Cancer Registry Program

Department of Health

PROCEDURE GUIDE

FOR STUDIES THAT UTILIZE
PATIENT IDENTIFIABLE DATA FOR
PATIENT CONTACT and/or PATIENT LINKAGE
and/or SPATIAL ANALYSIS

FROM THE
FLORIDA CANCER DATA SYSTEM

Revised July 2015

Before submitting an application for data you are strongly advised to review the new Automated Data Request instructional videos on the FCDS Data Request Web page. The tutorials explain how to navigate the new system. FCDS will no longer accept paper applications.

Approval Process Summary

Use of records for research must be approved by the institution holding the records and by an institutional review board (IRB).

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). The DOH IRB system is external to the FCDS Automated Data Request module.

Detail information regarding the DOH IRB application process can be found at the web site: **http://www.floridahealth.gov/provider-and-partner-resources/research/irb.html**. 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 this electronic system 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

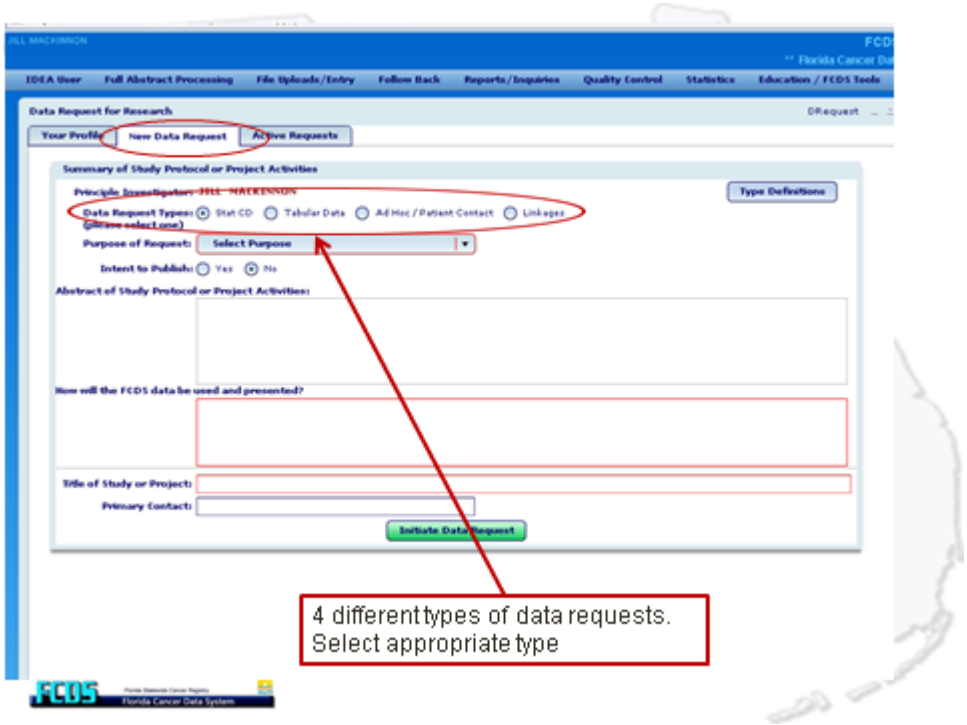
In addition to the IRB application (submitted to the DOH IRB outside the FCDS Automated system), the study investigator must complete the *Application for Research Use of the Florida Cancer Data System* on the FCDS Automated Data Request module This application requests scientific/technical information from the researcher to assist the FCDS biostatisticians in fulfilling the data request needed by the study.

It is the responsibility of the study investigator to provide the final recommendation (approval, rejection, pending) from the DOH IRB and/or Bureau of Vital Statistics (if applicable) to the Cancer Registry Program, Cancer Registry Review Committee (CRRC) thru the Automated Data Request module.

Approvals from the DOH IRB, the Office of Vital Statistics (if applicable) and the DOH Cancer Registry Program must be obtained before cancer registry data are released from the FCDS. Approvals from the DOH IRB and Office of Vital Statistics are obtained outside the Automated Data Request module and must be uploaded when prompted. The Cancer Registry Program, Cancer Registry Review Committee (CRRC) WILL NOT review any application until these external approvals are obtained and uploaded into the module.

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

1. Through the Automated Data Request module, please choose the 'Ad Hoc/Patient Contact' or 'Linkages' radio button and follow the instructions and prompts to submit your request for data extraction for your research proposal. The FCDS data can be requested for any of the following:
    a. *Case Ascertainment/Recruitment*: Using the 'Ad Hoc/Patient Contact' module, initiate your request 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*: : Using the 'Linkage' module, initiate your request 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 7 for data record linkage layout.
    c. *Other – Special Analysis*: Using the 'Ad Hoc/Patient Contact' module, initiate your request of the FCDS database for the purpose extracting patient geocoded data for a special analysis.



2. Study investigator must complete all fields of the on-line *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 not allow the application to move forward and will delay the review process by the Cancer Registry Program, Cancer Registry Review Committee (CRRC).

3. 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 using state of the art deletion software.**

4. All study personnel who will have access to information that identifies individual cancer patients must sign and have notarized the *Confidentiality Pledge*. These forms will be generated by the Automated Data Request system. Once signed and notarized, the respective forms will be uploaded into the Automated Data Request system when prompted.

5. Study investigator must sign a *Research Agreement* with the Florida Department of Health (DOH) for use of the Florida Cancer Data System (FCDS) data for patient information. The agreement will be generated by the Automated Data Request module once the DOH CRRC has approved the study. The *Research Agreement* will be auto generated and e-signed by both the researcher and the Florida DOH.

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 1) 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 Cancer Registry Program will provide the Department of Health letter once the study has been approved.

   A *Sample Patient Contact Letter* (Attachment 2) and a *Sample Patient Response Form* (Attachment 3) 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 2. *Sample Patient Contact Letter*)
   - Assurance of voluntary nature of participation
   - 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 4). 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 5. *How Did You Get My name? Questions and Answers*.

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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 6) 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
Cancer Registry Program
Florida Department of Health
4052 Bald Cypress Way, Bin #A-12
Tallahassee, FL 32399-1720

Telephone: 850-245-4401

Gary M. Levin, Deputy 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. The Automated Data Request module will

identify any variable that requires Office of Vital Statistics approval, provide a link for external submission of the your request to the outside agencies and prompt you to upload the approval letter when you receive it.

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.

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Attachment 1.

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 Gary M. Levin, Deputy Project Director of the Florida Cancer Data System, at (305) 243-4600, or Tara Hylton, Chronic Disease Epidemiologist at the Florida Department of Health, at (850) 245-4444 ext. 2441.

Sincerely,

State Surgeon General
Signature Block

Enclosures

Attachment 2.

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 3.

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 4.

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 5.

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 6.

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: _____, FCDS Patient ID _____

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:

Gary M. Levin, Deputy 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 7.

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)

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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