Bureau of Epidemiology

Department of Health

PROCEDURE GUIDE

FOR STUDIES THAT UTILIZE
PATIENT IDENTIFIABLE DATA FROM THE
FLORIDA CANCER DATA SYSTEM

Revised October 2007

Approval Process Summary

Federal regulations require that all research studies involving human subjects and materials of human origin be reviewed and approved by an Institutional Review Board before initiation. In compliance with this federal regulation, study investigators requesting patient identifiable data from the Florida Cancer Data System (FCDS) must submit an IRB application and applicable supporting documentation (i.e. study protocol and methodology, sample patient contact forms, sample consent forms, etc.) to the Florida Department of Health Institutional Review Board (DOH IRB).

Detail information regarding the DOH IRB application process can be found at the web site: http://www.doh.state.fl.us/execstaff/irb/index.html. IRB*Wise*, the electronic IRB application system, allows for online submission of protocols, amendments, continuing reviews, and supporting documents by study investigators. A username and password are needed to access the web-based IRB application system. Further instructions on how to navigate IRB*Wise* and to obtain a username and password can be found at the DOH IRB web site.

DOH IRB Contact Information:

E-mail	Phone Number	Fax Number
dohirb@doh.state.fl.us	(850) 245-4585	(850) 245-4371

In addition to the IRB application (submitted to the DOH IRB), the study investigator must complete the *Application for Research Use of the Florida Cancer Data System*. This application requests scientific/technical information from the researcher to assist the FCDS biostatisticians in fulfilling the data request needed by the study. Please submit a hardcopy of the application to:

Cancer Registry Program
Bureau of Epidemiology
Florida Department of Health
4052 Bald Cypress Way, Bin #A-12
Tallahassee, FL 32399-1720

It is the responsibility of the study investigator to provide the final recommendation (approval, rejection, pending) from the DOH IRB to the Bureau of Epidemiology, Cancer Registry Review Committee (CRRC). The *Application for Research Use of the Florida Cancer Data System* can not be processed until approval has been received from the DOH IRB.

Approvals from the DOH IRB and the DOH Bureau of Epidemiology must be obtained before cancer registry data are released from the FCDS.

Application for Research Use of the Florida Cancer Data System (FCDS) Instructions

1. Please indicate the purpose of the FCDS data for your research proposal. The FCDS data can be requested for any of the following:
    a. *Case Ascertainment/Recruitment*: Request use of the FCDS database for the purpose of patient recruitment for a study (i.e. utilize the FCDS database to identify cancer patients that may qualify or meet the study's selection criteria for inclusion).
    b. *Linkage*: Request use of the FCDS database for the purpose of linking the study's patient database to the FCDS database to obtain follow-up data (i.e. link to the FCDS database to obtain cancer outcome information). Refer to Attachment 9 for data record linkage layout.
    c. *Other – Special Analysis*: Request use of non-public FCDS data for a special analysis.

2. Study investigator must complete all fields of the *Application for Research Use of the Florida Cancer Data System*. If a field is not relevant, please indicate this is non-applicable to the study proposal. An incomplete application will delay the review process by the Bureau of Epidemiology, Cancer Registry Review Committee (CRRC).

3. Study investigator must sign a research agreement (See Attachment 1 for *Florida Department of Health RESEARCH AGREEMENT*) with the Florida Department of Health (DOH) for use of the Florida Cancer Data System (FCDS) data for patient information and contact. The signed, original must be sent with the *Application for Research Use of the Florida Cancer Data System* to the Bureau of Epidemiology CRRC.

4. All study personnel who will have access to information that identifies individual cancer patients must sign and have notarized the *Confidentiality Pledge* (See attachment 2), which is retained by the Bureau of Epidemiology CCRC.

5. All listings of cases, copies of reports, and any other materials that include confidential information must be kept in locked file drawers when not in use. Computer files must be stored on secured systems. **The original FCDS data with patients' confidential information must be destroyed upon completion of the study.**

6. For studies that utilize FCDS for patient recruitment and subsequently, patient contact:

    Please be advised that the FCDS will not extract data on those patients with whom we have a death certificate.

    A. The initial patient contact must be written correspondence summarizing your study with the lead letter from the Department of Health (Attachment 3) to request the patient's active consent for participation. The Investigator's patient contact letter and patient response form are sent simultaneously with the letter from the Department of Health. The DOH Bureau of Epidemiology will provide the Department of Health letter once the study has been approved.

    A *Sample Patient Contact Letter* (Attachment 4) and a *Sample Patient Response Form* (Attachment 5) are provided for the study investigator's reference. In addition to the study investigator's description of the study, the patient contact letter must include:
    - Language furnished by the FCDS regarding State reporting (paragraph 2 of Attachment 4. *Sample Patient Contact Letter*)
    - Assurance of voluntary nature of participation

Bureau of Epidemiology, Florida Department of Health Tel. (850) 245-4401 Fax (850) 922-9299

- Assurance that participation or non-participation will not affect medical care

If after three weeks from sending the initial (first) mailing there is no patient response, a second mailing can be sent with the addition of a telephone opt-out card (See Attachment 6). The telephone opt-out card explains to the patient if no response is received, the study investigator will attempt a telephone call to introduce the study. If there is no response to the second mailing and the telephone opt-out card after three weeks, a telephone call can be attempted by the study staff. Please provide a copy of the phone script that will be used to introduce the study to the patient.

PLEASE BE ADVISED…*Study investigator should avoid disclosing that the patient is being contacted for a study specific to cancer on the cover of mailings. Efforts to recruit a patient should stop immediately when the patient clearly indicates he or she does not wish to participate.*

B. Patients may be surprised to be contacted by an investigator or institution other than the physician(s) and institution(s) with whom they are familiar. All persons making patient contact must be capable of providing a clear and accurate description of cancer registration in Florida. More information about the FCDS can be found at http://www.fcds.med.miami.edu/. To assist study staff in providing clear and accurate responses, please see Attachment 7. *How Did You Get My name? Questions and Answers*.

Investigators must remember:

- The difficult emotional and physical circumstances that the patient may be experiencing; although many, if not most, patients welcome the opportunity to participate in research.
- Patients can always refuse to participate, even after having agreed to participate.

During the patient recruitment phase of the study, problems may arise with individual patients. Any patient who appears to be upset when contacted about participation in any study must be reported immediately (within 24 hours) to the DOH Cancer Epidemiologist. **Any patient who states that he/she does not wish to be contacted again must be reported promptly to the DOH Cancer Epidemiologist**; this fact will be recorded in the FCDS databases. That person will not be re-contacted.

If, in the course of the study, the investigator finds that contact information provided by the FCDS is missing or incorrect and correct information has been obtained, e.g., address, telephone number, etc., please use the *Patient Data Update Form* (Attachment 8) to notify the FCDS.

7. **Please send a copy of ALL published abstracts of presentations and papers that result from the study to the DOH Cancer Epidemiologist and the FCDS Director.** The bibliography of papers from investigations that have utilized the FCDS is used to track the use of the registry for epidemiologic studies. The DOH research agreement number and acknowledgments must be cited in all publications that result from studies that utilized the FCDS.

Copies of publications utilizing FCDS data can be mailed to:

Cancer Epidemiologist

Bureau of Epidemiology
Florida Department of Health
4052 Bald Cypress Way, Bin #A-12
Tallahassee, FL 32399-1720

Telephone: 850-245-4401

Dr. Jill MacKinnon, Project Director

Florida Cancer Data System
University of Miami Miller School of Medicine
Post Office Box 016960 (D4-11)
Miami, Florida 33101

Telephone: 305-243-4600

8. Please note that the Florida Cancer Data System (FCDS) is an incidence-only registry. The FCDS has collected the number of new cancers diagnosed in the state of Florida each year since 1981. If your study, requires both confidential cancer incidence and mortality data, a separate request to the Florida Department of Health, Office of Vital Statistics will need to be completed for re-release of cancer mortality data from the FCDS.

9. Please note that your request for use of patient identifiable data will be processed in a timely fashion. However, applications are processed on a first-come, first-serve basis and study approval from the DOH IRB may take several months.

FLORIDA DEPARTMENT OF HEALTH

APPLICATION FOR RESEARCH USE OF THE FLORIDA CANCER DATA SYSTEM (FCDS)

Send application to:

Cancer Registry Program
Florida Department of Health
Bureau of Epidemiology
4052 Bald Cypress Way – Bin A-12
Tallahassee, FL 32399-1720

For Office Use only
Project # _____
Date Received _____
Date Reviewed _____
Approved Yes _____ No_____

I. ORGANIZATION OR INDIVIDUAL REQUESTING USE OF FLORIDA CANCER DATA SYSTEM (FCDS) DATA

A. **Study (Principal) Investigator:**

B. **Title:**

C. **Organization (Include Branch, Division, Department, etc.):**

D. **Street Address or Post Office Box:**

E. **City/State/ZIP Code:**

F. **Telephone:**

G. **E-mail:**

H. **Primary Contact (If different from study investigator):**

Please attach study investigator(s) curriculum vitae/resume.

II. SUMMARY OF STUDY PROTOCOL OR PROJECT ACTIVITIES

A. **Title of Study or Project:**

B. **Name and address of sponsor(s) for this project (if any):**

C. **Specify all sources of funding for this project:**

D. **Please check the appropriate category. The above entitled study will utilize the Florida Cancer Data System (FCDS) for the following:**

_____Case Ascertainment/Recruitment

_____Database Linkage

_____Other: Special Analysis

Specify type of analysis:_____
_____
_____

E. Protection of Human Subjects: Has this project been reviewed and approved by an Institutional Review Board (IRB) for the protection of human subjects?

_____Yes. Give the name of the review board and date of approval.

NAME:_____

DATE:_____

Please attach a copy of the approval to this application.

NOTE: If requesting confidential, patient identifiable FCDS data, your study will still need to be reviewed and approved by the Florida Department of Health Institutional Review Board as well.

_____No. Indicate Reason: _____
_____
_____

F. Informed Consent:

Have you developed a written informed consent for use in this study?

_____Yes. Attach sample copy of consent form to this application.

_____No. Indicate the source of the identifying information of the persons in your study.
_____
_____
_____

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G. Abstract of Study Protocol or Project Activities ("Research Proposal"):

NOTE: You may append a copy of your complete study protocol (or selected sections) to this application. The abstract provided should be self-contained so that it can serve as a sufficient and accurate description of the project if separated from your appended document.

Include the following information (if applicable) in the description of your study:

a) **Primary focus. State the specific health or medical problems addressed, or other conditions or concerns of the study.**
b) **Objectives. State the hypotheses to be tested, if any.**
c) **Analyses to be performed, indicating specifically how data obtained from Florida Cancer Data System will be used.**
d) **Linkage, if any, with other data files, specifying the source of these files.**
e) **Release of Results, including interim and final reports and publications to be sent to the department upon completion.**

ABSTRACT:

III. CONFIDENTIALITY OF IDENTIFIABLE DATA

A. What specific data items from the Florida Cancer Data System do you request for use in your study?
Please visit http://www.fcds.med.miami.edu/inc/downloads.shtml to view the FCDS Data Acquisition Manual (DAM) on what data items are collected on cancer cases diagnosed in the State of Florida.

B. How will you maintain the confidentiality of identifiable data obtained from the Florida Cancer Data System? (Identifiable data refers to any information which would permit, directly or indirectly, the identification of any individual or establishment.) Include an explanation of how such data will be stored as well as how and when you plan to dispose of the data after your study is completed.

C. Will your study require "follow-back" investigation to obtain additional information from the individual, next-of-kin, physicians, and/or other individuals or institutions mentioned on the cancer reports?

_____No

_____Yes Briefly describe the following:

1. **Types of respondents to be contacted:**

2. **Information to be obtained from respondents:**

3. **Methods to be used in conducting such investigations:**

4. **Other organizations, co-investigators or consultants, if any, conducting the investigations:**

D. How will you maintain the confidentiality of identifiable data obtained from the follow-back investigation? (Include an explanation of how such data will be stored as well as how and when you plan to dispose of the data after your study is completed.)

IV. OTHER DATA AND USES

A. For the purpose of this research project as you described in Section II, will any of the identifiable data obtained from this project be used by other organizations; e.g., other divisions, agencies, consultants, contractors and/or subcontractors?

_____No

_____Yes Indicate the name of the organization(s) and role(s) in, this research project. If the name is unknown at this time, indicate the type of organization (s). Describe the safeguards that exist (or will be implemented) to ensure that the data will be used solely for the purposes of this research project:

B. Will any of the identifiable data obtained for this project be used as a basis for legal, administrative, or other actions which may affect particular individuals or establishments as a result of their specific identification in this project?

_____No

_____Yes. Indicate how the data will be used.

C. Will the identifiable data be used either directly or indirectly for any research project other than the one described in Section II, "Summary of Study Protocol or Project Activities"?

_____No

_____Yes

NOTE: A separate application must be submitted for each research project which will use the identifiable data obtained through this application.

V. TYPES OF DATA TO BE SUBMITTED (SECTION APPLICABLE ONLY TO LINKAGE STUDIES)

A. Each record (along with other information on a person in your study or project) which you submit can only be matched if the request contains, at a minimum, the following information:

First and last name AND Social Security Number AND Sex
or
First and last name AND Month and Year of Birth AND Sex

B. Multiple matches with insufficient information to uniquely identify the record of the person in your study or project will not be released. Review of possible matches may be undertaken under certain conditions, by the cancer registry. You should provide as much information about your subjects as possible in order that matches can be verified. For each item of information listed below, indicate what percent of your records contains the item.

	% of Record
1. Middle Name or Initial	_____
2. Date of Birth	_____
3. Date of Death	_____
4. Social Security Number	_____
5. County of Residence	_____
6. City, Town, or Village of Residence	_____
7. Zip Code (9 digits)	_____
8. Race	_____
9. Sex	_____
10. Other Items (list)	_____

Coded information must be submitted using Florida Cancer Data System Codes (See the Data Acquisition Manual at http://www.fcds.med.miami.edu/inc/downloads.shtml).

C. How many records do you expect to submit? _____
Number

D. Upon submission of these records, against which data year(s) will you want to conduct the search of the file?
Year(s): _____

VI. TECHNICAL INFORMATION ABOUT THE DATA TO BE SUBMITTED
(SECTION APPLICABLE ONLY TO LINKAGE STUDIES)

In order to search for the records of persons in your study, they must be submitted in a manner that adheres to magnetic tape or disk specifications, file format requirements, and coding instructions, as described in Attachment 9.

VII. PAST AND FUTURE REQUESTS FOR THIS STUDY

A. Have you requested information in the past in connection with this study?

_____No

_____Yes Indicate the project number assigned to you: Project No.:_____

B. Aside from this application, do you anticipate submitting another application in the future for the purpose of this study?

_____No

_____Yes Indicate if future "repeat" requests will be based on exactly the same names (excluding previously identified names) or will names be added to, or deleted from, your study files?

_____1. The same list of names.

_____2. The same list of names, plus _____ additional names.

_____3. The same list of names, excluding _____ names.

_____4. An entirely different list of names, such as:_____

_____5. How many "repeat" requests for this study do you expect to make?

_____
Signature

_____
Name

_____
Organization

_____
Date

Attachment 1.

Florida Department of Health
RESEARCH AGREEMENT

This agreement ("Agreement") is entered into by the Florida Department of Health ("DOH"), and _____, hereinafter referred to as the Investigator.

RECITALS

I. Under Section 385.202, Florida Statutes, DOH may exchange personal data from the statewide cancer registry with a contractual designee for the purposes of medical or scientific research, provided such designee complies with the limitations on disclosure as stated therein.

II. Investigator desires to become such a contractual designee, and in order to induce DOH's entry into this Agreement, desires to comply with the above-referenced statute, the terms below, and all other applicable requirements of law.

III. Investigator has submitted the Research Proposal to DOH specifying the personal data desired ("Research Proposal").

IV. Investigator has received approval for the Research Proposal, including the use of the above-referenced personal data, from DOH's federally mandated Institutional Review Board.

V. Investigator has the authority to bind Investigator's Institution as to relevant terms of this Agreement

NOW THEREFORE, for good and valuable consideration, the parties hereto agree:

A. COMPOSITION OF AGREEMENT

1. This Agreement,
2. Investigator's Research Proposal ("Research Proposal"), and
3. DOH Bureau of Epidemiology Procedure Guide, October 2005 ("Procedure Guide").

B. AGREEMENT PERIOD

This Agreement begins upon the date it is fully executed and ends upon completion of performance by the parties or termination consistent herewith.

C. TERMS

1. The above recitals are true and correct and incorporated as if fully stated herein;
2. Investigator shall comply with all terms of this Agreement and the Procedure Guide;
3. DOH shall create a data file in ASCII format of the personal data from the cancer registry as specified in the Research Proposal (the "Data File");
4. The costs of assembling the Data File shall be set consistent with Section 119.07(1)(a), Florida Statutes, and shall be paid to DOH prior to transfer of the Data File to Investigator;

5. Investigator shall arrange for transfer of the Data File in person, via messenger or by traceable delivery service, subject to DOH prior approval;
6. Investigator shall not use the Data File for any other purpose than that specified in the Research Proposal;
7. Upon completion of the work outlined in the Research Proposal, Investigator shall destroy the Data File and any and all copies thereof;
8. Upon completion of the work outlined in the Research Proposal, Investigator must provide prior to publication, a courtesy copy of the articles and/or reports accepted for publication to DOH.
9. The Investigator and Investigator's Institution, except where prohibited by applicable Florida Law, agree to hold harmless, indemnify, and defend DOH from all liabilities, demands, damages, expenses, or losses arising out of performance under this Agreement, except to the extent where such liabilities, demands, damages, expenses or losses are the result of DOH negligence or willful misconduct; and
10. The law governing this Agreement shall be Florida Law and the venue for disputes over this Agreement shall be a State Court of Competent Jurisdiction in Leon County, Florida.

IN WITNESS WHEREOF, the parties hereto executed this two-page Agreement, with attachments, on the dates stated below.

THE INVESTIGATOR

Signature: _____

Printed Name: _____

Title: _____

Organization: _____

Date: _____

DOH

Signature: _____

Title Chief, Bureau of Epidemiology

Date: _____

Attachment 2.

CONFIDENTIALITY PLEDGE

I recognize the importance of maintaining the confidentiality of all data collected by the Florida Cancer Data System (FCDS) and of assuring the right to privacy of persons whose records I receive.

I understand that confidential information or data is defined as any information where the individual, hospital(s), or physician(s) is named or otherwise identifiable.

I therefore agree to protect the confidentiality of the data in accordance with the following requirements:

I will avoid any action that will provide confidential information to any unauthorized individual or agency.

I will not make copies of any confidential records or data except as specifically authorized.

I will not remove confidential identifying information from my place of employment except as authorized in the performance of my duties.

I will not discuss in any manner, with any unauthorized person, information that would lead to identification of individuals described in confidential files or data.

I will use confidential files and data only for purposes for which I am specifically authorized.

I will not provide any computer password or file access codes which protect these data to any unauthorized person.

If I observe unauthorized access or divulgence of confidential data or records to other persons, I will report it immediately to the FCDS. I understand that failure to report violations of confidentiality by others is just as serious as my own violation, and may result in civil or criminal penalties and termination of current and future access to confidential data.

I therefore pledge that I will not divulge to any unauthorized person confidential information or data obtained from the FCDS files.

Name: _____
Print

Signature: _____

Date: _____

Address: _____

Notarized by: _____ NOTARY

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Attachment 3.

Department of Health Letter

Dear Floridian:

As you can see from the enclosures with this letter, you are being contacted by a research scientist regarding participation in a cancer research project. I would like to explain how your name was obtained for this purpose.

Every cancer diagnosed in Florida is required by law to be reported to the Florida Department of Health, which oversees the Florida Cancer Data System (FCDS). The FCDS was created by the Florida Legislature in response to public concern that not enough was being done to find the causes and cures of cancer. Information on individuals with cancer can be released from the FCDS for research purposes, and only to qualified researchers who have obtained approval for the study from a federally approved Committee for the Protection of Human Subjects and have agreed to maintain the confidentiality of the information they collect.

By law, the Florida Department of Health can provide cancer registry data for medical research or medical education. However, the department does not endorse, recommend, or favor any proposed research project.

Enclosed with this letter are materials from the researcher explaining further details of this specific study and giving you the option of whether or not you wish to participate. You are under no obligation to sign, nor will you incur any penalties or disadvantages if you decide not to do so. On the other hand, if you give your consent on the basis that the research will serve a useful purpose and that you would be comfortable as a participant, I want to assure you that your confidentiality and dignity will be protected.

Should you have any questions, either before making your decision or at any time in the course of this project, please feel free to call Dr. Jill MacKinnon, Director of the Florida Cancer Data System, at (305) 243-4600, or Dr. Youjie Huang, Chronic Disease Epidemiologist at the Florida Department of Health, at (850) 245-4407.

Sincerely,

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

Enclosures

Attachment 4.

SAMPLE PATIENT CONTACT LETTER

Dear Mr./Mrs. _____:

We are writing to ask you for your help in a very important study being conducted by _____. The purpose of this study is to learn more about factors that may be related to the development of ____ cancer in _____.

Your name was obtained from the Florida Cancer Data System (FCDS), which was created by the Florida Legislature in response to public concern that not enough was being done to find the causes and cures of cancer. Every cancer diagnosed in Florida is required by law to be reported to the Florida Department of Health, which is responsible for the FCDS. Information on individuals with cancer can only be released for research purposes to qualified researchers who have obtained approval for the study from a federally approved Committee for the Protection of Human Subjects, and have agreed to maintain the confidentiality of the information they collect.

The study would involve answering some questions over the telephone (or in person or via mailed questionnaire) regarding your lifetime exposures to environmental factors, past illnesses, and habits. The interview should take about ___ minutes. Your participation is entirely voluntary. Your decision whether or not to participate in this study will have no impact on your medical care. All information will be kept strictly confidential and is protected by law.

Please complete the enclosed response form and mail it back in the enclosed postage-paid envelope. An interviewer will call you to provide more information about the study and to answer any questions you may have. Your assistance in this effort is very much appreciated as the validity of this type of study depends on being able to interview as many patients as possible. If you have questions at this time, please call the study office at _____.

Sincerely,

Investigator
Title
Institution

Attachment 5.

SAMPLE PATIENT RESPONSE FORM

Please check one response and mail this form in the enclosed postage-paid envelope. If you have any questions, please call _____ at _____. Thank you.

☐ YES, I am interested in participating in the study.

☐ I would like more information.

☐ NO, I do not want to participate in the study.

Name: _____

Address: _____

_____

Telephone: Day: (___) _____ _____

Evening: (____) _____ _____

Best time to call: ☐ _____ a.m. ☐ _____ p.m.

Attachment 6.

Telephone Opt-Out Card for <Enter Study Title Here>

If you do **NOT** wish to be contacted by telephone regarding this study, please complete and return this card. If we do not receive this card from you within three weeks of the date you received this mailing, we will attempt to reach you by telephone. You may also call our study coordinator, <Enter contact name and number> to ask questions about this study, enroll in the study, or decline to participate.

☐ I do not wish to be contacted by telephone for <Enter Study Title Name Here>.

Primary Reason
- ☐ I am too busy to participate/do not have time
- ☐ I am too sick/ill to participate
- ☐ I have never had cancer
- ☐ I had cancer, but I do not feel this study is relevant to me now
- ☐ I am not interested in this study
- ☐ Other:_____

Your Name: _____
(Please Print - First, Middle, & Last Name)

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Attachment 7.

HOW DID YOU GET MY NAME? QUESTIONS AND ANSWERS

Q: How did you get my (or my relative's) name?

A: Like many other diseases, cancer is a reportable disease in Florida. This means that, by state law, a report of all cancer diagnoses must be prepared by the hospital or physician for use by the state health department. The law requires cancer reports to be collected by the Florida Cancer Data System under the Florida Department of Health. After the Florida Department of Health approved this study, your name was provided to Dr. (Investigator) to invite your participation.

Q: Why is cancer reportable?

A: The Florida Legislature, the Florida Department of Health and many Floridians place a high priority on seeking the causes of and methods for prevention of cancer. A statewide system of cancer registration provides a complete and timely mechanism for conducting research into cancer patterns and trends.

Q: Can I remove my name from the statewide cancer registry, the Florida Cancer Data System?

A: While the law includes no provision for removing a report from the registry, individuals may request that they not be contacted for future research studies.

Q: Why didn't the hospital tell me about cancer registration?

A: Hospitals are required by law to provide notification of the reportability of cancer in Florida. Some hospitals post notices on a wall; others include this notification on admitting forms.

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Attachment 8.

PATIENT DATA UPDATE FORM

In contacting the following patient, we ascertained that the following information provided by the FCDS was missing or incorrect.

Patient Name: _____, SSN _____

Incorrect or missing information: _____

Correct information: _____

Source of correct information (e.g., patient interview, telephone conversation with spouse.)

_____

Investigator's Name: _____

Study Title: _____

Name of person completing this form: _____

Date: _____

Please return to:

Dr. Jill MacKinnon, Project Director

Florida Cancer Data System
University of Miami Miller School of Medicine
Post Office Box 016960 (D4-11)
Miami, Florida 33101

Telephone: 305-243-4600

Thank you.

Attachment 9.

FLORIDA CANCER DATA SYSTEM
DATA RECORD LINKAGE LAYOUT

The Florida Cancer Data System (FCDS) can perform special data requests involving linkages between external and internal data sets (FCDS Master file, Agency for Healthcare Administration data, and Florida's Death Index data).

For the steps involved in a linkage project refer to the document titled "Procedures for Data Release".

There is a lot of preparation work to be done before a linkage is performed. The fields used in the linkage must be consistent in both data sets. Therefore, your data must be in a **FIXED length ASCII file** with the following record layout and format:

Variable	Position	Format
Patient ID	1-8	Numeric or Alphanumeric It should be a unique identifier Right Alignment, use leading zeros if less than 8 digits No empty spaces, or special characters like hyphens etc.
First Name	9-22	Alpha Left Alignment No hyphens, single quotes, slashes or any other special characters If more than 1 name, leave an empty space between them.
Last Name	23-37	Alpha Left Alignment No hyphens, single quotes, slashes or any other special characters If more than 1 name, delete the space between them.
SSN	38-46	Alphanumeric (only numeric characters allowed) Right Alignment, leading 0's if less than 9 digits No empty spaces, or special characters like dashes etc. Recode missing ssn's to 999999999
DOB	47-54	YYYYMMDD No empty spaces, or dashes or other special characters Recode missing month, day or year to 9's (ex: 1/3/97 should show as 19970103, Jan 1997 should show as 19970199)
Sex	55-55	Numeric *See attachment for Coding scheme*
Race	56-57	Alphanumeric (only Numeric characters allowed) No empty spaces, leading 0's if less than 2 digits *See attachment for Coding scheme*
Address Street	58-97	Alphanumeric Left Alignment
City	98-117	Alpha Left Alignment

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Variable	Position	Format
State	118-120	Alphanumeric (only numeric characters allowed) Right Alignment No empty spaces allowed, use leading 0's if less than 3 digits See attachment for coding scheme
County	121-122	Alphanumeric (only numeric characters allowed) Right Alignment, use leading 0's if less than 2 digits No empty spaces allowed *See attachment for coding scheme*
Zip Code	123-127	Alphanumeric (only numeric characters allowed) Right Alignment, use leading zeros if less than 5 digits Use 88888 for foreign countries, Use empty spaces for missing zip codes DO NOT use 99999 for missing values as it is a valid Alaska zip code
Maiden Name	128-142	Alpha Left Alignment No hyphens, single quotes, slashes or any other special characters If more than 1 name, leave an empty space between them.
Middle Name	143-156	Alpha Left Alignment No hyphens, single quotes, slashes or any other special characters If more than 1 name, leave an empty space between them.

The order of the variables may be changed as long as sufficient documentation is submitted.

The variable lengths and formats mentioned above are consistent with FCDS field standards. Any deviations in field length or variable format will require extra work and will be charged accordingly (Refer to Fees and Billing Procedure in Procedure for Data Release document). It is very important to make field length match in both data sets. If field lengths are not consistent in both data sets, then the field must be truncated in one of the data sets leading to less accurate and thus fewer matches. The same applies to the variable format; they must be identical in both data sets.

Most probably, the street address, city, state, maiden name, and middle name will not be used for matching. These fields, however, are useful in examining possible matches. Therefore, it is recommended that the researcher include them in the data set when they are available.

There are fees associated with data linkage. Please refer to the ***Data Release Procedure*** document at: http://www.fcds.med.miami.edu/inc/datarequest.shtml for the fee schedule.

Attached you will find the FCDS coding scheme for county, sex and race. For the state coding scheme refer to the "coding place of birth and residence" appendix B in the FCDS Data Acquisition Manual (DAM) http://fcds.med.miami.edu/downloads/dam/AppB.pdf.

Should you have any questions please call Brad Wohler at (305) 243-5527, email: bwohler@med.miami.edu.
Our address is: FCDS, University of Miami, P.O. Box 016960 (D4-11), Miami, FL 33101
Fax #: (305)243-4871

COUNTY CODES

for

County of Residence
&
County of Initial Diagnosis

11	Alachua
12	Baker
13	Bay
14	Bradford
15	Brevard
16	Broward
17	Calhoun
18	Charlotte
19	Citrus
20	Clay
21	Collier
22	Columbia
23	Dade
24	Desoto
25	Dixie
26	Duval
27	Escambia
28	Flagler
29	Franklin
30	Gadsden
31	Gilchrist
32	Glades
33	Gulf
34	Hamilton
35	Hardee
36	Hendry
37	Hernando
38	Highlands
39	Hillsborough
40	Holmes
41	Indian River
42	Jackson
43	Jefferson
44	Lafayette
45	Lake
46	Lee
47	Leon
48	Levy
49	Liberty
50	Madison
51	Manatee
52	Marion
53	Martin
54	Monroe
55	Nassau
56	Okaloosa
57	Okeechobee
58	Orange
59	Osceola
60	Palm Beach
61	Pasco
62	Pinellas
63	Polk
64	Putnam
65	St. Johns
66	St. Lucie
67	Santa Rosa
68	Sarasota
69	Seminole
70	Sumter
71	Suwannee
72	Taylor
73	Union
74	Volusia
75	Wakulla
76	Walton
77	Washington
88	OUT OF STATE/U.S.POSSESSION
90	OUT OF UNITED STATES
99	UNKNOWN (Not acceptable for county of residence)

Bureau of Epidemiology, Florida Department of Health Tel. (850) 245-4401 Fax (850) 922-9299

ITEM 21 - SEX
(Type=Numeric)

Enter the appropriate Sex code.

1 - Male
2 - Female
3 - Other (hermaphrodite)
4 - Transsexual
9 - Unknown/Not Stated

ITEM 22 - RACE
(Type=Numeric)

Enter the appropriate Race code.

*01 - White
**02 - Black
03 - American Indian, Aleutian, Eskimo
04 - Chinese
05 - Japanese
06 - Filipino
07 - Hawaiian
08 - Korean
09 - Asian Indian, Pakistani
10 - Vietnamese
11 - Laotian
12 - Hmong
13 - Kampuchean (Cambodian)
14 - Thai
20 - Micronesian, NOS
21 - Chamorran
22 - Guamanian, NOS
25 - Polynesian, NOS
26 - Tahitian
27 - Samoan
28 - Tongan
30 - Melanesian, NOS
31 - Fiji Islander
32 - New Guinean
96 - Other Asian including Asian, NOS and Oriental, NOS
97 - Pacific Islander, NOS
98 - Other
99 - Unknown

* White includes Mexican, Puerto Rican, Cuban, and all other Caucasians.
** Black includes the designations Negro or Afro-American.
A combination of white and any other race is coded to the other race.
A mixture of Hawaiian and any other race is coded Hawaiian.
A combination of nonwhite races is coded to the first nonwhite race documented.
Race is based on birthplace information when place of birth is given as China, Japan, or the Philippines and race is reported only as Asian, Oriental, or Mongolian.

STATE
See the FCDS Data Acquisition Manual (Appendix B) for the coding scheme
http://fcds.med.miami.edu/downloads/dam/AppB.pdf