a five would be written down as the result.

- 2. Add all the results together to obtain the resultant.
 - a. Examples: 1. 830002 = 13 2. 830550 = 21 3. 831100 = 13
- The last digit of the resultant is subtracted from 10 to obtain the check digit.
 - a. Examples: 1. 10 3 = 72. 10 - 1 = 93. 10 - 3 = 7
- The check digit is then added to the EPA number to create a seven-digit number called the EPA ID number.
 - a. Examples: 1. 8600017 2. 8607509 3. 8615007

COMPUTER PROGRAM FOR GENERATION OF EPA ID NUMBERS

```
O CLEAR, 2000:DIM R(6):CLS:INPUT"Starting label #":ST$:IF LEN(ST$)() & THEN 10

) LOCATE 3,1:PRINT" ":LOCATE 3,1:INPUT"Ending label #"
!EN$:IF LEN(EN$)() & THEN 20

O ST=VAL(ST$):EN=VAL(EN$):A=1:FOR K=ST TO EN

O ST$=RIGHT$(STR$(K),LEN(STR$(K))-1)

JO FOR L=1 TO 6:R(L)=VAL(MID$(ST$,L,1)):NEXT L

O FOR L=1 TO 6:IF L=2 OR L=4 OR L=6 THEN R(L)=R(L)*&

O IF R(L))9 THEN R(L)=R(L)-9

O NEXT L:X=0:FOR L=1 TO 5:X=X+R(L):NEXT L

90 E=INT(X/10):E=10-(X-(10*E)):IF E=10 THEN E=0

OO LPRINT ST$;CHR$(48+E);SPC(9);ST$;CHR$(48+E);SPC(7);

10 IF A/2=INT(A/2) THEN LPRINT":LPRINT:LPRINT
```

BOTTLE LABEL

| | וואט | | ES ENVIRONME | | CTION AGENCY ROGRAM |
|---|--------------|-------|---------------|--------|------------------------|
| N | AME OF HOSE | PITAL | | | |
| P | ATIENT'S INI | TIALS | PATIENT'S IDE | NT NO. | DATE COLLECTED |
| - | ADIPOSE | URINE | SERUM | BLOOD | OTHER (Specify) |

PLEASE RUSH

PERISHABLE KEEP AWAY FROM HEAT ORM-A DRY ICE

FROZEN MEDICAL SPECIMENS WARNING

DO NOT store in closed containers or unventilated spaces. DO NOT expose to high temperatures. IF DELIVERY IS DELAYED, please keep at freezing temperatures, if possible.

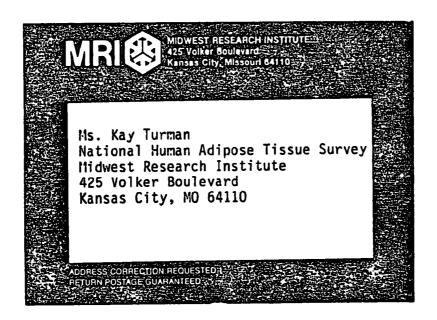
FROZEN MEDICAL SPECIMENS

ORM-A DRY ICE

Packaging Conforms with Standards in CFR 173.615(e), 173.387, 42 CFR 72.25(c) and NIH Guidelines.

EPA HQ FORM 7710-31 (10-79)

RETURN LABEL



MEDICAL RECORD: This form contains medical information the disclosure or release of which is restricted by U.S.C. 552, (b)(6); 45 CFR Part 5.

Farm Approved CMB No. 2000-0392 Approval expires 11-30-91

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF TOXIC SUBSTANCES EXPOSURE EVALUATION DIVISION (TS-798) FIELD STUDIES BRANCH WASHINGTON DC 20460

NATIONAL HUMAN ADIPOSE TISSUE SURVEY PATIENT SUMMARY REPORT (PSR)

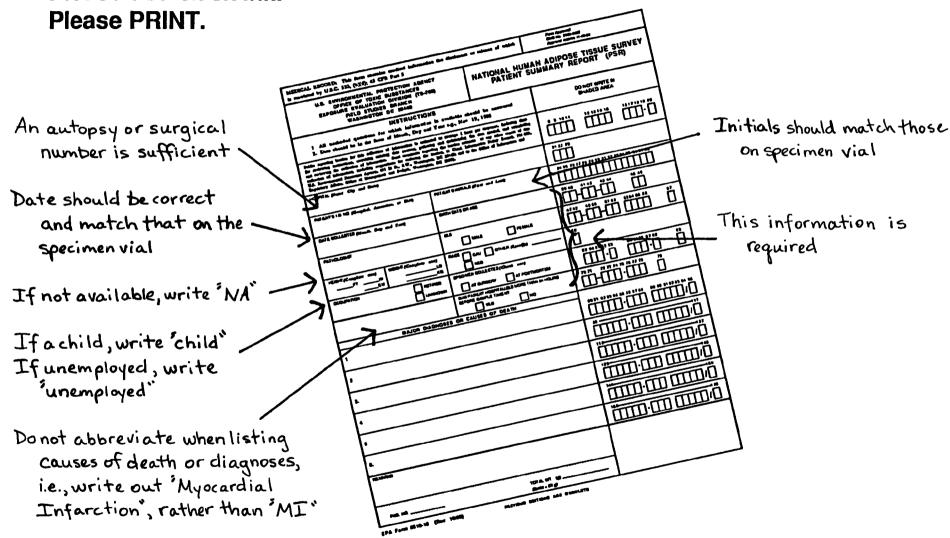
| INSTRUC 1. All unshaded questions for which infor 2. Date should be in the form of Month, D | DO NOT WRITE IN SHADED AREA | | |
|--|--|--|--|
| Public reporting burden for this collection of information is for reviewing instructions, searching existing data sources, a and reviewing the collection of information. Send comments collection of information, including riggsentons for reduring U.S. Environmental Protection Agency, 40t M St. S.W. Washing Regulatory Affairs, Office of Management and Budget, Weshing | schemes and manualing the data needed, and completing regarding the burden estimate or my other aspect of time- tics burden, to Chief, information Poincy Branch, PM-223, ingum, DC 20460; and to the Office of information and | 8 9 1011 121314.15 18171819 20 | |
| HOSPITAL (Name, City and State) | | 21 22 23 | |
| PATIENT'S LD. NO. (Hospital, Accession, or SSN) | PATENT'S INITIALS (First end Lest) | 24 25 28 27 28 29 30 31 32 33 34 35 36 37 38 | |
| DATE COLLECTED (Month, Day and Year) | BIRTH DATE OR AGE | 39 40 41 42 43 44 45 46 | |
| PATHOLOGIST | SEX FEMALE | 47 45 49 50 51 52 53 54 55 58 57 | |
| HEIGHT (Complete one) FTIN | RACE CAU OTHER (Specify) | 5 0 | |
| OCCUPATION RETIRED UNKNOWN | SPECIMEN COLLECTED (Check one) AT SURGERY AT POSTMORTEM | 59 60 61 62 63 64-65 65 67 68 69 | |
| | WAS PATIENT HOSPITALIZED MORE THAN 24 HOURS BEFORE SAMPLE TAKEN? YES NO | 7071 72737475767778 78 | |
| MAJOR DIAGNOSES C | OR CAUSES OF DEATH | | |
| 1. | 80 61 82 83 84 85 80 87 86 89 90 91 92 93 94 95 | | |
| 2. | ······································ | | |
| 3. | | | |
| 4. | 128 | | |
| 5. | 1 4 | | |
| 6. | 150 | | |
| REMARKS | | | |
| PKG. NQ | FCTAL WT. (g): (Bottle = 56 g) | | |

.PA Form 8510-10 (Rev. 10/88)

PREVIOUS EDITIONS ARE OBSOLETE

INSTRUCTIONS FOR COMPLETING PATIENT SUMMARY REPORT

Complete every box that is not shaded. Please use black ink.



NATIONAL HUMAN ADIPOSE TISSUE SURVEY

GUIDELINES AND HELPFUL HINTS FOR COOPERATORS

COLLECTION AND STORAGE OF SPECIMENS

- · Post quota sheet on wall in collection area.
- Mark off quota by age, sex and race as collected to ensure complete collection of the specimens.
- Use only vials and labels that are provided.
- · Complete label and affix securely to vial.
- Collect at least 5 g of high lipid-containing adipose tissue.
- Store specimens at 14°F (-10°C) or below until ready to ship.
- Fill out patient summary reports (PSRs) as soon as possible. One or two a week is easier than 20 or more all at once.

SHIPMENT OF SPECIMENS

- Ship when 6-8 specimens have been collected.
- Check PSRs and vials for complete information.
 Place PSRs under lid of shipping box.
- Tighten lids on vials and wrap vials with gauze to prevent breakage. Place vials in plastic bag for shipping.
- Include ~5 lb of dry ice to keep specimens frozen in transit.
- · Ship on Monday, Tuesday, or Wednesday.
- Use Federal Express airbill provided for shipping.

IF YOU HAVE A PROBLEM OR QUESTION

 Call Kay Turman (x185) or Lori Bailey (x552) collect at (816) 753-7600, from 8 am to 5 pm (CST).

COLLECTION QUOTA

National Human Adipose Tissue Survey National Human Monitoring Program Fiscal Year 1990 Survey (Oct. 1, 1989 to Sept. 30, 1990)

| Cooperator: | General Hospital | |
|-------------|------------------|-----------------|
| | Somewhere ST | Total Quota: 27 |

| ANNUAL QUOTA | AGE | SEX | DATE RECEIVED | NUMBER ACCEPTED | NUMBER SURPLUS | *NON- CAUCASIAN | BALANCE REMAINING |
|-----------------|-------|----------------|------------------|--|-------------------|---------------------------------------|----------------------|
| | 0-14 | Male | | | | | |
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| ┝╌┈┈┥ | | Female | | | | | |
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| ! | 15-44 | Male | | | | | |
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| | 15-44 | Female | | | | | |
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OPEN IMMEDIATELY

Important instructions are inside for the

NATIONAL HUMAN ADIPOSE TISSUE SURVEY (NHATS)

APPENDIX C

PROCESSING OF SPECIMENS

| 1. | Shipment Log | C-2 |
|-----|--------------------------------|------|
| 2. | Bag Insert | Č-3 |
| | | |
| 3. | PSR Cover Sheet | C-4 |
| 4. | Specimen Inventory Page | C-5 |
| 5. | NHATS Storage Facility Diagram | C-6 |
| 6. | Request for Payment Form | C-7 |
| 7. | Authorization for Payment Form | C-8 |
| 8. | Payment Letter | C-9 |
| 9. | Log Sheet of Batch Information | C-10 |
| lo. | PSŘ Transmittal Form | C-11 |

NHATS SAMPLE RECEIPT AND PROCESSING - FY90

| DATE REC D | COOPERATOR | LOCATION | SHIPMENT NO. | NO. REC D/FY | COPPENTS | SUPPLIES REPLACED | CHECKED IN |
|-------------|-------------|----------|---------------|---------------|-------------|----------------------|---------------|
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BAG INSERT

| | National Human Adipose Tissue Survey | |
|---------------|--------------------------------------|--|
| DATE SPECIMEN | S RECEIVED | |
| COOPERATOR | | |
| LOCATION | | |
| NUMBER OF SPI | CIMENS | |
| SHIPMENT NUM | ER | |

Kansas City Missouri 64110 Telephone (816) 753-7600



COVER SHEET TO ACCOMPANY PSRS

National Human Adipose Tissue Survey

| DATE SPECIMENS RECEIVED | |
|-------------------------|-------------|
| COOPERATOR | |
| LOCATION | |
| NUMBER OF SPECIMENS | |
| SHIPMENT NUMBER | |

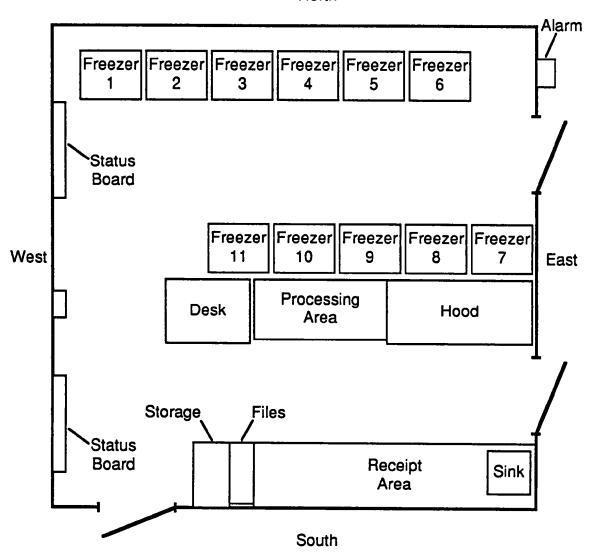
Revised 10/89

FY 90 INVENTORY

| SHIPMENT # / BOX # | COOPERATOR | CITY, STATE | DATE RECEIVED |
|--------------------|------------|----------------------|---------------|
| | | | |
| PATIENT ID # | EPA ID # | PATIENT ID # | EPA ID # |
| 1 | | 15 | |
| 2 | | 16 | |
| 3 | | 17 | |
| 4 | | 18 | |
| 5 | | 19 | |
| 6 | | 20 | |
| 7 | | 21 | |
| 8 | | 22 | |
| 9 | | 23 | |
| 10 | | 24 | |
| 11 | | 25 | |
| 12 | | 26 | |
| 13 | | 27 | |
| 14 | | 28 | |
| CHECKED IN | VERIFIED | TOTAL # OF SPECIMENS | COMMENTS |
| BY: | BY: | | |
| DATE: | DATE: | D S | #REJECTED |

NHATS STORAGE FACILITY

North



INTEROFFICE COMMUNICATION

MIDWEST RESEARCH INSTITUTE

To:

Michael Limbocker

From:

Kay Turman 45

Subject:

Check Request for Collection Services on Project

No. 8863-20-01

The following accounts payable are approved for payment. Please notify me when the checks are ready. I will pick them up.

Payable To

Payment Due

Person Hours

<u>Charge</u> 8863-20-01-6030

MIDWEST RESEARCH INSTITUTE



425 Volker Boulevard Kansas City, Missouri 64110 Telephone (816) 753-7600

AUTHORIZATION FOR PAYMENT NATIONAL HUMAN ADIPOSE TISSUE SURVEY

| Payment is | authorized i | n the amount | of \$ | for s | er- |
|------------|---------------|---------------------------|---------------------------------------|-------------|----------------|
| vices prov | ided in the c | collection of | human adipo | se tissue f | or |
| diagnostic | purposes to: | | | | |
| | | | | _ | |
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| | | | | - | |
| | | | | | |
| | | National | Human Moni | toring Prog | ram |
| Number of | samples accep | oted> | Rate | _ = \$ | |
| Word Proce | ssing: | | | | |
| Ad | dress # | | | | |
| | | Number <u>Accepted</u> | | Payment | <u>Balance</u> |

PAYMENT LETTER

//S// April 25, 1990

NO ITEM TO INSERT

Dear NO ITEM TO INSERT

Thank you for your recent shipment of tissue specimens to the National Human Adipose Tissue Survey. Enclosed is payment for services provided in the collection and shipment of human adipose tissue.

So that you are aware of the status of your collections, we have provided a report on the specimens you sent and the current monetary balance remaining in your account. You will also find enclosed a copy of your quota sheet indicating the number of specimens needed in each category for FY90.

| Date Shipment Received | Total Number Received | Number Accepted | Number Surplus | Amount of Payment | Balance in Account | |
|------------------------------|-----------------------------|--------------------|-------------------|-------------------------|--------------------------|--|
| | | - | - | | | |

NO ITEM TO INSERT

Should you have any questions or comments, please feel free to telephone me (collect) at (816) 753-7600.

Sincerely,

Kay Turman Program Coordinator National Human Adipose Tissue Survey

KT:1m

Enclosures

| Batch | Date Sent | | Patient_Su | ımmany Report | <u> Ar</u> | nalveis Repo | <u>rit</u> |
|-------|-------------|----------|------------|---------------|------------|--------------|------------|
| No. | To Battelle | lnitials | Form No. | # of PSRs | Form # | # of AKs | # of OC |
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NATIONAL HUMAN ADIPOSE TISSUE SURVEY PSR TRANSMITTAL

| Batch Numbe | r | | | Form PSR | |
|-------------------|---------------------|------------------|-------------------|--------------------|--------------|
| Shipped by | MRI: | | Received | at Battelle: | |
| Date | | | Date | | |
| Sent By | | | Recd By | | |
| | To Be Comp | oleted By MRI | | To Be Com By BM | <u> </u> |
| Package Number | Beginning EPA ID | Ending EPA ID | Number Shipped | Number Received | Hosp Code |
| | | | | | |
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| | | Total | | | |
| | | Incomplete PSR | Forms | | |
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APPENDIX D

REPORTING

| 1. | Monthly Progress Report | D-2 |
|----|---------------------------------|------|
| 2. | Collection Quota Status Reports | D-3 |
| | Recruitment Report | D-7 |
| | Trip Report | D-10 |
| | Additional Reports | 0-11 |

EXAMPLE OF MONTHLY PROGRESS REPORT

<u>Work Assignment 20 (25% Complete)</u>: National Human Adipose Tissue Survey (NHATS)

EPA Work Assignment Manager: Janet Remmers MRI Work Assignment Leader: Kay Turman

<u>Progress</u>: Two FY89 design specimens and 14 surplus specimens were received, bringing the totals to date to 1111 design specimens received and 483 surplus received, as shown in Table 2. Two hundred twenty-two (222) FY90 design specimens and 12 surplus specimens have been received to date, as shown in Table 3.

All cooperators were contacted by phone for status reports on collection efforts and to remind them to ship specimens.

Recruitment reports were submitted on December 19 and at the end of the month.

Work continued on the NHATS newsletter, which will include the final FY89 collection status.

Travel was completed to Salt Lake City, Utah, Sacramento, California, and Paterson, New Jersey, to visit five cooperators.

QA/QC Activity: None.

Problems: None.

Plans for the Coming Month: Specimens will be processed as received. PSRs will be batched and sent to BCL.

Calls to cooperators to request shipment and encourage collection will continue.

Work will continue on the reorganization of the sample repository.

The newsletter will be submitted to the EPA WAM for final review, and upon approval, will be distributed to all cooperators.

A brochure of the NHATS exhibit will be drafted and sent to the EPA WAM for review. Work will begin on revisions to the NHATS operation manual.

Table 2. Adipose Tissue Collection Quota Status Report: FY1990 April 30, 1990

| | Total | | | | Quot | 8 | | | | | Saa | ples | acce | pt ed | | | | S | urpl | us r | ecei | ved | | | | Sa | ap l es | | ining | l | | |
|----------------------------|--------------|---------|---------|----------|---------|---------|--------|----|----|----------|---------|----------|----------|-------|----|------|---------|---------|----------|----------|---------|--------|----|-----|----|---------|---------|----------|----------|----|-----|-------|
| NSA and Census Division | MSA quota | 0- M | 14 F | 15- H | 44 F | 45 H | + F | NC | M- | -14 F | 15 M | -44 F | 45+ H | F | KC | | 0- N | 14 F | 15. H | -44 F | 45 H | • F | NC | | 0- | 14 F | 15 M | -44 F | 45+ H | | NC | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| HEW ENGLAND | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Springfield, MA | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 2 | 0 | 0 | 0 | 0 | 4 | 5 | 0 | | 0 | 0 | 0 | 0 | 1 | 0 | 0 | | 3 | 3 | 6 | 6 | 0 | 0 | 2 | |
| Boston, NA | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 2 | 2 | 0 | 1 | 3 | 4 | 3 | 2 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 1 | 3 | 5 | 3 | 0 | 2 | 0 | |
| | 54 | | | | | | | | 2 | 0 | 1 | 3 | 8 | 8 | | - 22 | ō | 0 | 0 | 0 | 1 | 0 | _ | - 1 | 4 | 6 | 11 | 9 | 0 | 2 | _ | - 3 |
| HIDDLE ATLANTIC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Albany-Schenectady, NY | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 5 | | | | | | | | | | | | | | | | | 3 | 3 | 6 | 6 | 4 | 5 | 5 | |
| Binghetn-Eleira, NY | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 5 | ı | 1 | 5 | 6 | 4 | 5 | 4 | | 0 | 0 | 0 | 0 | 4 | 7 | 0 | | 2 | 2 | 1 | 0 | 0 | 0 | 1 | |
| New York, NY | 54 | 6 | 6 | 12 | 12 | 8 | 10 | 10 | 2 | 3 | 3 | 12 | 8 | 10 | 7 | | 0 | 0 | 0 | 1 | 0 | 0 | 0 | | 4 | 3 | 9 | 0 | 0 | 0 | 3 | |
| Paterson, M) | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 5 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | | ٥ | 0 | 0 | 0 | ð | 0 | 0 | | 2 | 2 | 5 | 6 | 4 | 4 | 4 | |
| Erie, PA | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 3 | | | | | | | | | | | | | | | | | 3 | 3 | 6 | 6 | 4 | 5 | 3 | |
| Philadelphia, PA | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 3 | | | | | | | | | | | | | | | | | 3 | 3 | 6 | 6 | 4 | 5 | 3 | |
| Pittsburgh, PA | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 3 | 0 | 0 | 0 | 2 | 4 | 4 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 3 | 3 | 6 | 4 | 0 | 1 | 3 | |
| | 216 | | | | | | | | - | 5 | 9 | 20 | 16 | 20 | | - 74 | • | 0 | 0 | 1 | 4 | 7 | | 12 | 20 | 19 | 39 | 28 | 16 | 20 | _ , | - 142 |
| EAST NORTH CENTRAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Chicago, IL | 54 | 6 | 6 | 12 | 12 | 8 | 10 | 8 | | | | | | | | | | | | | | | | | 6 | 6 | 12 | 12 | 8 | 10 | A | |
| Moline, IL | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 4 | 1 | 0 | ı | 6 | 4 | 5 | 2 | | 0 | 0 | 0 | 2 | 2 | 2 | 0 | | 2 | 3 | 5 | 0 | 0 | | 2 | |
| Detroit, HI | 54 | 6 | 6 | 12 | 12 | 8 | 10 | 8 | 2 | 0 | 1 | 1 | 8 | 10 | 8 | | 0 | 0 | 0 | | | 5 | | | 4 | _ | 11 | | ٥ | | 0 | |
| Akron, OH | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 4 | 0 | 0 | 0 | 4 | 1 | 3 | 2 | | 0 | 0 | 0 | | | 0 | | | 3 | 3 | 6 | 2 | 3 | | 2 | |
| Cleveland, OH | 27 | 3 | 3 | 6 | 6 | 4 | 5 | | 2 | 0 | 2 | 0 | 3 | 1 | 3 | | 0 | 0 | 0 | - | 0 | 0 | | | 1 | 3 | _ | 6 | _ | E | ~ | |

EXAMPLE OF COLLECTION QUOTA STATUS REPORT

Table 2 (continued)

| | Total | | | | Quot | a | | | | | Samp | ites | acce | p t ed | | | | S | urplo | | | | | | | ap i es | | | | |
|----------------------------|--------------|----|---------|----------|----------|---------|---|----|---------|---------|----------|----------|----------|---------------|----|-------|---------|---------|----------|----------|----------|---|------|---------|---------|---------|----------|----------|----|------|
| MSA and Census Division | MSA quota | 0- | 14 F | 15- H | -44 F | 45 H | F | NC | M 0- | 14 F | 15- H | -44 F | 45+ H | F | NC | | 0- M | 14 F | 15. H | -44 F | 454 H | F | HC | M 0- | 14 F | 15 H | -44 F | 45+ H | F | NC |
| Columbus, CH | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 4 | 3 | 3 | 1 | 6 | 1 | 5 | 3 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 3 | 0 | 1 |
| Dayton, OH | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 4 | 1 | 1 | 0 | 2 | 4 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 6 | 4 | 0 | 5 | 4 |
| Madison, WI | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 4 | 3 | 3 | 5 | 5 | 3 | 4 | 0 | | 0 | 0 | 1 | 1 | 1 | 2 | 0 | 0 | 0 | 1 | 1 | 1 | 1 | 4 |
| | 270 | | | | | | | | 12 | ? 7 | 10 | 24 | 24 | 28 | | - 105 | 0 | 0 | 1 | 3 | 7 | 9 | - 20 | 18 | 23 | 50 | 36 | 16 | 22 | - 10 |
| WEST NORTH CENTRAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| St. Louis, MO | 27 | 3. | 3 | 6 | 6 | 4 | 5 | 2 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 5 | 6 | 3 | 5 | 2 |
| Rochester, MN | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 1 | 3 | 0 | 6 | 5 | 4 | 5 | 1 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 1 | 0 | 0 | 0 |
| Dmaha, NE | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 2 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 5 | 5 | 4 | 5 | 2 |
| Grand Forks, ND | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 2 | 0 | 0 | 1 | 3 | 4 | 4 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 5 | 3 | 0 | 1 | 2 |
| Wichita, KS | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 2 | 3 | 3 | 6 | 6 | 4 | 5 | 2 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 135 | | | | | | | | 6 | 3 | 15 | 15 | 13 | 14 | _ | - 66 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9 | 12 | 15 | 15 | 7 | 11 | |
| SOUTH ATLANTIC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Washington, DC | 27 | 3 | 3 | 6 | 7 | 4 | 4 | 6 | 3 | 3 | 4 | 6 | 4 | 4 | 6 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 0 | 0 | 0 |
| West Palm Beach, FL | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 6 | | | | | | | | | | | | | | | | 3 | 3 | 6 | 6 | 4 | 5 | 6 |
| liami, FL | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 6 | 3 | 3 | 5 | 6 | 3 | 3 | 6 | | 0 | 0 | 0 | 0 | 2 | 1 | 3 | 0 | 0 | 1 | 0 | 1 | 2 | 0 |
| Charlotte-Gastonia, NC | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 6 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 6 | 6 | 4 | 4 | 6 |
| ĭampa, FL | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 6 | | | | | | | | | | | | | | | | 3 | 3 | 6 | 6 | 4 | 5 | 6 |
| Atlanta, GA | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 6 | 2 | 2 | 4 | 4 | 4 | 2 | 6 | | 0 | 0 | 1 | 1 | 1 | ı | 4 | 1 | 1 | 2 | 2 | 0 | 3 | 0 |
| ireenville, SC | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 6 | 3 | 2 | 2 | 4 | 4 | 3 | 6 | | 0 | 0 | 0 | 0 | 2 | 2 | 4 | 0 | 1 | 4 | 2 | 0 | 2 | 0 |
| lorfolk, VA | 27 | 3 | 3 | 6 | 7 | 4 | 4 | 6 | 3 | 2 | 6 | 3 | 4 | 2 | 6 | | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0 | 4 | 0 | 2 | 0 |
| | 216 | | | | | | | | 174 | 12 | 21 | 22 | 10 | 16 | | - 104 | _ | 0 | 1 | 1 | 5 | | - 12 | 10 | 12 | 27 | 27 | 13 | 23 | 11 |

Table 2 (continued)

| | Total | _ | | | Quo | | | | _ | | | - | | ept ed | | | _ | | • | us r | | | | | | | | rema | | | |
|----------------------------|--------------|---------|----------|----------|---------|---------|---|----|---------|---------|---------|-----------|------------|--------|---|----------|---------|----------|----|----------|---------|---|----|------|----------|---------|------|------|----------|---|-------|
| MSA and Census Division | MSA quota | M 0- | -14 F | 15- H | 44 F | 45 H | F | HC | 0- M | 14 F | 15 M | - 44 F | 45 H | F | N | : | 0- M | -14 F | | -44 F | 45 H | | NC | | 0-1 M | 14 F | H 1: | F | 45+ H | f | NC |
| EAST SOUTH CENTRAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mashville, TN | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 5 | 3 | 3 | 6 | | 5 4 | 5 | • | 5 | 0 | 1 | 3 | 0 | 1 | 1 | 1 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Lexington, KY | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 5 | 1 | 1 | 5 | | 2 4 | 3 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 2 | 2 | 1 | 4 | 0 | 2 | 4 |
| Memphis, TN | 27 | 3 | 3 | 6 | 6 | 4 | 5 | 5 | 2 | 2 | 5 | | 5 4 | 5 | : | 5 | 0 | 0 | 0 | 0 | 4 | 4 | 4 | | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| | 81 | | | | | | | | 6 | 6 | 16 | 13 | 12 | 13 | | - 66 | ō | ì | 3 | 0 | 5 | 5 | | - 14 | 3 | 3 | 2 | 5 | 0 | 2 | — . ı |
| WEST SOUTH CENTRAL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dallas, TX | 27 | 4 | 3 | 6 | 6 | 4 | 4 | 6 | 4 | 3 | 6 | | i 4 | 4 | (| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| New Orleans, LA | 27 | 4 | 3 | 6 | 6 | 4 | 4 | 6 | 2 | 2 | 6 | | 5 4 | 4 | (| 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 2 | 1 | 0 | 0 | 0 | 0 | 0 |
| Houston, TX | 27 | 4 | 3 | 6 | 6 | 4 | 4 | 6 | 4 | 3 | 1 | 1 | 4 | 3 | (| i | 6 | 1 | 0 | 0 | 5 | 2 | 10 | | 0 | 0 | 5 | 5 | 0 | 1 | 0 |
| Brownsville-Hrlngn, TX | 27 | 4 | 3 | 6 | 6 | 4 | 4 | 6 | 0 | 1 | 6 | 5 | 5 2 | 4 | 1 | l | 0 | 0 | 3 | 0 | 0 | 0 | 0 | | 4 | 2 | 0 | 1 | 2 | 0 | 5 |
| San Antonio, TX | 27 | 4 | 3 | 6 | 6 | 4 | 4 | 6 | 4 | 3 | 6 | 6 | . 4 | 4 | 4 | l | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | 135 | | | | | | | | 14 | 12 | 25 | 24 | 18 | 19 | | - 112 | 6 | 1 | 3 | 0 | 5 | 2 | | - 17 | 6 | 3 | 5 | 6 | 2 | 1 | 2 |
| NEATHUON | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Denver, CO | 27 | 3 | 3 | 7 | 7 | 3 | 4 | 2 | 2 | 1 | 3 | 1 | 2 | 1 | 2 | ! | 0 | 0 | 2 | 0 | 2 | 0 | 4 | | ı | 2 | 4 | 6 | 1 | 3 | 0 |
| Salt Lake City, UT | 27 | 3 | 3 | 7 | 7 | 3 | 4 | 2 | 3 | 3 | , | , | 3 | 4 | 1 | ı | 3 | 0 | 9 | 6 | 3 | 4 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| | 54 | | | | | | | | 5 | 4 | 10 | 8 | 5 | 5 | | - 37 | 3 | 0 | 11 | 6 | 5 | 4 | | • 29 | 1 | 2 | 4 | 6 | 1 | 3 | — . ı |
| PACIFIC | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sacramento, CA | 27 | 3 | 3 | 6 | , | 4 | 4 | 7 | 2 | 3 | 3 | 7 | 4 | 4 | 5 | i | 0 | 0 | 0 | 6 | 5 | 6 | 0 | | 1 | 0 | 3 | 0 | 0 | 0 | 2 |
| San Francisco, CA | 27 | 3 | 3 | 6 | 7 | 4 | 4 | 7 | 0 | 0 | 0 | 0 | 4 | 1 | C | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 3 | 3 | 6 | 7 | 0 | 3 | 7 |
| Los Angeles. CA | 54 | 6 | 6 | 12 | 14 | 8 | 8 | 14 | 6 | 6 | 0 | 0 | 1 | 0 | 4 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | 0 | 0 | 12 | 14 | , | | 10 |
| Port land, OR | 27 | 3 | 3 | , | 7 | 3 | 4 | 2 | ٥ | 1 | 2 | 0 | 1 | 2 | 2 | | ٥ | 0 | 0 | 0 | 0 | 0 | 0 | | , | 2 | 5 | | 2 | | 0 |

Table 2 (concluded)

| | Total | | | | Quot | 6 | | | | | Sam | les | acce | p t ed | | | | S | urplu | | | | | | | a p1es | | _ | | |
|--------------------|---------|-----|---|------|------|----|---|----|----|----|-----|------|-------|---------------|------|-------|-----|----|-------|-----|----|-------|-----------|----|----|---------------|-----|------|---------|---------|
| MSA and Census | MSA | 0-1 | 4 | 15-4 | 14 | 45 | • | | 0- | 14 | 15 | - 44 | 45. | | | | 0-1 | 14 | 15. | -44 | 45 | • | | 0- | 14 | 15 | -44 | 45+ | | |
| Division | quota | Ħ | F | M | F | M | F | NC | M | F | M | F | M | F | HC | | H | F | H | F | H | F | NC | H | F | H | F | H | F | NC |
| icattle, WA | 27 | 3 | 3 | , | , | 3 | 4 | 2 | | | | | | | | | - | | | | | | | 3 | 3 | 7 | 7 | 3 | 4 | 2 |
| Spokane, WA | 27 | 3 | 3 | 7 | 7 | 3 | 4 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 0 | | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 3 | 5 | 5 | 1 | 2 | 2 |
| Tacoma, WA | 27 | 3 | 3 | 7 | 7 | 3 | 4 | 2 | | | | | | | | | | | | | | | | 3 | 3 | 7 | 7 | 3 | 4 | 2 |
| | 216 | | | | | | | | 8 | 10 | 7 | 9 | 12 | 9 | | - 55 | 0 | 0 | 0 | 6 | 5 | 6 | - 17 | 16 | 14 | 45 | 47 | 16 | 23 | —. 10 |
| DESIGN GRAND TOTAL | • 1,377 | | | | | | | | | | | DES | IGN (| COLLE | CTED | - 641 | | | | | : | SURPI | .US = 122 | | | | TO | BE C | OL LE (| TED - 7 |

Note: MC - Non-caucasian. Not included in regional or grand totals.

MIDWEST RESEARCH INSTITUTE



425 Volker Boulevard Kansas City, Missoun 64110 Telephone (816) 753-7600 Telefax (816) 753-8420

EXAMPLE OF RECRUITMENT REPORT

February 5, 1990

Ms. Janet Remmers
Field Studies Branch, TS-798
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Subject: NHATS Recruitment Report No. 78, Work Assignment No. 20,

EPA Contract No. 68-02-4252.

Dear Janet:

Attached is the recruitment report for January 16 through January 31, 1990. If you have any questions or comments, please call me.

Sincerely,

Kay Turman

Work Assignment Leader

KT/1m

cc: Lori Bailey Carolee King

8863-20 File (2 copies)

RECRUITMENT ACTIVITIES NHATS (8863-20-01)

January 16-31, 1990

| MSA/Target cooperator | Activities | Future activities | Remarks/comments |
|---|--|-------------------|---|
| Denver, CO St. Joseph Hospital | Identified prospective cooperator (Dr. Tim Morgan) and sent recruitment packet on January 17. When contacted January 23, Dr. Morgan declined to participate, due to low staffing. | None. | Problems have arisen with one of the current cooperators. |
| Denver, CO St. Anthony Hospital Central | Identified prospective cooperator (Dr. Elwin Smith) and sent recruitment packet on January 17. When contacted January 23, Dr. Smith said they were still understaffed. He passed the packet to Dr. Derek Knopka, who was out of town that day. When contacted January 26, Dr. Knopka said "no" to participation. | None. | Previous "no" due to low staffing (5/87), they said to recon- tact them in the future. |
| Denver, CO AMI-Presbyterian- St. Luke's Medical Center | Identified prospective cooperator (Dr. Kenneth Holloman) and sent recruitment packet on January 17. When contacted on January 23, Dr. Holloman said. "yes" to participation, after. his questions on confidentiality were answered. Post-recruitment letter and supplies sent January 24. | New cooperator. | Previous cooperator, dropped out when the contact person (a resident) left and was not replaced (6/88). |

(continued)

D-9

RECRUITMENT ACTIVITIES (CONTINUED) NHATS (8863-20-01)

January 16-31, 1990

| MSA/Target cooperator | Activities | Future activities | Remarks/comments |
|---|---|--|--|
| Richland-Kennewick- Pasco, WA Franklin County Coroner's Office | Identified prospective cooperator (Ms. Mavis Williams) and sent recruitment packet on January 23. Left message January 26. When contacted January 29, Ms. Williams said that they did very few actual autopsies (only 18 in 1989), and would not be able to participate. She said that Benton County has a much greater case load. | None. | Replacement MSA for Medford, OR. |
| Richland-Kennewick- Pasco, WA Benton County Coroner | Identified prospective cooperator (Mr. Floyd Johnson) and sent recruitment packet on January 23. Left message January 29 and Mr. Johnson called back the same day. He said that they hire a different pathologist to do each autopsy. If the case is in Richland, it is performed at the hospital and if the case is in Kennewick, the autopsy is performed at a mortuary. It would be too hard to coordinate collection, so he said "no" to participation. | None. | Replacement MSA for Medford, OR. |
| Richland-Kennewick- Pasco. WA Kadlec Medical Center | Identified prospective cooperator (Dr. Thomas Mahony) and sent recruitment packet on January 31. | Contact Dr. Mahony the week of February 5 to answer questions and request participation. | No other possibili- ties in this MSA. |

NHATS TRIP REPORT

Date of Visit 03-16-90
Cooperator Ohio State University
Hospital (Columbus)
NHATS Staff Kay Turman

SUMMARY OF VISIT

I met with Scott Jewell, the replacement for Karen Donovan, in their new enlarged facilities. He had familiarized himself with the program, and we briefly discussed the purpose and operation of the program. He assured me that the people doing the collection will continue. Also, he is enlisting the help of autopsy service to collect more cases. We went over the missing information, and he requested I send the PSRs by mail and he will obtain the information and mail it to me. Scott introduced me to Teresa, one of the contact people I have spoken with on the phone. Status calls can be directed to Teresa or Scott. They would like copies of results as they become available.

CONCLUSIONS

Collection is going well at this facility. Involvement of autopsy service should permit them to fill the quota. New contact person appears very cooperative and willing to improve the collection at his facility.

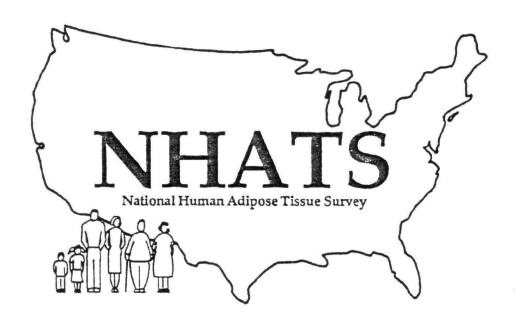
ACTION ITEMS

Continue regular contact. Send request for missing information on previously received PSRs to Scott.





NEWSLETTER COVER



Newsletter January 1990

Midwest Research Institute 425 Volker Boulevard Kansas City, MO 64110 U.S. Environmental Protection Agency National Human Monitoring Program Exposure Evaluation Division (TS-798) Field Studies Branch 401 M Street, S.W. Washington, DC 20460

National Human Adipose Tissue Survey

FY88 Summary FY89 Outlook

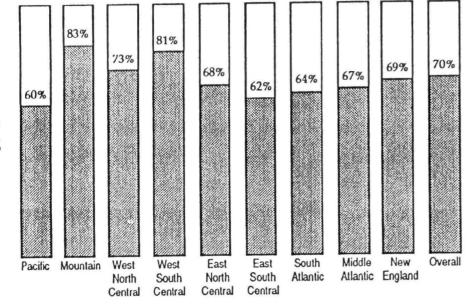
MRI 🕸

SEPA

Last Year

Fiscal Year 1988 (October 1, 1987 - September 30, 1988)

With 95% of shipments received ... approximately 70% of the FY88 goal has been achieved:



With all 47 cities in the survey contributing ... 936 adipose tissue specimens have been received for research purposes.

THANK YOU FOR YOUR CONTRIBUTION!

This Year

Fiscal Year 1989 (October 1, 1988 - September 30, 1989)

 With your help, the FY89 goal of 1377 adipose tissue specimens can be achieved!

Collection and shipment early in the fiscal year helps us to process the specimens more effectively and to identify and solve problem areas quickly.

- Collect and ship at least 1/2 of your quota by March 31.
- Use the Federal Express airbill supplied for shipping your adipose tissue specimens to Midwest Research Institute.
- Research Results Upcoming!
 Final analysis reports are expected:
 - Comparing Vietnam veterans' adipose tissue levels of dioxins and furans with those of the U.S. population.
 - Summarizing baseline levels of pesticides, PCBs and other semi-volatile compounds in the FY 86 specimens.
 - Summarizing baseline levels of dioxins and furans in the FY 87 specimens.

D-1