



RESEARCH AND EVALUATION ETHICS REVIEW COMMITTEE HANDBOOK

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INTRODUCTION

The Children's Board of Hillsborough County has established a Research and Evaluation Ethics Review Committee (ERC) with the purpose of providing guidelines for safeguarding the rights and safety of human subjects participating in research carried-out under contract with the Children's Board (CBHC). The Children's Board Research and Evaluation Ethics Review Committee (ERC) reviews all research involving human subjects that is conducted by CBHC staff, funded or supported totally or partially by CBHC. These guidelines are based on widely accepted principles of respect for the dignity of research subjects, voluntary participation, informed consent, confidentiality, anonymity and avoidance of harm.

The ethical principle of respect for persons requires that subjects be given the opportunity to choose what shall and shall not happen to them. Informed consent requires the **disclosure** of relevant information to prospective subjects about the research. The Investigator needs to ensure that the participant **comprehends** the information, and agree to research participation **voluntarily**, free of coercion and undue influence (NIH Guidelines for Writing Informed Consent Documents, Revised 11/20/2006, <http://www.nihtraining.com/ohsr/site/info/sheet6.html>). The signing of the written informed consent document is an integral part of the informed decision-making. However, depending on the nature and duration of the research, ongoing discussion and education of the participants may continue long after the informed consent document is signed.

Research is defined as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge" (Code of Federal Regulations, DHHS 2005 45 CFR 46.102(d)). Human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or, (2) identifiable private information." Research involving the collection or study of existing data, documents and/or records publicly available is exempt of review by the ERC (refer to Protocol Manual page 7-8 for a list of research activities involving human subjects that may be exempt from ERC).

Applicants are required to comply with the Children's Board Term and Conditions for funded organizations as well as the Guiding Principles for Evaluators established by the American Evaluation Association. In addition, applicants must comply with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Practices if applicable.

This handbook includes guidelines, policies and procedures with instructions to help you prepare a protocol for submission to the CBHC's Ethics Review Committee. This handbook consists of two sections. Section 1 provides an overview of the CBHC Research and Evaluation Ethics Review process. Section 2 contains the Protocol Manual with instructions and the application forms to request ERC review.

SECTION 1

OVERVIEW OF CBHC ETHICS REVIEW COMMITTEE (ERC)

Types of Requests for ERC Review

All requests for ERC must be submitted with the Cover Page for Approval of All Research Projects. Applications forms are found in Part 3 of the Protocol Manual. Note that the Proposed Project dates need to take into consideration the time needed for completion of the ERC review process. Research cannot be initiated until ERC approval is received. Informed Consent, Responsibilities of the Investigators and Qualification/Resume of the Investigators are also required. Other forms required vary (1A, 1B or 1C) depending on the type of request. Incomplete applications will not be accepted.

There are three types of requests:

- Exempt
- Expedited
- Full CBHC ERC Review

Exempt Status

This type of application, if approved, does not require full ERC approval. All research that is exempt from full review must be certified as such by the Children's Board Research and Evaluation ERC. Refer to the Protocol Manual, Page 12 and Attachment 1A for an explanation of categories of Exempt Status and application forms. Complete and attach Attachment 1A, Attachment 2, Consents, Attachment 3, Responsibilities of Investigators, and Attachment 4, Resume of Investigator(s).

The following are research activities involving human subjects that may be exempt from ERC Review:

- Research conducted in established or educational settings involving normal educational practices such as (a) research on regular and special educational practices, or (b) research on the effectiveness of instructional techniques, curricula or classroom management methods.
- Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior, unless the information is recorded in a manner that human subjects can be identified or indirectly linked to the subjects.
- Research involving the collection or study of existing data, documents and records if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or linked to the subjects.

Expedited Status

This type of research presents minimal risk to the human subjects participating in research. Minimal risk means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (US Department of Health & Human Services, 45 CFR 46.102(i). Refer to Protocol Manual, Request for Expedited ERC

Review, Attachment 1B for Application form. Attach Attachment 2 (Consents), Attachment 3 (Responsibilities of Investigators), and Attachment 4 (Resume of Investigator(s)).

Full Review

All research that does not meet either the exempt or expedited review criteria will require a Request for Full Review. The application forms for Full Review found in the Protocol Manual must be fully completed. Refer to Protocol Manual, Attachment 1C, “Full Research Protocol Form” for application forms. Complete and attach Attachment 1C, Attachment 2, Consents, Attachment 3, Responsibilities of Investigators, and Attachment 4, Resume of Investigator(s).

Note that researchers who are affiliated with an institution that has an Institutional Review Board (IRB), or a similar body, that have received approval by such body may submit verification of institutional review and approval, and the research protocol that pertains to the CBHC research project to meet CBHC ERC requirements.

ERC Review Process

Once a research project application has completed the funding review process established by the Children’s Board and received approval by the Funding Review and/or Management Team, it will then be reviewed by the CBHC ERC Committee. Research and Evaluation Team member Dr. Lydia Medrano will coordinate the CBHC ERC review process. The CBHC ERC Chairperson will convene the review meeting. Only applications that are complete will be reviewed. All required documentation will be reviewed to reach a decision.

Exempt Status: These requests are reviewed by the CBHC ERC Chairperson to determine either that (a) the project meets the criteria for “exempt” status; (b) additional information or revisions to the request are needed; or (c) refer the request to the CBHC ERC for full review.

Expedited Status: The ERC Chairperson will convene a minimum of two (2) members of the CBHC ERC committee to review the request which may be approved or referred for review by the full CBHC ERC committee.

Full Review: The ERC Chairperson will convene the CBHC ERC with a minimum of five (5) members (refer to ERC Membership information in this section) to conduct a full review of the request.

These requests may result in either:

- Approval
- Denial
- Approval with conditions
- Additional information requested

It is the responsibility of the applicant to make the modifications resulting from the ERC review and to track and inform the ERC of any other necessary changes. All changes made after the initial submission must be reviewed and approved by the ERC.

The CBHC ERC approval will result in Letter of Approval. The Letter of Approval is the official notification that the research project or activity involving human subjects has been reviewed and approved by the internal CBHC ERC in accordance with set guidelines.

After the research project is approved for funding, the estimated timeline for the ERC review to be completed and a certification be issued is as follows:

- Exempt Certification – 6 work days
- Expedited Certification – 10 work days
- Full Review Certification – 30 calendar days

All members of the ERC Committee and the CBHC Management Team will be notified of research proposals which have been approved by the exempt and expedited procedure and will have access to copies of all documentation.

A log of all CBHC ERC activities and adequate documentation will be maintained in CBHC files, including:

- Copies of research proposals, approved consent documents, progress reports submitted by the investigators, and any problems and concerns reported.
- Minutes from CBHC ERC meetings.
- Records of continuing review activities.
- Correspondence

These records are retained for at least three (3) years after completion of the research.

Unanticipated risks are sometimes discovered during the course of research. Information that may impact on the risk/benefit ratio should be promptly reported to, and reviewed by, the ERC to ensure adequate protection of the welfare of the subjects. Based upon such information, the ERC may need to reconsider its approval of the study, require modifications to the study or, revise the continuing review timetable. For Responsibilities of Investigators, see the Protocol Manual, Attachment 3.

Continuing Review of Approved Research

The HHS regulations for the protection of human subjects ([45 CFR Part 46](#)) require that, among other things, (1) review entities have written procedures for (a) conducting its continuing review of research and for reporting its findings and actions to investigators and the institution, and (b) determining which projects require review more often than annually; (2) except when an expedited review procedure is used, proposed research shall be reviewed at convened meetings at which a majority of the members of the ERC are present, including at least one member whose primary concerns are in the nonscientific areas; and (3) continuing review of research is conducted at intervals appropriate to the degree of risk, but not less often than once a year (45 CFR 46.109(e)).

Continuing Review Guidelines

Continuing review of research must be substantive and meaningful and follow the established review procedure with recorded vote on each study unless the research is otherwise appropriate for expedited review. The expedited review procedure (Section 46.110) may be used to review either or both of the following: (a) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk (see attachment 1B), and (b) to review minor changes in previously approved research during the period (of one year or less) for which approval is authorized. **Additional** criteria that must be satisfied include, among other things, determinations regarding risks, potential benefits, informed consent, and safeguards for human subjects. The ERC must ensure that these criteria are satisfied at the time of both initial and continuing review.

Following the HHS human subjects regulations (at 45 CFR 46.110(b)(1) the use of expedited review procedures is limited to specific research categories (see <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>), and to the review of minor changes in previously approved research during the period (of one year or less) for which approval is authorized. The use of expedited review for the continuing review of research is permitted only when one or more of the activities published in the Federal Register at 63 FR 60364-60367 are involved.

To comply with the above regulations the Children's Board Research & Evaluation Committee has established the following Continuing Review procedures.

- A. PIs must submit a request for continuing review 30 days before the anniversary of the original ERC approval.
- B. PIs request for Continuing Review requires a completed Cover Page for All Research Requests form with the pertinent attachments for the type of review being requested.
- C. Continuing Review Requests should include a report that includes:
 - The number of subjects accrued;
 - A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last ERC review;
 - A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
 - Any other relevant information, especially information about risks associated with the research; and
 - A copy of the current informed consent document and any newly proposed consent document.
- D. Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the ERC.
- E. Informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

ERC Continuing Review process will follow the timelines established for each type of request (refer to ERC Handbook, Overview – ERC Review Process section).

ERC Membership

The CBHC ERC consists of at least five (5) sufficiently qualified and experienced members, with varying backgrounds, to promote complete and adequate review of research activities commonly conducted by CBHC. All ERC members, as needed, will receive training on the Protection of Human Subjects.

The CBHC ERC includes persons knowledgeable of the specific area of research. It includes members in the following four (4) categories:

- **Chairperson:** The Director of Research and Evaluation, Dr. Peter Gorski, shall serve as Chairperson.
- **Research & Evaluation staff:** at least two (2) members will serve; these are members with training, background, experience and sufficient knowledge of research methodology and content knowledge relevant to the research area of review.
- **Affiliation to CBHC:** one CBHC staff person, such as paid staff, governing board, interns, consultants and volunteers working on business unrelated to the ERC will serve; these staff members possess content knowledge relevant to the area of review.
- **Community Representative (1),** with related experience and knowledge in the content area of review (current Funding Review Team community representatives could be a resource).

Alternate members of primary members have comparable qualifications, knowledge and skills of the primary member whom the alternate will replace (see above categories). Primary and alternate members may attend the same review but only one, representing a specific category, can act as a voting partner.

At least one member of the CBHC ERC is not affiliated with the Children’s Board. The ERC Committee may not consist entirely of members of one profession. Individuals with competence in a specific area may be invited to assist in the review of issues that require certain expertise but these individuals may not vote with the ERC. Consideration must be given to diversity in terms of gender, race, cultural backgrounds and sensitivity to safeguarding the rights and welfare of human subjects.

CBHC will maintain a file with names of ERC members and credentials of each member and alternate member.

ERC Review Application and Protocols

The Protocol Manual contained in this handbook provide the guidelines, policies, procedures and instructions as well as the forms needed to prepare a protocol for submission to the CBHC’s Research and Evaluation Ethics Review Committee.

Guiding Principles for Evaluators

The American Evaluation Association (AEA), the professional association for evaluators, works to ensure ethical work in the evaluation of programs, products, personnel, and policy. To proactively guide the professional practice of evaluators, and to inform evaluation clients and the general public of expectations for ethical behavior, the AEA developed the following guiding principles:

A. Systematic Inquiry: Evaluators conduct systematic, data-based inquiries.

1. To ensure the accuracy and credibility of the evaluative information they produce, evaluators should adhere to the highest technical standards appropriate to the methods they use.
2. Evaluators should explore with the client the shortcomings and strengths both of the various evaluation questions and the various approaches that might be used for answering those questions.
3. Evaluators should communicate their methods and approaches accurately and in sufficient detail to allow others to understand, interpret and critique their work. They should make clear the limitations of an evaluation and its results. Evaluators should discuss in a contextually appropriate way those values, assumptions, theories, methods, results, and analyses significantly affecting the interpretation of the evaluative findings. These statements apply to all aspects of the evaluation, from its initial conceptualization to the eventual use of findings.

B. Competence: Evaluators provide competent performance to stakeholders.

1. Evaluators should possess (or ensure that the evaluation team possesses) the education, abilities, skills and experience appropriate to undertake the tasks proposed in the evaluation.
2. To ensure recognition, accurate interpretation and respect for diversity, evaluators should ensure that the members of the evaluation team collectively demonstrate cultural competence. Cultural competence would be reflected in evaluators seeking awareness of their own culturally-based assumptions, their understanding of the worldviews of culturally-different participants and stakeholders in the evaluation, and the use of appropriate evaluation strategies and skills in working with culturally different groups. Diversity may be in terms of race, ethnicity, gender, religion, socio-economics, or other factors pertinent to the evaluation context.
3. Evaluators should practice within the limits of their professional training and competence, and should decline to conduct evaluations that fall substantially outside those limits. When declining the commission or request is not feasible or appropriate, evaluators should make clear any significant limitations on the evaluation that might result. Evaluators should make every effort to gain the competence directly or through the assistance of others who possess the required expertise.
4. Evaluators should continually seek to maintain and improve their competencies, in order to provide the highest level of performance in their evaluations. This continuing professional development might include formal coursework and workshops, self-study, evaluations of one's own practice, and working with other evaluators to learn from their skills and expertise.

C. Integrity/Honesty: Evaluators display honesty and integrity in their own behavior, and attempt to ensure the honesty and integrity of the entire evaluation process.

1. Evaluators should negotiate honestly with clients and relevant stakeholders concerning the costs, tasks to be undertaken, limitations of methodology, scope of results likely to be obtained, and uses of data resulting from a specific evaluation. It is primarily the evaluator's responsibility to initiate discussion and clarification of these matters, not the client's.
2. Before accepting an evaluation assignment, evaluators should disclose any roles or relationships they have that might pose a conflict of interest (or appearance of a conflict) with their role as an evaluator. If they proceed with the evaluation, the conflict(s) should be clearly articulated in reports of the evaluation results.

3. Evaluators should record all changes made in the originally negotiated project plans, and the reasons why the changes were made. If those changes would significantly affect the scope and likely results of the evaluation, the evaluator should inform the client and other important stakeholders in a timely fashion (barring good reason to the contrary, before proceeding with further work) of the changes and their likely impact.
4. Evaluators should be explicit about their own, their clients', and other stakeholders' interests and values concerning the conduct and outcomes of an evaluation.
5. Evaluators should not misrepresent their procedures, data or findings. Within reasonable limits, they should attempt to prevent or correct misuse of their work by others.
6. If evaluators determine that certain procedures or activities are likely to produce misleading evaluative information or conclusions, they have the responsibility to communicate their concerns and the reasons for them. If discussions with the client do not resolve these concerns, the evaluator should decline to conduct the evaluation. If declining the assignment is unfeasible or inappropriate, the evaluator should consult colleagues or relevant stakeholders about other proper ways to proceed. (Options might include discussions at a higher level, a dissenting cover letter or appendix, or refusal to sign the final document.)
7. Evaluators should disclose all sources of financial support for an evaluation, and the source of the request for the evaluation.

D. Respect for People: Evaluators respect the security, dignity and self-worth of respondents, program participants, clients, and other evaluation stakeholders.

1. Evaluators should seek a comprehensive understanding of the important contextual elements of the evaluation. Contextual factors that may influence the results of a study include geographic location, timing, political and social climate, economic conditions, and other relevant activities in progress at the same time.
2. Evaluators should abide by current professional ethics, standards, and regulations regarding risks, harms, and burdens that might befall those participating in the evaluation; regarding informed consent for participation in evaluation; and regarding informing participants and clients about the scope and limits of confidentiality.
3. Because justified negative or critical conclusions from an evaluation must be explicitly stated, evaluations sometimes produce results that harm client or stakeholder interests. Under this circumstance, evaluators should seek to maximize the benefits and reduce any unnecessary harms that might occur, provided this will not compromise the integrity of the evaluation findings. Evaluators should carefully judge when the benefits from doing the evaluation or in performing certain evaluation procedures should be foregone because of the risks or harms. To the extent possible, these issues should be anticipated during the negotiation of the evaluation.
4. Knowing that evaluations may negatively affect the interests of some stakeholders, evaluators should conduct the evaluation and communicate its results in a way that clearly respects the stakeholders' dignity and self-worth.
5. Where feasible, evaluators should attempt to foster social equity in evaluation, so that those who give to the evaluation may benefit in return. For example, evaluators should seek to ensure that those who bear the burdens of contributing data and incurring any risks do so willingly, and that they have full knowledge of and opportunity to obtain any benefits of the evaluation. Program participants should be informed that their eligibility to receive services does not hinge on their participation in the evaluation.
6. Evaluators have the responsibility to understand and respect differences among participants, such as differences in their culture, religion, gender, disability, age, sexual orientation and ethnicity, and to account for potential implications of these differences when planning, conducting, analyzing, and reporting evaluations.

E. Responsibilities for General and Public Welfare: Evaluators articulate and take into account the diversity of general and public interests and values that may be related to the evaluation.

1. When planning and reporting evaluations, evaluators should include relevant perspectives and interests of the full range of stakeholders.
2. Evaluators should consider not only the immediate operations and outcomes of whatever is being evaluated, but also its broad assumptions, implications and potential side effects.

3. Freedom of information is essential in a democracy. Evaluators should allow all relevant stakeholders access to evaluative information in forms that respect people and honor promises of confidentiality. Evaluators should actively disseminate information to stakeholders as resources allow. Communications that are tailored to a given stakeholder should include all results that may bear on interests of that stakeholder and refer to any other tailored communications to other stakeholders. In all cases, evaluators should strive to present results clearly and simply so that clients and other stakeholders can easily understand the evaluation process and results.

4. Evaluators should maintain a balance between client needs and other needs. Evaluators necessarily have a special relationship with the client who funds or requests the evaluation. By virtue of that relationship, evaluators must strive to meet legitimate client needs whenever it is feasible and appropriate to do so. However, that relationship can also place evaluators in difficult dilemmas when client interests conflict with other interests, or when client interests conflict with the obligation of evaluators for systematic inquiry, competence, integrity, and respect for people. In these cases, evaluators should explicitly identify and discuss the conflicts with the client and relevant stakeholders, resolve them when possible, determine whether continued work on the evaluation is advisable if the conflicts cannot be resolved, and make clear any significant limitations on the evaluation that might result if the conflict is not resolved.

5. Evaluators have obligations that encompass the public interest and good. These obligations are especially important when evaluators are supported by publicly-generated funds; but clear threats to the public good should never be ignored in any evaluation. Because the public interest and good are rarely the same as the interests of any particular group (including those of the client or funder), evaluators will usually have to go beyond analysis of particular stakeholder interests and consider the welfare of society as a whole.

Developed by the AEA in 1994 and revised and approved in 2004.

References

U.S. Department of Health and Human Services Code of Federal Regulations

<http://hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

For information on human subjects protection and Code of Federal Regulations visit the U.S. Department of Health and Human Services

www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

For on-line Training on Human Participant Protections Education for Research visit the U.S. National Cancer Institute

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

American Evaluation Association (AEA)

<http://www.eval.org/Publications/GuidingPrinciplesPrintable.asp>

For the National Institute of Health (NIH) Guidelines for Writing Informed Consent Forms Documents

<http://www.nihtraining.com/ohrsite/info/sheet6.html>

For information on HIPAA

<http://www.hhs.gov/ocr/hipaa/finalreg.html>

<http://www.research.usf.edu/cs/hipaa.htm>

<http://www.research.usf.edu/cs/hipaadecisiontree.htm>



CHILDREN'S BOARD OF HILLSBOROUGH COUNTY

SECTION 2 PROTOCOL MANUAL

FOR

RESEARCH AND EVALUATION ETHICS REVIEW COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

PART 1: ETHICS REVIEW COMMITTEE (ERC) POLICIES AND PROCEDURES

- I. Purpose.** The purpose of these policies and procedures is to establish guidelines for the protection of human subjects in research carried out by or under contract with the Children’s Board of Hillsborough County (CBHC).
- II. Scope.** All activities undertaken in the completion of CBHC's internal or contracted research activities shall be consistent with the accepted standards of a formal Institutional Review Board (IRB) for the Protection of Human Subjects in Experimentation. If a contracted research provider does not have a formal Institutional Review Board or Ethics Review Committee process, an ERC process will be defined in consultation with the CBHC ERC Chairperson. Instructions and forms for applying for ERC review are described in Section IV.

Although the federal regulations apply to federally-funded research, the CBHC applies the federal regulations in 45 CFR Part 46 regardless of whether federal funds are involved in the research. Since your research will involve human subjects, your project will require review to determine if you have employed adequate measures to protect those individuals involved in your study. CBHC reviews all research proposals involving human subjects, regardless of the funding source or amount.

The box below contains the Children’s Board of Hillsborough County policy statement for carrying out federal regulations concerning Ethics Review Committee (ERC) governance of research involving human subjects.

Statement of Principles

The CBHC’s principles applicable to human subject research, regardless of funding source are those statements of ethical principles in the Belmont Report and 45 CFR Part 46. It is also a principle of CBHC-sponsored research that researchers must know and apply the CBHC’s statement of principles in all CBHC-sponsored research

The Office for the Protection from Research Risks (OPRR) has published regulations regarding institutional review governance of research involving human subjects [Federal Register (June 18, 1991, 45CFR46)]. CBHC adheres to these regulations and has adopted the Belmont Report (April 18, 1979), which provides ethical principles and guidelines for the protection of human subjects of research. Anyone intending to use human subjects in research is required to read these two publications.

III. Definitions.

- A. Ethics Review Committee (ERC). An ERC (also known as Institutional Review Board or IRB) is a committee established by an organization to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice, in order to safeguard the rights and safety of human subjects.

- B. Research. For the purpose of ERC review, research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.” (Federal Register, June 18, 1991, 45CFR46).
- C. Exempt Research, Attachment 1A. Exempt research is a category of research, defined by Title 45 Code of Federal Regulations, Part 46, that does not require full ERC review and approval; however, such research must be certified as exempt. It is anticipated that most research involving adults as subjects that is conducted by or funded by the CBHC will qualify for exempt status. Some research involving minors may also qualify. To request exempt status, submit the Cover Page and Attachment 1A which includes definitions of the six classes of exempt research. Also submit Attachments 2 through 4 along with any additional requested information.
- D. Expedited Review, Attachment 1B. Research that the Federal government has found to present minimal risks to subjects is eligible for expedited review. Expedited reviews are conducted by at least two members of the ERC Committee assigned according to expertise in the area of research to be reviewed. Upon evaluation of the project, the ERC may require review by the full committee. To request expedited review for research eligible for expedited review, submit the Cover Page and Attachment 1B which includes definitions of the criteria for expedited review. Also submit Attachments 2 through 4 along with any additional requested information.
- E. Full Review, Attachment 1C. All research that does not meet either exempt or expedited review criteria must be reviewed by the entire ERC. To request a full review, submit a Cover Page and Attachment 1C. Also submit Attachments 2 through 4 along with any additional requested information.

If you have any additional questions regarding the completion of the protocol or the Federal regulations, contact the Research and Evaluation Department at the CBHC at (813) 229-2884 or (813) 204-1772).

IV. The ERC Process

This brief synopsis will help you decide which parts of the protocol packet to complete and will explain the review process. If you plan to conduct your research at another facility that has a formal ERC or Institutional Review Board (IRB) review, have that facility submit to the CBHC a copy of your approved protocol, a copy of your instruments, CBHC’s Cover Page, and the letter (which includes their assurance number) stating that that facility’s ERC has approved your protocol.

Providers that conduct research projects under a grant from or in cooperation with CBHC must define an ERC review process as part of the process of submitting a research proposal to CBHC.

- A. Categories: There are two categories investigators will use to meet the CBHC ERC requirement. Use the Cover Page for CBHC Human Subjects Research Request For Approval) to select from the following categories.

Category 1. If the research provider is affiliated with an institution that requires ERC approval, and has an operational Institutional Review Board, the provider may meet CBHC's requirements by submitting verification of the ERC approval and the research protocol that pertain to the CBHC research project.

Category 2. If the research provider is not affiliated with or has no other access to an established review process, the provider may request review through the CBHC ERC process.

- B. CBHC Ethics Review Committee. The Director of Research and Evaluation shall serve as the Chairperson of the CBHC ERC. Other members of the ERC Committee include Research and Evaluation professional staff and community representatives with related experience/knowledge. The ERC will be convened periodically to review requests for ERC approval or receive status reports from previously approved projects.

- C. Steps in the Review Process:

1. Submit Request for Approval of Human Subjects Research: The researcher must complete a Human Subjects Research Request For Approval that includes:
 - a. Cover Page. (all research review requests submit Cover Page)
 - 1) If Category 1 is selected, attach copy of the ERC (or IRB) approval from the affiliated institution and the approved research protocol.
 - 2) If Category 2 is selected, proceed as follows:
 - b. Request for Exempt Status. To request that your research be certified as exempt, use Attachment 1A, Request for Exempt Status.
 - c. Request for Expedited Status. To request expedited status for eligible research, use Attachment 1B, Request for Expedited Status.
 - d. Request for Full Review. To request a full review, use Attachment 1C, Full Review.
 - e. All researchers shall submit proposed Consent/Assent forms (see samples provided in Attachment 2. All researchers submit signed Responsibilities of Investigators, Attachment 3.
 - f. All researchers submit resume of principal investigator(s), Attachment 4.
2. Review of Requests for Exempt Status. If the ERC Chairperson determines that the project meets criteria for exempt status, the Chairperson will approve and sign the request, and return a copy to the provider. If not, the ERC Chairperson may request additional information or revisions to the request, or may refer the request to the ERC for full review, and notify the applicant of this decision. The CBHC Management Team shall also be notified of the decision.

3. Review of Requests for Expedited Status. The ERC Chairperson will convene a minimum of two members of the ERC committee to review the request. The request may be approved, the provider may be asked to submit additional information or revisions, or the request may be referred for review by the full ERC. All members of the ERC shall be advised by e-mail of research proposals which have been approved under the expedited procedure. If an ERC member did not previously receive the Request for Approval of Human Subjects Research, the e-mail to that ERC member shall also include or provide the URL to the Request for Approval of Human Subjects Research.
4. Full ERC review. The ERC Chairperson will convene the full ERC to review the request. The request may be approved, approved with conditions, the provider may be asked to submit additional information or revisions, or the request may be denied.

All researchers must submit the Cover Page and either Attachment 1A, 1B, or 1C as well as Attachment 2, Consents, Attachment 3, Responsibilities of Investigators, and Attachment 4, Resume of Investigator(s).

PART 2: FEDERAL ASSURANCES

I. Statement of Principles [45 CFR 46.103(b)(1)]

- A. The CBHC assures that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles in the Belmont Report and 45 CFR Part 46.
- B. Researchers must know and apply the CBHC's Statement of Principles in all CBHC research.

II. Designation of ERC [45 CFR 46.103(b)(2)]

- A. By this Protocol Manual, the CBHC designates the CBHC Ethics Review Committee (ERC) as the review board required by 45 CFR 46.103(b)(2).
- B. All the authority and power of a review board described in 45 CFR Part 46 are incorporated into this Protocol Manual, and the CBHC ERC shall possess all authority and power of a review board described in 45 CFR Part 46.
- C. It is the policy of the CBHC that the ERC shall have sufficient meeting space and staff support to support the ERC's review and recordkeeping duties.
- D. ERC members, their earned degrees, representative capacity; indications of experience, and any employment or other relationship between each member and the institution are available for review upon request.

III. Written Procedures [45 CFR 46.103(b)(4)]

- A. This Protocol Manual contains procedures for:
1. Conducting the ERC's initial and continuing review of research.
 2. Reporting the ERC's findings and actions to the investigator and the CBHC.
 3. Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous ERC review.
 4. Ensuring prompt reporting to the ERC of proposed changes in a research activity.
 5. Ensuring that such changes in approved research during the period for which ERC approval has already been given may not be initiated without ERC review and approval, except when necessary to eliminate apparent immediate hazards to the subject.
 6. Ensuring prompt reporting to the ERC, appropriate CBHC officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the ERC and (ii) any suspension or termination of ERC approval.

PART 3: ERC ADMINISTRATION PROCEDURES

- A. The following procedures shall be used by the ERC to determine which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since the previous ERC review. The ERC members, appropriate for the type of research (exempt, expedited, full), will consider the following factors in determining whether a project requires review more often than annually and which project needs verification from sources other than the investigators report that no material changes have occurred since the previous ERC review:
1. The known risks to subjects
 2. The potential for significant unknown risks to subjects
 3. The anticipated benefits to subjects
 4. The manner of selecting subjects
 5. The scope of the informed consent;
 6. The level of monitoring of subjects and the type of data collected
 7. The procedures used to maintain confidentiality of data and the privacy of subjects
 8. The age, health, and educational level of subjects
 9. The qualifications of the investigators
 10. The extent to which the research involves new procedures or tests
- B. The following procedures shall be used by the ERC to ensure prompt reporting to the ERC, appropriate CBHC officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the ERC and (ii) any suspension or termination of ERC approval:

ERC continuing review responsibilities include reviewing reports of adverse reactions and unexpected events involving risks to subjects or others. Reports considered to be of minor

significance will be reviewed by an expedited process. More serious reports and those requiring significant revisions to the protocol and/or the consent form will receive full ERC review at the next convened meeting of the ERC or sooner at the request of either of the ERC Co-Chairs.

(The ERC will provide a brief form to be completed by the principal investigator when an adverse event occurs asking for his/her opinion as to whether the event was related to the study and other information to aid the ERC in an appropriate and efficient review of the event.)

Researchers should be made aware of the ERC's policies and procedures concerning reporting and continuing review requirements. This can be accomplished by notifying the investigator, in the ERC's letter of approval, of the requirement to report changes and unanticipated problems in research activities. The ERC's written procedures pertaining to continuing review and reporting requirements should be distributed to ensure that all individuals involved in research activities understand their obligations.

- C. Unanticipated risks are sometimes discovered during the course of research. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the ERC to ensure adequate protection of the welfare of the subjects. Based upon such information, the ERC may need to reconsider its approval of the study, require modifications to the study or, revise the continuing review timetable.

§46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary, HHS, has established, and published as a Notice in the FEDERAL REGISTER, a [list of categories](#) of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

Children's Board of Hillsborough County
Human Subjects Research Request for Approval
Cover Page For All Research Requests

Agency/Institution (Research Organization) _____

Address _____

Research Project Title _____

Principal Investigator _____ **Phone** _____

E-Mail address _____

Funding Agencies/research sponsors: _____

Is this a: ___ New Submission ___ Resubmission ___ Modification

___ Continuing Review: CBHC ERC # ____.

Proposed Project Dates: _____

INDICATE IF THE PROJECT INVOLVES ANY OF THE FOLLOWING:

___ minors

___ developmentally disabled

___ prisoners

___ random sample population

___ pregnant women

___ a cooperating or partner organization

This request is submitted to meet CBHC's requirement for an ERC approval for research involving human subjects. The category selected is:

___ **Category 1.** The proposed research has been reviewed and approved by a qualified ERC or IRB affiliated with _____.
A copy of the ERC approval and research protocol is attached.

___ **Category 2.** A review by the CBHC ERC is requested. The type of approval requested is for:

___ **Exempt research.:** ___ Exemption Class(es) _____ (Insert Exempt Class number of all that are applicable. Attach Attachments 1A, Attachment 2

(Consents), Attachment 3 (Responsibilities of Investigators), and Attachment 4 (Resume of Investigator(s))

_____ **Expedited research:** Expedited Class(es) _____. (Insert Expedited Class number of all that are applicable) Attach Attachment 1B, Attachment 2 (Consents), Attachment 3 (Responsibilities of Investigators), and Attachment 4 (Resume of Investigator(s)).

_____ **Full ERC review.** Attach Attachment 1C, Attachment 2 (Consents), Attachment 3 (Responsibilities of Investigators), and Attachment 4 (Resume of Investigator(s))

On behalf of the Research Organization, the undersigned certify that the information contained in this proposal is complete and accurate. The procedures are in accord 45 CFR Part 46 without regard to whether or not the research is federally funded and the Belmont Report (April 18, 1978) for the protection of human participants in research. Furthermore, HIPPA Procedures as well as the Terms and Conditions of the Children’s Board of Hillsborough County have been reviewed and are accepted in their totality.

We certify that changes in approved research, during the period for which ERC approval has already been given, may not be initiated without ERC review and approval except when necessary to eliminate apparent immediate hazards to the subject. 45 CFR 46.103(b)(4).

Signature of principal investigator

Authorized Organizational Representative

Signature of co-principal investigator

Authorized Organizational Representative

Date _____

Date _____

_____ Reviewed by ERC Chairpersons

Date _____

_____ Referred for Expedited review

Date _____

_____ Referred for Full review

Date _____

For Committee Use Only

Disposition:

_____ Approved.

_____ Acceptable when you submit requested information

_____ Undecided Until additional information is provided

_____ Not Approved.

ERC Chairperson Signature _____ Date _____

ATTACHMENTS

1 Attachment Forms for ERC Review Application

1A Exempt Application

1B Expedited Application

1C Full Research Protocol

3 Responsibilities of Investigators

4 Resumes of Investigators

ATTACHMENT 1A

Children’s Board of Hillsborough County – Ethics Review Committee

Research “Exempt” from Review

EXEMPT research is research, defined by Title 45 Code of Federal Regulations Part 46, that does not require full ERC review and approval. Research that is neither conducted nor supported by a federal department or agency or subject to regulation is, nevertheless, subject to review according to the CBHC Protocol Manual without regard to the lack of federal funding or regulation and must be reviewed and approved by the CBHC ERC which applies 45 CFR Part 46 to all CBHC-sponsored research. Unless otherwise required by department or agency heads, research activities that only incorporate human subject involvement will qualify for one or more of the following EXEMPT classes. Read through the following six EXEMPT classes to see if your research qualifies for EXEMPT status. Place an X or check mark besides each Exempt Class applicable to your research. Then cite the exemption class number next to the EXEMPT box on your Cover Page (located on page 17 and follow the procedures for EXEMPT review on page 13, paragraph C.

Note: These exemptions do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization.

<u>Exempt Class</u>	<u>Description of Research</u>
_____	1. Research conducted in established or commonly accepted educational settings ¹ , involving normal educational practices, such as <ul style="list-style-type: none">(i) research on regular and special education instructional strategies, or(ii) research on the effectiveness of or the comparison among instructional techniques¹, curricula¹, or classroom management methods¹.
_____	2. Research involving the use of educational tests ¹ (cognitive, diagnostic, aptitude, achievement), survey procedures, ² interview procedures, ² or observation of public behavior ³ [Applies to research with minors] unless: <ul style="list-style-type: none">(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

¹ **Applies to minors**

² **Does not apply to research with minors**

³ **Applies to research with minors only when the investigator(s) does not participate in the activities observed**

_____ 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not already EXEMPT under #2, if:

- (i) The human subjects are elected or appointed public officials or candidates for public office; or
- (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

_____ 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [**Applies to research with minors**].

_____ 5. Research and demonstration projects which are conducted by or subject to the approval of federal, state, or local governmental entities or corporation exempt under section 501(c)(3) of the IRS Code (not otherwise subject to regulation under 45 CFR 46) and which are designed to study, evaluate, or otherwise examine:

- (i) public benefit or service programs;
- (ii) procedures for obtaining benefits or services under these programs;
- (iii) possible changes in or alternatives to those programs or procedures; or
- (iv) possible changes in methods or levels of payment for benefits or services under those programs.

_____ 6. Taste and food quality evaluation and consumer acceptance studies

- (i) if wholesome foods without additives are consumed or
- (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

ATTACHMENT 1B

Children’s Board of Hillsborough County – Ethics Review Committee

Request for Expedited ERC Review

Research Activities Which May Be Reviewed Through Expedited Review Procedures

Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories carried out through standard methods, may be reviewed by the Ethics Review Committee through the expedited review procedure, authorized in §46.110 of 45 CFR Part 46 (see footnote). Insert the Expedited Class number on the Cover Page in the section regarding Expedited Review.

Expedited Class Description of Research

- _____ 1. Research on individual or group behavior or characteristics of individuals, such as studies of perception cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior, and the research will not involve stress to subjects.

- _____ 2. The study of existing data, documents, records, pathological specimens, or diagnostic specimens

- _____ 3. Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction

- _____ 4. Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor

- _____ 5. Recording of data from subjects 18 years of age or older, using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance, and do not involve input of matter or significant amounts of energy into the subject, or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves)

- _____ 6. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period, and no more often than two times per week, from subjects 18 years of age or older, and who are in good health and not pregnant

- _____ 7. Collection of both supra- and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic sealing of the teeth, and the process is accomplished in accordance with accepted prophylactic techniques
- _____ 8. Voice recordings made for research purposes such as investigations of speech defects
- _____ 9. Moderate exercise by healthy volunteers
- _____ 10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required

Note: These exemptions do not apply to research: (1) involving prisoners, fetuses, pregnant women, other dependent populations, or human in vitro fertilization and (2) involving children except for research limited to observations of public behavior when the investigator(s) do not participate in the activities being observed. If the research falls under categories (1) and (2), the project is not exempt and must be reviewed by the ERC.

Request for Expedited ERC Review Attachment 1B (Continued)

Answer all items. Failure to include the requested information and documentation will prevent ERC consideration of your protocol.

Project Title: _____

1. PURPOSE OF THE PROPOSED STUDY?

2. DESCRIBE THE PARTICIPANT POPULATION AND PROCEDURE FOR RECRUITING PARTICIPANTS. (Attach a copy of any letter or other materials used to solicit institutional and/or individual participation.) The researcher has attached this information as Attachment _____.

3. IS THIS STUDY A COMPLETE REPLICATION OR EXTENSION OF A PRIOR STUDY?

No Yes

If so, provide the approval number, investigator name, and date of the original study.

4. WILL SUBJECT'S NAME OR OTHER IDENTIFIERS POTENTIALLY ENABLING AN INDIVIDUAL'S IDENTITY BE REQUIRED No Yes

↓
FULLY DESCRIBE
PROCEDURES TO BE
← USED TO ENSURE
SUBJECTS ANONYMITY

5. CHECK THE APPROPRIATE BOX FOR EACH OF THE FOLLOWING QUESTIONS:

IF THE ANSWER TO ANY ITEM IN #5 IS "YES", THEN THE RESEARCH IS NOT APPROPRIATE FOR EXEMPT STATUS. PLEASE FOLLOW THE PROCEDURES FOR "NON-EXEMPT, NON-EXPEDITED" RESEARCH.

	No	Yes
a. Does the research involve minors?		
b. Does the research involve fetuses, pregnant women, or in-vitro fertilization?		
c. Does the research involve any dependent populations (e.g., prisoners)?		
d. Will participants be subject to any physical or psychological stress beyond that associated with normal social interactions and discourse?		
e. Will participants be subject to more than minimal physical or psychological risk?		
f. Will participants be tested or observed without their knowledge or consent?		
g. Will participants be deceived or misinformed in any way?		

Attach complete copies of any instruments (e.g., questionnaires, interviews) and stimuli that will be used with participants. The researcher has attached this information as Attachment _____.

Attach complete copies of information to be distributed to subjects regarding the purpose of the study, description of risk(s), procedures by which participants may contact investigators with questions and gain access to findings. The researcher has attached this information as Attachment _____.

Include a copy of the actual consent form(s) to be used when obtaining participants' agreement to participate (and allow audio or videotaping). The researcher has attached this information as Attachment _____.

NOTE: If tacit or implicit consent is to be used, please describe the procedures and provide documentation indicating how subjects will be apprised. The researcher has attached this information as Attachment _____.

ATTACHMENT 1C
Children's Board of Hillsborough County – Ethics Review Committee

Part A. Full Research Protocol Form

1. Expected dates of the study, beginning _____ and ending _____.
2. Expected duration of the study for each individual participant: _____.
3. Participant Information:
 - a) Type of participants to be studied (i.e., children, sexual offenders, adolescent dropouts) _____
 - b) Estimated number of participants: _____
 - c) Age range: _____ years to _____ years
 - d) Is selection of participants based on gender: ____yes ____no
If yes; check one: ____males ____females
If yes, reason for selection:
_____ only the gender selected has the condition
_____ other, please specify:
 - e) Is the selection of participants based on a racial/ethnic basis? ____yes ____no

List which race(s) will be entered into study.

Reason for selection.

- f) If participants are pregnant, explain why it is essential to use these individuals:

N/A

g) If participants are impaired, explain why it is essential to use these individuals.

N/A

h) Describe the dominant relationship between investigator(s) and participants.

4. Compensation to Research Participant:

a) Monetary: ____yes ____no, Amount \$ _____

b) Reimbursement of expenses: ____yes ____no

c) If appropriate, could monetary compensation unduly influence a participant to participate or remain in this study when otherwise might not? If yes, explain.

5. Location of study:

6. Who will request the participation in this study? [Please note that if the ERC determines that participants will be placed at more than original risk, informed consent/assent must be obtained directly by investigators with the research.].

7. Who will provide informed consent/assent (i.e., participant's parent, teacher, investigation, etc.)?

13. Describe how risks to subjects are minimized.

14. Describe how risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

15. Describe why selection of subjects is equitable.

16. IF APPROPRIATE, DESCRIBE HOW THE RESEARCH PLAN MAKES ADEQUATE PROVISION FOR MONITORING THE DATA COLLECTED TO ENSURE THE SAFETY OF SUBJECTS.

17. IF APPROPRIATE, DESCRIBE ADEQUATE PROVISIONS TO PROTECT THE PRIVACY OF SUBJECTS AND TO MAINTAIN THE CONFIDENTIALITY OF DATA.

18. WHEN SOME OR ALL OF THE SUBJECTS ARE LIKELY TO BE VULNERABLE TO COERCION OR UNDUE INFLUENCE, SUCH AS CHILDREN, PRISONERS, PREGNANT WOMEN, MENTALLY DISABLED PERSONS, OR ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED PERSONS, DESCRIBE ADDITIONAL SAFEGUARDS THAT HAVE BEEN INCLUDED IN THE STUDY TO PROTECT THE RIGHTS AND WELFARE OF THESE SUBJECTS.

19. IF THE RESEARCH INVOLVES CHILDREN:

- a) Is this research not involving greater than minimal risk? 45 CFR 46.404

_____ Yes

_____ No

- b) Is this research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects? 45 CFR 46.405

_____ Yes

_____ No

- c) Is this research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition? 45 CFR 46.406

_____ Yes

_____ No

- d) Is this research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children? 45 CFR 46.407

_____ Yes

_____ No

- e) Is this research requiring permission by parents or guardians and assent by children? 45 CFR 46.408

_____ Yes

_____ No

20. DESCRIBE AND EXPLAIN ANY "YES" ANSWER IN THE PREVIOUS QUESTION.

21. ATTACH ALL CONSENT FORMS TO BE USED IN YOUR STUDY AS ATTACHMENT 2. Valid informed consent requires the **disclosure** of relevant information to prospective subjects about the research and should be complete and clearly written. Investigators should ensure that the information is understandable to research subjects (refer to Attachment 2; NIH Guidelines for Writing Informed Consent Documents, 3. Suggestions for Writing Informed Consent Documents, Revised 11/20/2006, <http://www.nihtraining.com/ohsrsite/info/sheet6.html>).

[Note: For questions regarding informed consent guidelines, investigators should consult Ethical Principles in the Conduct of Research with Human Participants (published by the American Psychological Association) and the guidelines set forth by the Society for Research in Child Development.]

The Informed Consent Form should include the following elements:

- **Project Title**
- **Introduction:** Explain the purpose of the research.

Sample text:

I am John Jones, Professor at the Department of Psychology at the University of Florida. My graduate student, Ann Smith, and I are conducting research. This purpose of the research is to study how medical professionals relate to patients. We would appreciate your participation in this research, as it will assist us in making recommendations for improving the teaching of health professionals and the way they treat you.

- **Explanation of Procedures:** Give a full explanation of your procedures including the following:
 1. The number of questionnaires, surveys, etc., that you want them to complete for your study
 2. The total amount of time it will take to complete each questionnaire, survey, etc.
 3. The total amount of participation time required of the participants
 4. The duration of the project
 5. The identification of any experimental procedures
 6. The approximate number of participants in the study

- **Alternative Procedures**

Sample text:

Although we could study this question by just interviewing our doctor and the office staff, we feel that speaking with patients is the best way to find out if they are receiving good medical treatment. //or// There were no alternatives to studying subjects in this manner (with explanation).

- **Risks and Discomforts**
 1. List any foreseeable risk or discomforts such as inconvenience of time requirements, anxiety regarding sensitive questions, or additional costs that the subject may incur as a result of participation.
 2. List where medical treatment is available for the subject if he/she is susceptible to injury, illness, or distress as a result of participation in your study. If medical treatments are available, describe what the medical treatment consists of, or where further information may be obtained.

- **Benefits: Give a full explanation of the risks and benefits of the study, including the following:**
 1. List any benefits to the subjects or others resulting from this study. This includes compensation. If you will compensate your subjects, indicate the type of compensation, the amount of the compensation, when the subject will receive the compensation, and whether the participant will still receive the compensation if they withdraw from the study.

- **Safeguards: Give a full explanation of the safeguards you will use to protect the identity of your subjects:**
 1. State whether your subjects will be identifiable directly or indirectly through identifiable information linked to the subjects. State how you will link the subjects' to their data. If the data collected has no identifying information to link a subject to his/her data, the data is anonymous. If the investigator will not share subjects' data with anyone except in the aggregate form, the data is confidential.
 2. List the agencies or groups to whom you will release the data you obtain from your subjects.
 3. State that the published data will be in aggregate form (if applicable).

- **Confidentiality: Describe the extent, if any, to which confidentiality of records identifying the subject will be maintained.**

- **Participation is Voluntary and Freedom to Withdraw:** This section should indicate the following:
 1. State that the participation is completely voluntary and that the subjects may withdraw from the study at any time and for any reason without penalty.
 2. State that participation or decision not to participate will not affect treatment or involve penalty or loss of benefits to which the subject is otherwise entitled (i.e., at a clinic, hospital, organization, etc.). State what you will do with the information that you have gathered from that subject if a subject withdraws.
 3. Give an explanation about the circumstances under which you might terminate the subject's participation without regard to the subject's consent (if appropriate).

- **Offer to Answer Inquiries:** (sample text)

Once the study is completed, we would be glad to give the results to you. In the meantime, if you have any questions, please ask us or contact:

The Children's Board of Hillsborough County
Ethics Review Committee
1002 East Palm Avenue
Tampa, Florida 33605-3550
(813)204-1797

- **Third Party Referral:** You must include the following information in every Informed Consent Form:

1. If you have any complaints about your treatment as a participant in this study, please call or write:
2. Although (_____), will ask your name, all complaints are kept in confidence.

- **Closing:** You must insert the following two paragraphs and a signature/date line* (if you are conducting survey research, omit the signature line in order to avoid linkage to the subjects.)

I have received an explanation of this study and agree to participate. I understand that my participation in this study is strictly voluntary.

Name

Date

This research project has been approved by the Children's Board of Hillsborough County Ethics Review Committee for the Protection of Human Subjects for a one year period.

* If your subjects are minors, you should obtain informed consent from the parents of the subject and insert a second signature line for the minor subjects' assent.

For a sample of Informed Consent Forms refer to Attachment 2.

ATTACHMENT 3

RESPONSIBILITIES OF INVESTIGATORS

The Principal Investigator is responsible for assuring that research is carried out safely, effectively, and in accordance with the rules and regulations of the Ethics Review Committee (ERC). Please read the following responsibilities, fill in the information requested, and return to the ERC with a copy of your resume or curriculum vitae.

ERC REVIEW

A review is required for all research involving human subjects. After an application is filed with the CBHC ERC, it will be disposed in one of several routes. Recommendations by the ERC Chairperson or subcommittee will be brought to a vote by the full committee at the next scheduled meeting. The routes are as follows:

1. Protocols which pose no risk to the subjects may be determined by the co-Chairpersons to be exempt from further review, according to the categories published in the Federal Register 1991. Informed consent is not required.
2. Protocols that pose no more than minimal risk to the subjects may be approved by the Chairperson under expedited review, according to the categories published in the Federal Register 1991. Informed consent is required and a minimal risk consent is available.
3. Protocols which pose more than minimal risk to the subjects will be given full review at the next scheduled meeting.
4. Therapies which provide emergency experimental medical care are exempt from prior ERC review; "in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain ERC approval." Informed consent must be obtained, and FDA guidelines for obtaining informed consent and documenting need for emergency treatment are available through the ERC. The ERC would prefer prior notification of emergency experimental treatment in order to aid with the process, but, by FDA Regulations, treatment must be reported to the ERC within five (5) working days of the occurrence. The Exemption is for one emergency use of a test article; further use must be approved by the ERC after full review. The ERC is required to report to the FDA any Investigator who fails to comply with these regulations.

Applications

Applications must be completed in full, preferably in the Investigators' own words. Incomplete applications will be sent back. The hypothesis should be a statement that the research will prove true or false.

Protocols

Protocols must explain the research in detail. Study design must minimize risk to subjects. References should be properly noted. Any payment of participants should accrue as the study progresses and not be contingent on completion of the study.

Drugs

Drugs used in the protocol must be stored and dispensed from a regulated pharmacy, by a pharmacist.

Informed Consents

Informed consents should be easily understood by a reader with an 8th grade education (or lower depending on age) and may not contain coercive or exculpatory language. Write the text as if you were giving an oral explanation directly to the subject. Requirements of an Informal consent are:

- Informed consent is required of children > 12 years of age. A child's assent is required of children 7-12 years of age. Assent is not required of children < 7 years of age. Exceptions may be made for intellectually impaired individuals.
- The information and informed consent must be given to the subject in language understandable to the subject or the subject's representative.
- A pregnancy statement should be included in the informed consent when females of childbearing age are included and there is any foreseeable risk to the fetus.
- Include the name and phone number of a person to contact for questions. Mark the informed consent document with the date the ERC approval will expire (usually one year from date on approval letter).

Any investigator must obtain Informed Consent from all participants. Informed consent can be obtained by the Principle Investigator or Co-Investigators only. Co-Investigators must be fully knowledgeable about details of the study. Each participant must be given a copy of the informed consent document. The original or a copy of the signed informed consent must be kept in a secure file.

Change in Research

Report any requested changes in the research to the ERC in writing thirty (30) days prior to any change.

Adverse Events

Report any on-site adverse participant response to the ERC Committee within five (5) days. For offsite adverse events, please report these events within ten (10) days.

Continuing Review

Renew protocol yearly. Renewal applications should report available results of the research and reassess the risk /benefit ratio of the study. Failure to complete renewal application in time will result in withdrawal of ERC approval for the study.

Final Reports

Once a study has been closed, a final report must be submitted to the ERC with all pertinent closing data. If data analysis is not complete from the sponsor, once it has been finished, a copy must be forwarded to the ERC for the protocol file.

Keep all records, protocols, including informed consents, for at least three (3) years, so that they would be available for review if necessary. Audits will be conducted to insure that your files are kept in a proper and compliant manner.

I hereby acknowledge that I have received and read "The Responsibilities of the Investigator," as well as the "Belmont Report" [Part 1 herein, Statement of Principles].

Signature of Investigator

Printed Name of Investigator

Date

Address

Department

Phone/Fax Number

Ethics Review Committee (ERC)/ERC Protocol Packet

ATTACHMENT 4

RESUMES OF PRINCIPAL INVESTIGATORS

[Insert resumes here.]

APPENDICES

1 NIH OHSR Information Sheet 6 Guidelines for Writing Informed Consent Documents

2 Samples of Informed Consent Documents

USF Informed Consent to Participate in Research (English & Spanish)

USF Informed Consent to Participate in Research/Telephone Interviews (English & Spanish)

FDJJ (1999)

CBHC Caring for the Youngest Among Us Informed Consent Document

ELLM Permission Slip for Child's Participation in Evaluation/Research Study

ELLM Permission Slip for Photographs or Videotapes of Child

APPENDIX # 1

NATIONAL INSTITUTE OF HEALTH OHSR INFORMATION SHEETS

Sheet 6 — GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS

National Institute of Health (NIH)

OHSR Information Sheets/Forms

Sheet 6 — GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS

1. INTRODUCTION

The ethical principle of respect for persons requires that subjects be given the opportunity to choose what shall and shall not happen to them. Valid informed consent requires:

1. **Disclosure** of relevant information to prospective subjects about the research;
2. their **comprehension** of the information, and
3. their **voluntary agreement**, free of coercion and undue influence, to research participation.

The process of informed decision-making by research subjects generally includes discussion of the research study with the Principal Investigator (PI), and others as appropriate, and signing the written informed consent document. Depending on the nature, type and duration of the research, ongoing discussion with and education of subjects about the study may continue long after the informed consent document is signed.

A goal of the NIH is to assure that all written informed consent documents are complete and clearly written so as to promote informed decision-making by subjects participating in its research activities. This information sheet provides guidance to NIH clinical researchers and IRBs on the procedures and requirements for informed consent to research participation and the content and format of written consent documents.

2. REQUIREMENTS FOR INFORMED CONSENT

A. General Procedures

Unless otherwise waived by the IRB, NIH research investigators should obtain valid informed consent from all research subjects (or their legally authorized representatives) who participate in their research studies. Generally, after the Principal Investigator has explained the research study to the subject, the subject's informed consent is documented by signing the protocol's written consent document, which an IRB must have previously reviewed and approved. The NIH consent document form **NIH-2514-1** (Consent to Participate in a Clinical Research Study), obtainable from IRB Protocol Administrators, is used for all subjects enrolled in research conducted at the Clinical Center. Form **NIH-2514-1** is also available from the Clinical Center's Protocol Coordination Service Center (301-496-0744).

The subject is given a copy of the signed document, and, when the research is conducted in the Clinical Center, the Principal Investigator ensures that the original signed consent document is filed in the subject's permanent medical record maintained by the Clinical Center's Medical Record Department. In cases where subject accrual occurs elsewhere,

signed consent documents are retained according to the policies of the institution where the research is conducted.

B. General Principles

Unless otherwise authorized by an IRB, research investigators are responsible for ensuring that informed consent shall:

- be obtained in writing from the subject or the subject's legally authorized representative;
- be understandable to the subject or her/his representative. Suggestions for writing consent documents are provided in 3., below.
- be obtained in circumstances that are not coercive and that offer the subject (or her/his representative) sufficient opportunity to decide whether she/he should participate. The consent document should not contain language that implies or suggests that the subject (or her/his
- representative) gives up any legal rights or releases research investigators or the NIH from liability for negligence.

C. Basic Elements for Written Informed Consent Documents

Unless otherwise authorized by an IRB, research investigators must provide the following information to each subject in writing:

The basic elements which have an asterisk (*) are incorporated in existing language printed on form NIH-2514-1 (Consent to Participate in a Clinical Research Study). Nevertheless, to enhance comprehension and readability, investigators are strongly urged to use a format in the body of the consent form that presents information in sections, introduced by headings, and that clearly and simply identifies and describes each of the elements to be discussed, even if the sections repeat information that appears on the printed form. For an example of an effective way to use headings, see 4. below.

- A statement that the study involves research;*
- An explanation of the purpose of the research and the expected duration of the subject's participation;
- A description of the procedures to be followed and identification of any procedures that are experimental;
- A description of any foreseeable risks or discomforts to the subject, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them;
- A description of any benefits to the subject or to others that may reasonably be expected from the research. Monetary compensation is not a benefit. If compensation is to be provided to research subjects or healthy volunteers, the amount should be stated in the consent document;
- A disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject;

- A statement describing to what extent records will be kept confidential, including a description of who may have access to research records;*
- For research involving more than minimal risk, an explanation and description of any compensation and any medical treatments that are available if research subjects are injured; where further information may be obtained, and whom to contact in the event of a research-related injury;*
- An explanation of whom to contact for answers to pertinent questions about the research and the research subject's rights (include the Clinical Center's Patient Representative and telephone number);* and
- A statement that participation is voluntary and that refusal to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled.*

D. Additional Elements

When appropriate, and required by the IRB, one or more of the following elements of information will also be provided to each research subject:

- If the subject is or may become pregnant, a statement that the particular treatment or procedure may involve risks, which are currently unforeseeable, to the subject or to the embryo or fetus;
- A description of circumstances in which the subject's participation may be terminated by the investigator without the subject's consent;
- Any costs to the subject that may result from participation in the research;
- What will happen if the subject decides to withdraw from the research and how withdrawal will be handled;
- A statement that the Principal Investigator will notify subjects of any significant new findings developed during the course of the study that may affect them and influence their willingness to continue participation;
- The approximate number of subjects involved in the study;
- The amount of remuneration/compensation, if any, that will be provided to subjects. See Information Sheet #20 "Information on Remuneration of Research Subjects in the Intramural Research Program."
- When appropriate, a statement concerning an investigator's potential financial or other conflict of interest in the conduct of the study.

E. Waiver or Alteration of the Required Elements of Informed Consent

In certain circumstances prescribed by the Federal Regulations (45 CFR 46.116(d)), an IRB may waive the requirement to obtain informed consent, or may approve a consent process which does not include or alters some or all of the elements in (c) above. For more information, see the NIH Standard Operating Procedures for IRBs.

3. SUGGESTIONS FOR WRITING INFORMED CONSENT DOCUMENTS

When an investigator writes or reviews a research consent document, she/he should ask the following questions:

Question 1: Is it written at a reading level understandable to research subjects?

- A general rule of thumb is that consent documents should be written so that they are understandable to people who have not graduated from high school. The reading level of a document is more difficult if it contains long sentences, words with more than two syllables, and continuous run-on text.
- Therefore, if possible use words with fewer than three syllables; use non-scientific/non-medical words; use short sentences, and break the text up into short sections.

Question 2: Is the document formatted well? Does it have headings which break the text into short sections?

Question 3: Does the document contain the basic elements for informed consent and are they presented in a clear, easy-to-understand way? Even though the printed NIH consent form incorporates some of the elements of consent, depending on the particular research study, it may be useful to include the information a second time but in a simpler form.

Question 4: Can the document be shortened without compromising clarity or other requirements?

Usually, before a person agrees to take part in a research study, he/she not only reads a written consent document but also discusses the study with a researcher. A suggestion when writing consent documents is to assume that prospective subjects will not talk to a researcher (or research nurse) at all about the study, and that all their information will come entirely from the consent document. If this approach is used the document is more likely to be clear, complete, devoid of medical/scientific terminology and able to “stand alone.”

4. THE USE OF HEADINGS TO FORMAT INFORMED CONSENT DOCUMENTS

The use of headings in informed consent documents helps to ensure that all the basic elements of informed consent are conveyed to the prospective research subject in a simple, efficient way. Headings promote comprehension and readability. The number, order, and language of headings are left to the author of the informed consent document with the approval of the IRB. The following headings are included in the Clinical Center consent writing module of Prototype.

0. Introduction:

Use the CC standard language which is part of the consent form template; starting with “We invite you . . .” and ending with “. . . personal physician or other health professional.”

1. Why is this research being done?
2. Why are you being invited to participate?
3. How many people will take part in this research study?
4. How long will you take part in this research study?
5. What do we do to decide if you are eligible for this research study?
6. What procedures, drugs or other treatments are involved in this research study?
7. What are the risks and discomforts of this research study?
8. Are there any benefits to you if you take part in this research study?
9. What other choices do you have?
10. Are there reasons that your research participation may end early?
11. What will happen when the research study is over?
12. Will your clinical and other test results be shared with you?
13. Will the results of this research study be shared with you?
14. Will any of your blood, tissue or other samples be stored and used for research in the future?
15. Will you receive any compensation (money or other) for taking part in this Research study?

The following CC minimum language is part of the consent template and must be used: “In general, patients are not paid for taking part in research studies at the NIH. The amount paid to research volunteers is guided by National Institutes of Health policies.”

Add appropriate language if compensation is to be paid, including the amount of compensation.

16. Do any of the researchers or the NIH have a financial interest related to this research study?

17. What privacy and confidentiality procedures apply to the information gathered about you in this study?

The following CC standard minimum language is part of the consent template and must be used: “When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical records. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance. The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical records without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or other authorized people.”

18. What is the NIH's policy regarding research-related injuries?

The following standard CC minimum language is part of the consent template and must be used: “The Clinical Center of the NIH will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.”

19. Who can answer your questions about the research and your rights as a research subject?

The following standard CC minimum language is part of the consent template and must be used: “If you have any problems or questions about this study, about your rights as a research participant, or about any research-related injury, contact the Principal Investigator of this study INSERT at telephone number INSERT. His/her address is INSERT. Another researcher you may call is: INSERT., telephone INSERT.”

You may also call the Clinical Center Patient Representative at 301-496-2626.

Revised: 12/28/06

Sample Informed Consent Forms

SAMPLE CONSENT FORM

(Substitute your own form in place of this page)

Please include:

1. A brief description of what participation involves, including the nature of the tasks.
2. An assertion that participation is voluntary and that participants may withdraw participation at any time without loss of credit or monetary remuneration.
3. An offer to answer any questions participants have.
4. An assertion that confidentiality will be maintained, and how that will be guaranteed.
5. Information clearly identifying the Study and the Researcher(s)' (and Faculty Sponsor's where appropriate) name(s), affiliation(s), and contact information (i.e., address and phone where informational inquiries may be directed).

Please provide participants with a copy of the consent form.

STUDY NAME
RESEARCHERS NAME & AFFILIATION

Brief description and info detailed in item 1-5 above.

I understand the basic procedure of this study, and am aware that I may discontinue participation at any time. I hereby give my consent to participate.

Participant's Signature

Date

I have personally discussed the research procedure, and any possible risk, with the above named individual. I am satisfied that she/he understands the information provided.

Researcher's Signature

Date

SAMPLE TAPE CONSENT FORM

Instructions: modify portions or substitute your own form in place of this page, but subjects must give permission for each type of usage. In addition, subjects must be given the option of erasing the tape upon conclusion of the interview, task, etc. Permissions should also be time-bound and specify an expiration whereby the tape will be destroyed.

CONSENT TO AUDIO – OR VIDEO – TAPING & TRANSCRIPTION

STUDY NAME **RESEARCHERS NAME & AFFILIATION**

I understand that this study involves the audio taping (videotaping) of my interview with the researcher. Neither my name nor any other identifying information will be associated with the audiotape (videotape) or the transcript. Only the researcher(s) will be permitted to listen (view) to the tapes.

I understand that the tapes will be transcribed by the researcher and erased once the transcriptions are checked for accuracy. Transcripts of my interview may be reproduced in whole or in part for use in presentations or written products that result from this study. Neither my name nor any other identifying information (such as my voice or picture) will be used in presentations or in written products resulting from the study.

I further understand that immediately following the interview I will be given the opportunity to have the tape erased.

Please check one of each pair of options.

- A. _____ I consent to have my interview taped.
 _____ I do not consent to have my interview taped.
- B. _____ I consent to have my taped interview transcribed into written form.
 _____ I do not consent to have my taped interview transcribed.
- C. _____ I consent to the use of the written transcription in presentations and written products
 resulting from the study, provided that neither my name nor other identifying information
 will be associated with the transcript.
 _____ I do not consent to the use of my written transcription in presentations or written products
 resulting from the study.

The above permissions are in effect until _____. On or before that date, the tapes will be destroyed.

Participant's Signature

Date

I hereby agree to abide by the participant's above instructions.

Investigator's Signature

Date

APPENDIX # 2

SAMPLES OF INFORMED CONSENT DOCUMENTS



Informed Consent to Participate in Research

Information to Consider Before Taking Part in this Research Study

Researchers at the University of South Florida (USF) study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study.

We are asking you to take part in a research study that is called:

Developing Sustainable Infrastructure in Support of Quality Field-Based Practice

The person who is in charge of this research study is Sharon Hodges, Ph.D.

Other research personnel who you may be involved will include: Kathleen Ferreira, M.S.E., Frances Wallace, M.P.H., Melissa Van Dyke, M.S.W., Bobbie Vaughn, Ph.D., Mario Hernandez, Ph.D., Karen Blase, Ph.D. Jessica Mazza, B.A., Richard Briscoe, Ph.D., Debra Mowery, Ph.D., David Acevedo, M.S., Teresa Nesman, Ph.D., Linda Callejas, M.A., Amina Mahmood, B.A., Maria Dalal Safa, B.A., Janis Prince Inniss, Ph.D.

The research will be done at Family and School Support Teams (FASST) and the Children’s Board of Hillsborough County.

This research is being paid for by The Children’s Board of Hillsborough County.

Purpose of the study

The purpose of this project is to study the work that the FASST program does. We will look at services they provide and how they put these services in place. We will study how these practices are the same or different from current literature in children’s mental health. We will also look at how the FASST program fits into the bigger service system for children with mental health needs.

Study Procedures

If you take part in this study, you will be asked to participate in a semi-structured Interview related to the implementation of the FASST program. The interview will take no longer than 1 hour and will occur in 1 or 2 visits. The research will be done at the Children’s Board of Hillsborough County and FASST offices and will be conducted between April, 2007 and March, 2009.

The interviews may be audio recorded with your permission. No audio recording will be conducted without your consent.

Do you agree to have these interviews audio recorded? Yes No

Alternatives

You have the alternative to choose not to participate in this research study.

Benefits

The potential benefits to you are that the overall results of this project will be used to develop strategies that support, improve, and sustain best practice in local programs.

Risks or Discomfort

There are no known risks to those who take part in this study.

Compensation

We will not pay you for the time you volunteer while being in this study

Confidentiality

We must keep your study records confidential. Your privacy and research records will be kept confidential to the extent of the law. You will not be identified by name in any reports or publications that result from this study. Audio tapes, transcripts, field notes and analysis records will be stored in a locked room when not in use. They will be used throughout the duration of the study (2 years) and will be destroyed 5 years after completion of the study.

However, certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety. These include:
 - the University of South Florida Institutional Review Board (IRB) and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
 - the Florida Department of Health and people from the Department of Health and Human Services (DHHS).

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study, to please the investigator or the research staff. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

Questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, call *Sharon Hodges, Principal Investigator* or *Kathleen Ferreira, Co-Principal Investigator* at 813-974-4651

If you have questions about your rights, general questions, complaints, or issues as a person taking part in this study, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-9343.

If you experience an adverse event or unanticipated problem call *Sharon Hodges, Principal Investigator* or *Kathleen Ferreira, Co-Principal Investigator* at 813-974-4651.

Consent to Take Part in this Research Study

It is up to you to decide whether you want to take part in this study. If you want to take part, please sign the form, if the following statements are true.

I freely give my consent to take part in this study. I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

Signature of Person Taking Part in Study

Date

Printed Name of Person Taking Part in Study

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.

This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

This person is not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

Signature of Person Obtaining Informed Consent

Date

Printed Name of Person Obtaining Informed Consent

IRB Number: _____
IRB Adult Minimal Risk ICF Template Version: 2006-12-1

IRB Consent Rev. Date: _____
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Consentimiento Informado

Universidad del Sur de la Florida

Información para Considerar Antes de Participar en este Estudio de Investigación

La siguiente información está siendo presentada para ayudarle a decidir si usted quiere participar en un estudio de investigación de riesgo mínimo. Por favor lea esta forma con cuidado. Si hay algo que usted no entiende, pregunte a la persona responsable del estudio.

Título del Estudio: Desarrollando Infraestructura Sostenible en apoyo de la Calidad de la Práctica.

Investigador Principal: Sharon Hodges, Ph.D.

Co-investigadores: Kathleen Ferreira, M.S.E., Frances Wallace, M.P.H., Melissa Van Dyke, M.S.W., Bobbie Vaughn, Ph.D., Mario Hernandez, Ph.D., Karen Blase, Ph.D. Jessica Mazza, B.A., Richard Briscoe, Ph.D., Debra Mowery, Ph.D., David Acevedo, M.S., Teresa Nesman, Ph.D., Linda Callejas, M.A., Amina Mahmood, B.A., Maria Dalal Safa, B.A., Janis Prince Inniss, Ph.D.

Lugar (es) del Estudio: El Programa de Familia y Equipos de Apoyo Escolares (FASST) y La Junta de Niños del Condado de Hillsborough.

Le piden participar porque usted esta involucrado en el proceso de la entrega de servicios a niños en riesgo de trastornos emocionales o desafíos de comportamiento.

Información General sobre el Estudio de Investigación

El objetivo de este estudio de investigación es el de investigar la intervención vigente y los componentes de implementación del programa FASST, y vincular estos componentes a la base de literatura existente, para proporcionar evidencia y reforzar el programa FASST corriente y para analizar la implementación del Programa FASST dentro de un sistema de infraestructura más amplio; y documentar el proceso, los resultados, y las lecciones aprendidas en la creación de pautas de desarrollo del programa e instrumentos para asistir al Children's Board (La Junta de Niños del Condad Hillsborough) en sus esfuerzos a desarrollar prácticas basadas en investigación dentro de un marco que mantendrá la fidelidad.

El número de personas que podrían participar en este estudio es: 50

Plan de Estudio

Le pedirán participar en una entrevista informal relacionada con la implementación del programa FASST. Las entrevistas no duraran más de 1 hora.

Las entrevistas pueden ser grabadas, con su permiso. Ninguna grabación será conducida sin su consentimiento.

¿Acepta usted que estas entrevistas sean grabadas? Si No

Es esperado que los resultados totales de este proyecto sean usados para desarrollar estrategias que apoyan, mejoran, y sostienen la mejor práctica en programas locales.

Beneficios por participar de este Estudio de Investigación

No le pagarán por su participación en la evaluación de este proyecto.

Riesgos de participar de este Estudio de Investigación

No hay ningunos riesgos conocidos implicados.

Confidencialidad de sus Archivos

Su privacidad y archivos de entrevistas serán guardados de manera confidencial como lo indica la ley. Usted no será identificado por su nombre en ningún informe o publicaciones que resulten de este estudio. Las cintas de audio, las transcripciones, las notas de trabajo y los archivos de análisis serán almacenados en un cuarto cerrado con llave cuando no estén en uso. El acceso a los datos de investigación será restringido al equipo de investigación en el Instituto de Salud Mental de la Florida Louis de la Parte. El personal de investigación autorizado, los agentes del Departamento de Salud y Servicios Humanos, el Comité Institucional Examinador de USF y su personal, y cualquier otro individuo que actúa de parte de USF pueden inspeccionar los archivos de este proyecto de investigación. Sin embargo, se espera que informes y artículos sean generados sobre la base de estos datos de investigación, usted será identificado sólo por su papel dentro de la organización, no por su nombre.

Ofrecerse para ser parte de este Estudio de Investigación

Su decisión de participar en este estudio de investigación es completamente voluntaria. Usted es libre de participar en este estudio de investigación o retirarse en cualquier momento. Si usted decide no participar, o si usted se retira, no habrá ninguna penalidad o pérdida de beneficios que usted tiene derecho a recibir.

Preguntas y Contactos

- Si usted tiene cualquier pregunta sobre este estudio de investigación, *llame a Sharon Hodges, Investigador Principal o a Kathleen Ferreira, Investigador Co-Principal, al teléfono numero 813-974-4651*
- Si usted tiene preguntas sobre sus derechos como una persona que participa en un estudio de investigación, usted puede ponerse en contacto con la División de Integridad de Investigación y Conformidad de la Universidad del Sur de la Florida en el teléfono numero (813) 974-9343.

Consentimiento de participar en este Estudio de Investigación

Firmando esta forma estoy de acuerdo que:

- He leído totalmente o he leído y me han explicado esta forma de consentimiento informado que describe este proyecto de investigación.
- He tenido la oportunidad de preguntar a una de las personas responsables de esta investigación y he recibido respuestas satisfactorias.
- Yo entiendo que me han pedido participar en una investigación. Entiendo los riesgos y las ventajas, y libremente doy mi consentimiento de participar en el proyecto de investigación detallado en esta forma, en las condiciones indicadas en ella.
- Me han dado una copia firmada de esta forma de consentimiento informado, que es la mía para conservar.

Firma de Participante

Nombre Impreso Participante

Fecha

Declaración del Investigador

He explicado con cuidado a la persona la naturaleza del susodicho estudio de investigación. Por este medio certifico que, por mi mejor conocimiento, la persona que firma esta forma de consentimiento entiende la naturaleza, demandas, riesgos, y beneficios implicados en la participación en este estudio. También certifico que un número de teléfono ha sido proporcionado en caso de preguntas adicionales.

Firma del Investigador
o investigador autorizado para
la investigación designado por
el Investigador Principal

Nombre Impreso Investigador

Fecha



**Informed Consent to Participate in Research
Information to Consider Before Taking Part in this Research Study**

(Telephone Interviews)

[Every effort will be made to fax or mail this consent in advance of the interview]

The following information is being presented to help you decide whether or not you want to take part in a minimal risk research study. Please listen carefully as I read this consent to you. If you do not understand something, please ask for clarification.

Researchers at the University of South Florida (USF) study many topics. To do this, we need the help of people who agree to take part in a research study. This form tells you about this research study.

We are asking you to take part in a research study that is called:

Developing Sustainable Infrastructure in Support of Quality Field-Based Practice

The person who is in charge of this research study is Sharon Hodges, Ph.D. Other research personnel who you may be involved will include: Kathleen Ferreira, M.S.E., Frances Wallace, M.P.H., Melissa Van Dyke, M.S.W., Bobbie Vaughn, Ph.D., Mario Hernandez, Ph.D., Karen Blase, Ph.D. Jessica Mazza, B.A., Richard Briscoe, Ph.D., Debra Mowery, Ph.D., David Acevedo, M.S., Teresa Nesman, Ph.D., Linda Callejas, M.A., Amina Mahmood, B.A., Maria Dalal Safa, B.A., Janis Prince Inniss, Ph.D.

The research will be done at Family and School Support Teams (FASST) and the Children's Board of Hillsborough County.

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Study Procedures

If you take part in this study, you will be asked to participate in a semi-structured Interview related to the implementation of the FASST program. The interview will take no longer than 1 hour and will occur in 1 or 2 visits. The research will be done at the Children's Board of Hillsborough County and FASST offices and will be conducted between April, 2007 and March, 2009.

The interviews may be audio recorded with your permission. No audio recording will be conducted without your consent.

Do you agree to have these interviews audio recorded? Yes No

Alternatives

You have the alternative to choose not to participate in this research study.

Benefits

The potential benefits to you are that the overall results of this project will be used to develop strategies that support, improve, and sustain best practice in local programs.

Risks or Discomfort

There are no known risks to those who take part in this study.

Compensation

We will not pay you for the time you volunteer while being in this study

Confidentiality

We must keep your study records confidential. Your privacy and research records will be kept confidential to the extent of the law. You will not be identified by name in any reports or publications that result from this study. Audio tapes, transcripts, field notes and analysis records will be stored in a locked room when not in use. They will be used throughout the duration of the study (2 years) and will be destroyed 5 years after completion of the study. However, certain people may need to see your study records. By law, anyone who looks at your records must keep them completely confidential. The only people who will be allowed to see these records are:

- The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff.
- Certain government and university people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety. These include:
 - the University of South Florida Institutional Review Board (IRB) and the staff that work for the IRB. Other individuals who work for USF that provide other kinds of oversight may also need to look at your records.
 - the Florida Department of Health and people from the Department of Health and Human Services (DHHS).

We may publish what we learn from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Voluntary Participation / Withdrawal

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study, to please the investigator or the research staff. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study.

Questions, concerns, or complaints

If you have any questions, concerns or complaints about this study, call *Sharon Hodges, Principal Investigator or Kathleen Ferreira, Co-Principal Investigator at 813-974-4651.*

If you have questions about your rights, general questions, complaints, or issues as a person taking part in this study, call the Division of Research Integrity and Compliance of the University of South Florida at (813) 974-9343.

If you experience an adverse event or unanticipated problem call *Sharon Hodges, Principal Investigator or Kathleen Ferreira, Co-Principal Investigator at 813-974-4651.*

Questions:

- Do you have any questions at this time?

Consent to Take Part in this Research Study

It is up to you to decide whether you want to take part in this study. If you want to take part, please provide verbal consent.

Verbal Consent:

- Are you willing to participate in this process? Yes No

Statement of Person Obtaining Informed Consent

I have carefully explained to the person taking part in the study what he or she can expect.

I hereby certify that when this person signs this form, to the best of my knowledge, he or she understands:

- What the study is about.
- What procedures/interventions/investigational drugs or devices will be used.
- What the potential benefits might be.
- What the known risks might be.

I also certify that he or she does not have any problems that could make it hard to understand what it means to take part in this research. This person speaks the language that was used to explain this research.

This person reads well enough to understand this form or, if not, this person is able to hear and understand when the form is read to him or her.

This person does not have a medical/psychological problem that would compromise comprehension and therefore makes it hard to understand what is being explained and can, therefore, give informed consent.

This person is not taking drugs that may cloud their judgment or make it hard to understand what is being explained and can, therefore, give informed consent.

Signature of Person Obtaining Informed Consent

Date

Printed Name of Person Obtaining Informed Consent

Consentimiento Informado

Universidad del Sur de la Florida

Información para Considerar Antes de Participar en este Estudio de Investigación

(Entrevistas Telefónicas)

[Todo esfuerzo será hecho para mandar este consentimiento por fax o por correo antes de la entrevista]

La información siguiente está siendo presentada para ayudarle a decidir si usted quiere participar en un estudio de investigación. Por favor escuche con cuidado mientras le leo este consentimiento. Si usted no entiende algo, por favor pida la aclaración.

Los investigadores en la Universidad del Sur de la Florida (USF) estudian muchos temas. Para hacer estos estudios, necesitamos la ayuda de la gente que este de acuerdo en participar en un estudio de investigación. Esta forma le habla sobre este estudio de investigación.

Le pedimos participar en un estudio de investigación que es llamado:

Desarrollando Infraestructura Sostenible en apoyo de la Calidad de la Práctica.

La persona que es responsable de este estudio de investigación es Sharon Hodges, Ph.D.

Otro personal de investigación con quienes usted puede estar implicado incluirá: Kathleen Ferreira, M.S.E., Frances Wallace, M.P.H., Melissa Van Dyke, M.S.W., Bobbie Vaughn, Ph.D., Mario Hernandez, Ph.D., Karen Blase, Ph.D. Jessica Mazza, B.A., Richard Briscoe, Ph.D., Debra Mowery, Ph.D., David Acevedo, M.S., Teresa Nesman, Ph.D., Linda Callejas, M.A., Amina Mahmood, B.A., Maria Dalal Safa, B.A., Janis Prince Inniss, Ph.D.

La investigación será hecha en el programa de Familia y Equipos de Apoyo Escolares (FASST) y el Children's Board (La Junta de Niños del Condado Hillsborough).

Esta investigación está siendo pagada por el Children's Board (La Junta de Niños del Condado Hillsborough).

Objetivo del estudio

El objetivo de este proyecto es estudiar el trabajo que el programa FASST hace. Miraremos servicios que ellos proporcionan y como ellos implementan estos servicios. Estudiaremos como estas prácticas son las mismas o son diferentes de la literatura vigente acerca de la salud mental de los niños. También miraremos como el programa FASST cabe en el sistema más amplio de servicios para niños con necesidades de salud mental.

Procedimientos de Estudio

Si usted participa en este estudio, le pedirán participar en una entrevista semi-estructurada relacionada con la implementación del programa FASST. La entrevista no durara mas de 1 hora y ocurrirá en 1 o 2 visitas. La investigación será hecha en el Children's Board (La Junta de Niños del

Condad Hillsborough) y las oficinas del programa FASST y será conducida entre Abril del 2007 y Marzo del 2009.

Las entrevistas pueden ser grabadas con su permiso. Ninguna grabación será conducida sin su consentimiento.

¿Acepta usted que estas entrevistas sean grabadas? Si No

Alternativas

Usted tiene la alternativa de decidir no participar en este estudio de investigación.

Beneficios

Las ventajas potenciales para usted son que los resultados de este proyecto serán usados para desarrollar estrategias que apoyan, mejoran, y sostienen la mejor práctica en programas locales.

Riesgos o Inconformidad

No hay ningunos riesgos conocidos para aquellos que participan en este estudio.

Compensación

No le pagaremos por participar en este estudio.

Confidencialidad

Tenemos la obligación de guardar sus archivos de estudio de manera confidencial. Su privacidad y archivos de entrevistas serán guardados de manera confidencial como lo indica la ley. Usted no será identificado por su nombre en ningún informe o publicaciones que resulten de este estudio. Las cintas de audio, las transcripciones, las notas de campaña y los archivos de análisis serán almacenados en un cuarto cerrado con llave cuando no estén en uso. Ellos serán usados por el tiempo de duración del estudio (2 años) y serán destruidos 5 años después de la finalización del estudio. Sin embargo, ciertas personas pueden necesitar ver sus archivos de estudio. Según la ley, cualquiera que tenga acceso sus archivos debe guardarlos completamente confidenciales. Las únicas personas que tendrán permiso a ver estos archivos son:

- El grupo de investigación, incluyendo el Investigador Principal, el coordinador del estudio y todo el resto del personal de la investigación.
- Ciertas personas del gobierno y de la universidad que necesitan saber más sobre el estudio. Por ejemplo, los individuos que proporcionan supervisión en este estudio pueden necesitar ver sus archivos. Esto se hace para asegurar que el estudio es hecho del modo correcto. Ellos también tienen que asegurarse que protegemos sus derechos y su seguridad. Éstos incluyen:
 - El Comité Institucional Examinador de la Universidad del Sur de la Florida (IRB) y el personal que trabaja para el IRB. Otros individuos que trabajan para USF que proporcionan otras clases de supervisión también pueden necesitar ver sus archivos.

- El Departamento de Salud de la Florida y el personal del Departamento de Salud y Servicios Humanos (DHHS).

Pudiéramos publicar lo que aprendamos de este estudio. Si lo hacemos, no le dejaremos saber su nombre a nadie. No publicaremos algo que le permita a la gente saber quien es usted.

Participación Voluntaria / Retiro

Usted sólo debería participar en este estudio si usted quiere ofrecerse. Usted no debería sentir que hay alguna presión para participar en el estudio, complacer al investigador o al personal de investigación. Usted es libre de participar en esta investigación o retirarse en cualquier momento. No habrá ninguna penalidad o pérdida de beneficios que usted tiene derecho a recibir si usted deja de participar en este estudio.

Preguntas, preocupaciones, o quejas

Si usted tiene preguntas, preocupaciones o quejas sobre este estudio, llame a *Sharon Hodges, Investigador Principal* o *Kathleen Ferreira, Investigador Co-Principal* al teléfono numero 813-974-4651.

Si usted tiene preguntas sobre sus derechos, preguntas generales, quejas, o asuntos como persona que participa en este estudio, llame a *la División de Integridad de Investigación y Conformidad de la Universidad del Sur de la Florida*, al teléfono numero (813) 974-9343.

Si usted experimenta un acontecimiento adverso o problema inesperado llame a Sharon Hodges, Investigador Principal o Kathleen Ferreira, Investigador Co-Principal al teléfono numero 813-974-4651.

Preguntas:

¿Tiene usted alguna pregunta hasta este momento?

SAMPLE

FLORIDA DEPARTMENT OF JUVENILE JUSTICE

Informed Consent to Participate in Research

You are being invited to participate in a research study. This form is designed to provide you with information about this study. The Principal Investigator or representative will describe this study to you and answer any of your questions. If you have any questions or complaints about the informed consent process or the research study, please contact the Department of Juvenile Justice IRB, the committee that protects research participants, at ...

1. Name of Participant

2. Title of Research Study

3. a. Principal Investigator(s) and Telephone number(s)

- b. Sponsor of the Study (if any)

4. The Purpose of the Research

5. Procedures for this Research

SAMPLE (continuation)

6. Potential Health Risks or Discomforts

If you wish to discuss these or any other discomforts you may experience, you may call the Principal Investigator listed in #2 of this form.

7. Potential Health Benefits to You or to Others

8. Potential Financial Risks

9. Potential Financial Benefits to You or to Others

10. Compensation for Research Related Injury

In the unlikely event of you sustaining a physical or psychological injury which is proximately caused by this study;

_____ professional medical: or _____ professional dental: or _____ professional consultative care will be provided by _____ without charge.

SAMPLE (continuation)

11. Conflict of Interest

12. Alternatives to Participating in this Research Study

You are free not to participate in this study. If you choose to participate, you are free to withdraw your consent and discontinue participation in this research study at any time without this decision affecting your care and treatment by the Department of Juvenile Justice. If you have any question regarding your rights as a participant, you may phone the ...

13. Withdrawal From this Research Study

If you wish to stop your participation in this research study for any reason, you should contact _____ at _____. You may also contact the IRB ...

14. Confidentiality

_____ will protect the confidentiality of your records to the extent provided by Law. You understand that the Study Sponsor, The Department of Juvenile Justice, and the IRB Committee have the legal right to review your records.

15. Assent Procedure (if applicable)

SAMPLE (continuation)

**TEAR OFF AND RETURN THIS PAGE.
KEEP THE OTHER PAGES FOR FUTURE USE.**

16. Signatures

Participant's Name

The Principal or Co-Principal Investigator or representative has explained the nature and purpose of the above-described procedure and the benefits and risks that are involved in this research protocol.

Signature of Principal or Co-Principal
Investigator or representative obtaining consent

Date

You have been informed of the above-described procedure with its possible benefits and risks and you have received a copy of this description. You have given permission for your participation in this study.

Signature of Participant or Representative

Date

If you are not the participant, please print your name and indicate the following:

- The participant's parent
- The participant's guardian
- Department representative as guardian
- A surrogate
- A durable power of attorney
- A proxy
- Other, please explain:

Signature of Witness

Date

If a representative signs and if appropriate, the participant of this research should indicate assent by signing below.

Participant's Signature

Date

SAMPLE

Caring for the Youngest Among Us in Hillsborough County: What Really Matters to Babies and their Primary Caregivers



INFORMED CONSENT DOCUMENT

We are developing a community research effort to learn about what really helps babies and young children develop in healthy ways in Hillsborough County. This community research involves collecting stories, observing interactions and gathering ongoing feedback. Participating in this community research is completely voluntary.

Information that is gathered for this community research will be kept confidential. Your perspectives will be described as research findings and will not identify you personally.

We do not anticipate that participating in this research will place you or your child at risk or cause you or your child any discomfort. If at any point you want to stop participating, you are always free to do so with no penalty. You will still be able to request and access any and all resources and supports that you are interested in receiving. You will also still be invited to participate in future opportunities to contribute to the local community.

We are bound by law to contact the Florida Department of Children and Families if we learn about a child who might be getting neglected or abused. If you were to share this kind of information with us about a child you know, we would first discuss the process of contacting Florida DCF and then we would make the call and fill out any necessary paperwork together with you.

Audio and video recording are very helpful ways to gather and share information about how babies and young children are supported as they grow up. As part of this project, we would like to audio- and videotape our conversations with you, and possibly your interactions with the baby or child you take care of. It also might be helpful for us to videotape your child in other settings where he or she is cared for.

At any point you can pause or turn off the recorder if you do not want the information that you are sharing to be recorded. At the end of a session, you can also request to have the recording erased if you do not want the recording to be saved.

If you choose to participate, we hope that you will enjoy it. You will be contributing to the community's growing understanding of what helps young children the most.

Please complete the following:

I have received an explanation of this study and I am aware that I may discontinue participation at any time. By signing below, I give my consent to participate.

_____ (Initial) I give my permission to be **audio-recorded**.

