NYS OFFICE OF CHILDREN & FAMILY SERVICES: *GUIDELINES FOR SUBMITTING A RESEARCH PROPOSAL FOR REVIEW*

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This document sets forth the process and standards for the submission, review, and approval of research proposals involving children, youth, and families served by programs operated, regulated, or supervised by OCFS. These programs include residential and community-based services for juvenile delinquents administered by OCFS as well Child Protective Services (CPS), Preventive Services, Foster Care, Adoption, and Adult Protective Services, which are supervised by OCFS but administered by local Departments of Social Services (LDSS). Social Services Law Section 372.4b and certain CPS and Adoption statutes require OCFS approval of all requests to LDSS for access to CPS, Foster Care, Adoption, and Adult Protective Services data for bona fide research purposes.

The OCFS research approval process applies to research involving the use of individual-level data obtained from databases or case records maintained by OCFS, LDSS and/or voluntary agencies, or from clients themselves through interviews, surveys, or observations, which is <u>not</u> undertaken by OCFS, an LDSS, or agents operating on their behalf. An agent is defined as an independent researcher that is under contract with OCFS or an LDSS to conduct a research project. Research that is based solely on aggregate data or the aggregated results of statistical analyses is exempt from the OCFS research approval process.

The purposes of the OCFS research approval process are: 1) to protect the safety of human subjects involved in research; 2) to protect the confidentiality of data; 3) to protect the security of data used in research projects from unauthorized use or release; and 4) to foster research that meets prevailing methodological standards and is relevant to the agency's mission or furthers knowledge in the field of study.

OVERVIEW OF OCFS REVIEW PROCESS

OCFS has a multi-phase process for reviewing research proposals. The proposal is first reviewed by OCFS's Bureau of Research, Evaluation and Performance Analytics (BREPA) on the basis of the following standards: 1) relevance to the OCFS mission or contribution to the body of literature in the field; 2) methodological adequacy; 3) procedures for ensuring confidentiality of subject data; 4) human subjects protections, including the potential risks of the research and procedures to ensure the safety of participants; 5) adherence to OCFS's data security requirements; 6) impact on OCFS or local agency operations; and 7) support from involved parties. If the proposal does not meet all of these standards, BREPA staff works with the Researcher to attempt to revise the proposal until it is acceptable. If BREPA grants its approval, then the research proposal is forwarded to OCFS' Division of Legal Affairs for the second phase of review. BREPA will notify the researcher when the proposal has successfully completed the first phase of review, and is sent on to OCFS Legal Affairs for the second phase. Legal Affairs will review proposals for compliance with applicable statutes, policies, and procedures. If Legal Affairs has legal issues

with the proposal that require changes, BREPA staff serves as an intermediary between Legal Affairs and the Researcher, conveying the concerns raised and seeing that the requested changes are made.

If Legal Affairs approves the revised proposal, an attorney will draft a confidentiality agreement that is sent to BREPA. BREPA will then send the Agreement to Maintain Confidentiality to the Researcher, along with the Research Employee/Volunteer Certification form that all research staff must complete, with instructions to have two originals of the Agreement to Maintain Confidentiality signed and notarized and all the completed Research Employee/Volunteer Certification forms returned to BREPA. Upon the Researcher's return of all properly executed legal documents, OCFS, in turn, will execute these documents. Only when all the legal documents have been signed and executed by OCFS, will BREPA issue a final letter of approval for the research project. No research activities may commence prior to the issuance of the final approval letter by BREPA. The date of the approval letter is considered the official date when the project begins for purposes of complying with all terms of the Agreement to Maintain Confidentiality regarding completion of the project and data retention.

WHO MAY CONDUCT RESEARCH INVOLVING CASES UNDER OCFS' PURVIEW?

Only bona fide researchers may conduct research involving children, youth, and families served by programs operated, regulated, or supervised by OCFS. To be eligible to conduct research, the Researcher must be a faculty member or graduate student at an accredited institution of higher education, or hold a research position at a reputable research organization or at a government agency.

The Researcher must demonstrate the capacity to complete the research project per prevailing academic and professional standards, particularly if the research involves contact with human subjects. The Researcher and organization must have a demonstrated record of using sensitive data per commonly accepted standards of research ethics. Graduate students must submit a letter indicating formal approval by their committee or faculty advisor.

LIMITATIONS ON RELEASE OF DATA TO RESEARCHERS NOT EMPLOYED BY OR ACTING AS AGENTS OF OCFS/ LDSS

Statutory provisions prohibit the release of certain data for research purposes to individuals not employed by, or serving as agents of, OCFS or an LDSS.

These data include:

1. Individually identifiable data (i.e., personal information that is likely to enable an individual to be identified) on persons named in reports made to the New York State Central Register of Child Abuse and Maltreatment that are determined to be unfounded;
2. Individually identifiable data on persons who are the source of reports to the New York State Central Register of Child Abuse and Maltreatment;
3. Individually identifiable data pertaining to the HIV/AIDS status of individuals;
4. Individually identifiable data on children who are adopted and their adoptive parents; and
5. Individually identifiable data pertaining to the educational performance of children, in the absence of the consent of their parents. The Federal Educational Rights and Privacy Act (FERPA) applies to all educational agencies and institutions that receive federal funds under any program administered by the Secretary of Education. FERPA requires that to disclose “educational records” as defined in the Legislation, the consent of the parent/guardian or student (if at the age of the legal consent) must be obtained.

LIMITATIONS ON RELEASE OF PERSONAL HEALTH INFORMATION DATA (PHI)

With respect to research where the request is for protected health information (PHI) in the records of DJJOY, researchers must comply with the regulations implementing the Health Insurance Portability and Accountability Act (HIPAA).

Under HIPAA OCFS may disclose PHI to a researcher (the PHI disclosed must be the minimum necessary to conduct the research) under the following circumstances:

- The researcher obtains a HIPAA authorization from the subject to obtain a copy of PHI.
- When documentation that an alteration or waiver of a research participant's authorization for use/disclosure about him/her for research purposes has been approved by an Institutional Review Board (IRB) or Privacy Board, provided documentation of all the following is obtained:

    1. identification of the IRB or Privacy Board and the date on which the alteration or waiver of authorization was approved;

    2. a statement that the IRB or Privacy Board has determined that the alteration or waiver of authorization, in whole or in part, satisfies the following criteria:

        a. The use/disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

            i. an adequate plan to protect the identifiers from improper use/disclosure;

            ii. an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

            iii. adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project or for other research for which the use/disclosure of PHI would be permitted under the federal HIPAA regulations;

        b. The research could not practicably be conducted without the waiver or alteration; and

        c. The research could not practicably be conducted without access to and use of the PHI.

- A data use agreement has been entered into by both OCFS and the researcher, pursuant to which OCFS may disclose a limited data set. A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

    (i) Names;
    (ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;
(iv) Fax numbers;
(v) Electronic mail addresses;
(vi) Social security numbers;
(vii) Medical record numbers;
(viii) Health plan beneficiary numbers;
(ix) Account numbers;
(x) Certificate/license numbers;
(xi) Vehicle identifiers and serial numbers, including license plate numbers;
(xii) Device identifiers and serial numbers;
(xiii) Web Universal Resource Locators (URLs);
(xiv) Internet Protocol (IP) address numbers;
(xv) Biometric identifiers, including finger and voice prints; …

NYS OFFICE OF CHILDREN & FAMILY SERVICES
RESEARCH PROPOSAL APPLICATION PACKET

Please carefully review the required information and supporting materials. Also, please note: if the research involves child welfare cases, a letter must be secured from each local social services department and each voluntary agency responsible for the cases in the sample. Also, OCFS will not review any proposal that involves New York City Administration for Children's Services (ACS) cases unless it is accompanied by a **final** letter of approval from ACS. In addition, for research involving youth in OCFS custody, a letter of approval must be obtained from the OCFS Deputy Commissioner for the Division of Juvenile Justice and Opportunities for Youth.

YOU MUST PROVIDE THE FOLLOWING INFORMATION:

Researcher Specific Information:
First Name
Last Name
Credentials
Affiliation
Street Address
City
State
Zip Code
Phone Number
Fax Number
Email Address
Proposal Specific Information:
Thorough and comprehensive literature review
Delineation of the specific research questions to be addressed
Detailed description of the proposed research design
Discussion of sampling approach and selection procedures
Description of kinds of data to be collected
Specification of sources of data and data collection procedures to be used in the research project
Copies of all data collection instruments
Description of the analytic approach to be used
Procedures to protect confidentiality of respondents including a description of any circumstances which would require identifying the respondent (**see additional instructions later in this document**)
Informed consent procedures for subjects and parent/guardian if subject is under age 18 along with copies of all written informed consent forms (**see additional instructions later in this document**)
A discussion of the risks and benefits of the research to the subjects and any remediation protocols

A data security plan in compliance with the detailed requirements specified later in this document (**see additional instructions later in this document**)
Plans for reporting the results to ensure that data is presented only in aggregate form or to prevent the identification of any individual
Explanation of the relevance of the research to the OCFS mission and expected contribution to the field of study
Possible impacts on OCFS and local agency operations
Clear statement of the purpose of the proposed research

REQUIRED ACCOMPANYING DOCUMENTATION:

Vitae for All Members of Research Team
Institutional Review Board Letter of Approval (*If you are not affiliated with OCFS or a LDSS*)
Letters of Support from ALL Involved Organizations (*If Applicable*)
Finalized Letter of Approval from ACS (*If Applicable*)
Finalized Letter of Approval from OCFS Deputy Commissioner for DJJOY (*If Applicable*)
Statement of Federal Funding (*If Applicable*)
Documentation of Federal Funding (*If Applicable*)

EMAIL COMPLETED APPLICATIONS & SUPPORTING DOCUMENTATION TO:

OCFS Research Proposal Review Team
Bureau of Research, Evaluation and Performance Analytics
NYS Office of Children and Family Services
e-mail: ocfs.sm.ResearchProposal@ocfs.ny.gov

INFORMED CONSENT REQUIREMENTS/INSTRUCTIONS

If the research involves contact with human subjects who are not anonymous, the researcher must obtain their informed written consent to participate in the study. Any "human research" as defined by Section 2441 of Article 24-A of the Public Health Law involving subjects under age 18 also requires the informed written consent of the parent or guardian. In cases where parental rights have been terminated, consent must be obtained from the responsible local department of social services. The consent must inform research subjects of the following:

1. the purpose and nature of the study;
2. the nature and duration of their participation;
3. an overview of kinds of questions they will be asked;
4. how the information will be used;
5. how long the information will be retained and final disposition of information;
6. who will have access to the information;
7. that all information will be kept confidential, except for circumstances where disclosure is mandated by law such as suicide threat, threat of harm to others, and child abuse (any disclosure circumstances need to be clearly specified on the consent form);
8. that should the researcher have reasonable cause to suspect that a child is being abused or neglected, this information will be reported to the Statewide Central Register of Child Abuse and Maltreatment;
9. that their participation is voluntary and they may refuse to answer any question or to participate in follow-up activities, and may withdraw at any time;
10. that their assent or refusal to participate will have no effect on the treatment, services or privileges they will receive;
11. a description of any compensation to the subject, if applicable, including type and amount of compensation and schedule for payment;
12. information on how to contact the researcher regarding any questions about the research; and
13. information on how to contact the person responsible for Human Subject Protection for the research project if the subject feels his/her rights have been violated.

For research involving youth in OCFS custody, OCFS will allow the youth to be approached by the researchers regarding his/her interest in participating in a research project. If the youth expresses interest in participating, then the Youth Consent Form must also contain a statement that the youth is consenting to providing contact information (name, address, telephone number, etc.) for his/her parent/legal guardian for obtaining written parental consent for the youth's participation in the research project. The researcher may then use this contact information to obtain written parental consent. Under no circumstances will the youth be allowed to begin participation without prior written parental consent. The Youth Consent Form containing an original signature, and when necessary, the Parental Consent Form with an original signature, must be kept in the youth's OCFS case file.

A copy of the research project description and signed consent form must be given to the youth and parent/guardian. An original signed youth consent form must be given to OCFS or the local agency maintaining the youth's case file so that it may be included in the official case record. An original signed parent/guardian consent form must also be supplied to OCFS or the local agency for inclusion in the case record.

CONFIDENTIALITY INSTRUCTIONS

Only the Researcher and individuals who are directly involved in the collection, processing, analysis, interpretation, or reporting of the subject data and have submitted signed confidentiality agreements (see below) are authorized to access the subject data. The Researcher shall not make any release of subject data listing information regarding individuals, even if the individual identifiers have been removed, unless such release has been authorized in the confidentiality agreement with OCFS. The Researcher may publish the results, analysis, or other information developed because of any research based on subject data made available under the confidentiality agreement with OCFS only in summary, aggregated, or statistical form so that the identity of individuals contained in the subject data is not revealed.

A completed and signed Research Employee/Volunteer Certification and initials next to each paragraph for each individual involved in the collection, processing, analysis, interpretation, or reporting of the subject data must be executed at the same time the Agreement to Maintain Confidentiality between OCFS and the Researcher is signed and executed. The Research Employee/Volunteer Certification requires involved parties to affirm that they will maintain the confidentiality of all identifiable juvenile justice and child welfare information, that they do not have a criminal conviction, and that they have not been the subject of an indicated report of child abuse or maltreatment. If the researcher or support staff has a criminal conviction or indicated child abuse or maltreatment report, the OCFS Division of Legal Affairs will review these facts and the nature of the access being requested for this person's role in the research project to make a final determination as to whether the person will be permitted to work on the project.

INSTRUCTIONS FOR CREATING A DATA SECURITY PLAN

Researchers must submit a data security plan that addresses the requirements described below and contains the name and contact information for the person(s) responsible for implementing and monitoring adherence to the Data Security Plan. The Researcher, to the extent applicable, shall adhere to the minimum standards identified in the New York State Office of Information Technology Services' Information Security Policy NYS-P03-002.

All Personal, Private or Sensitive Information (PPSI) on human subjects who are in the custody of OCFS or over whom OCFS has oversight, which are collected by or provided to the Researcher, and all information derived from those data must be covered by a Data Security Plan. Personal identifying information is any information that is likely to enable an individual to be identified, such as name, date of birth, social security number, race/ethnicity, etc. This includes combinations of variables that alone may not qualify as personal information, but which in combination could potentially identify an individual. Private or sensitive information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). PPSI also includes other information that is protected from disclosure by law or relates to subjects and areas of concern as determined by OCFS, which includes but is not to limited information relating to juvenile justice services, child protective services, preventive services, foster care, and/or adoption services whether or not client identifiers have been removed from the information.

Research data may be stored on computer tapes, diskettes, CD-ROMs, USB storage drives, hard drives, electronic files, hard copy, or other transferable media. The Researcher may only use the subject data in a manner and for a purpose consistent with the purpose for which the data were supplied, as stated in the researcher's description of the research in the proposal and the limitations imposed under the provisions of the confidentiality agreement between OCFS and the Researcher.

To comply with the minimum standards identified in the NYS Information Security Policy NYS-P03-002, and NYS Encryption Standard NYS-S14-007, the subject data shall be installed only on workstations that meet the security requirements outlined below:

- If the data are located on a file server, the storage space must be accessible only by authorized persons through password-protected accounts;
- Software will be used to encrypt the personal identifying data, and the password for accessing this software will be available only to the authorized researcher;
- The console of the server or workstation with the data must be password protected and limited to authorized persons; and
- The server or the computer that houses the data must not have remote-control software like PCAnywhere, etc.

User accounts that provide access to the data and console logins at the data storage stations must conform to these rules:

- Each user shall have a unique user-ID and password;

- Passwords must be changed at regular intervals;
- Passwords will contain a mix of at least 8 alphabetic, numeric, and upper/lower case characters. Additionally, password will always have 3 of the following four types of characters: alpha, upper and lower, numeric and symbol;
- Data must not be accessible by multi-user login accounts or passwords;
- The workstations used to access the data must automatically lock after five minutes of non-use (example: screen saver) and require a login or other password to unlock; and
- Laptops shall use whole disk encryption

Direct identifying information such as names, social security numbers, and addresses must be kept in a data file separate from the other subject data and encrypted. If interviews and focus groups are to be audio- or video-taped, an encryptable recorder may be required, depending on the content. Removable electronic storage media such as diskettes, CD-ROMs, and USB storage devices that contain the subject data must be encrypted and stored in a locked cabinet. Paper files, recording devices, and tapes also must be stored in a secure/locked cabinet. The full or partial subject data must not be accessible through the Internet.

The date by which the research data must be destroyed is stipulated in the Confidentiality Agreement between OCFS and the Researcher governing the research project, which is based on the data collection and analysis timetable necessary for completion of the research. All methods of destruction must comply with the New York State Office of Information Technology Services' NYS S13-003, Sanitization/Secure Disposal Standard. It is the Researcher's responsibility to be aware of existing sanitization standards, and to check for updated standards prior to disposal.