Collecting and Sharing JCPS Student and Staff Information

Procedure Manual for
District Staff
School Staff
External Entities
and the
JCPS Institutional Review Board (IRB)

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Purpose

This document defines the procedures and conditions for collecting and sharing personal identifiable information (PII) of JCPS students and staff in Jefferson County Public Schools (JCPS). Many of these requests require approval by the JCPS Institutional Review Board (IRB) in order to comply with federal law. All district and school staff as well as external entities must follow these procedures to meet federal regulations and JCPS policies.

The document also specifies written procedures for the JCPS IRB, such as membership determination, methods for conducting reviews and approving requests, communication protocols, and decision rules. The scope of these written procedures satisfies the regulatory requirements of 45 CFR 46 Protection of Humans Subjects.

Overview

JCPS publishes a substantial amount of district data and reports on students and staff on its website. Other external sources also provide additional access to JCPS summative data and reports [1]. These data are made publicly available in ways that protect the privacy of individual students and staff as required by various U.S. data privacy laws (e.g., Family Educational Rights and Privacy Act, or FERPA).

JCPS and other districts and schools also receive requests for non-public information from external entities to provide services, comply with grants, or assess programs as well as to study JCPS students and staff directly. These requests are subject to additional State (e.g., Open Records Act; criminal background checks) and federal (e.g., Protection of Human Subjects) laws.

The procedures for accessing non-public data from JCPS vary depending on the reason for the request, who is making the request, and the sensitivity of the information in order to comply with these laws. Traditional research and evaluation activities must follow IRB procedures for approval under 45 CFR 46 Protection of Humans Subjects. Some of these requests require completion of additional JCPS procedures to meet State and federal laws as well as JCPS policies. Other JCPS procedures include establishing data sharing agreements (DSA), contracts, or memorandums of understanding or agreement (MOU or MOA). In some cases, the request may simply involve submitting an Open Records Request. These other procedures are referenced within this document along with the appropriate JCPS office who manages the procedures.

Definitions

The following definitions apply to procedures used by the JCPS IRB.

45 CFR 46.102 Definitions for the Purposes of this Policy

(a) *Certification* means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

[1] The following sites provide other aggregated JCPS data: Kentucky Department of Education (KDE) School Report Card, KYStats, TELL Kentucky, the National Student Clearinghouse, and National Center for Education Statistics (NCES) Data Tools.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. NOTE: Research may not be conducted prior to receipt of approval by the authorized IRB.

(j) *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.

(l) *Research* means 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 that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Program evaluation is considered research under the federal definition.

2 CFR §200.79 PII

Personally identifiable information, or PII, means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. Some information that is considered to be PII is available in public sources such as telephone books, public Web sites, and university listings. This type of information is considered to be public PII and includes, for example, first and last name, address, work telephone number, email address, home telephone number, and general educational credentials. The definition of PII is not anchored to any single category of information or technology. Rather, it requires a case-by-case assessment of the specific risk that an individual can be identified. Non-PII can become PII whenever additional information is made publicly available, in any medium and from any source, that, when combined with other available information, could be used to identify an individual.

Terms related to 45 CFR 46 and further defined by JCPS for clarity include:

Daily operational and educational decisions means activities with human subjects that are usually exempt from this policy, referred to as “normal educational practices” in the classroom under 45 CFR 46.104. This includes any *new information* collected by school staff, or JCPS staff who directly support schools, on students, families, or school employees to assess immediate needs, communication strategies, or future programming or staffing decisions. Methods to collect information may include surveys, observations, focus groups, or PLCs. *NOTE*: JCPS staff collecting information for program evaluation purposes do not fall under this definition. Furthermore, any sharing of information with external entities is outside the scope of this definition. See Program Evaluation and Improvements.

Direct intervention or service is an intervention provided to individual students or groups of students in direct response to academic or behavioral assessment outcomes. This applies to JCPS employees in these roles and external service providers contracted to provide direct intervention.

Informed consent refers to the process by which a person learns about and understands the purpose, scope, benefits, and potential risks of activities or interventions before they begin their participation as well as a process for obtaining permission from the person before sharing their personal information with a third party.

Program evaluation and improvement research include activities requiring access to existing non-public student or staff information, or to collect new data, in order to monitor and evaluate fidelity or impact of programs, interventions, or technologies on students or staff.

Traditional research includes activities requiring access to existing non-public student or staff information, or to collect new data, in order to address a question or test a hypothesis for which the data were not collected originally.

Other definitions

Data sharing agreement, or DSA, is a legal agreement between JCPS and an individual or group that provides access to agreed upon JCPS student or staff PII and parameters for how the individual/group can use that information.

Administrative Requirements and Procedures

Creation, Authority, and Membership of IRB

The JCPS IRB is a registered institutional review board (IORG 0002516) with the federal Office for Human Research Protections (OHRP) under the U.S. Department of Health and Human Services (HHS).

An IRB is accountable first to HHS and its codes. This relationship gives an IRB sole authority to protect human subjects (students, families, and staff). Organizational and institutional reporting chains are secondary under IRBs to reduce potential conflicts of interest with the institution and to protect subjects. Thus, "no institutional official may approve research that has not been approved by the IRB" (OHRP Guidance, 2018).

The JCPS IRB is designated under an OHRP assurance. The membership of a registered IRB under this assurance must meet the following minimum requirements pursuant to §46.107.

a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The JCPS IRB includes district and community members with expertise in research methods and K-12 education, special populations of students (e.g., special education, homeless, racial equity, ESL), school leadership, and legal counsel.

Review of Documented IRB Procedures

The JCPS IRB will review the procedures set forth in this document at each OHRP-determined renewal period and as changes to 45 CFR 46 and other relevant federal laws require updates to these procedures.

Ethical Principles

The JCPS IRB functions according to the three basic ethical principles of the Belmont Report regarding (1) respect for persons, (2) beneficence, and (3) justice. In addition, the JCPS IRB abides by the JCPS Ethics Guidelines. Finally, the JCPS IRB considers the Standards for Educational Evaluation and the Standards for Educational and Psychological Testing as appropriate when reviewing applications and making decisions.

Conflict of Interest

The JCPS IRB and its members abide by 45 CFR 46.108 (d) which states, "No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB." If the JCPS IRB chairperson or member is directly involved in a project submitted to the Committee, this circumstance is considered a conflict of interest. Involvement in the project includes: direct sponsorship, project development or planning, or analysis and evaluation services. In such cases, the conflicted chairperson, member, or alternate does not vote or count towards the quorum.

General JCPS Requirements for Collecting and Sharing Student and Staff Information

Criteria for IRB Submission and Review

The JCPS IRB will review requests that meet all of the following three conditions.

1. *Protection of Human Subjects*. The study complies with all relevant components of 45 CFR 46 Protection of Human Subjects as well as any other relevant federal laws.
2. *JCPS Policies*. The study does not violate any JCPS policy.
3. *Chief Endorsement*. The activities, programs, interventions, or technologies proposed directly support current districtwide initiatives and priorities as determined by JCPS Chiefs. Requests involving individual schools or JCPS departments also require a Supervisor (e.g., Assistant Superintendent) letter of support. Written endorsement from relevant Chief (s) is required before the JCPS IRB will review an application.

If any condition individually is not met, the activity will not be approved by the JCPS IRB. Activities involving human subjects not approved by the institutional IRB cannot be implemented according to federal law.

In addition, every individual will always be required to pass a criminal records check for Kentucky in order to work directly with students and staff in any JCPS, or affiliate (e.g., YMCA), school site pursuant to KRS 161.148 and also provide a letter from the Kentucky Cabinet for Health and Family Services confirming no substantiated findings of abuse and neglect (referred to as a Child Abuse and Neglect, or CAN, check) pursuant to the Kentucky Unified Juvenile Code.

If the proposed activities and individuals meet the criteria described above, applicants may submit an online application through the secure JCPS Data Request Management System platform using the IRB Request form.

JCPS will show preference for activities as displayed in Figure 1. In addition, the JCPS IRB will work with the JCPS Cabinet to weigh the benefits of the proposed research against current district priorities and district capacity to support the research appropriately.

YES	NO
Supports expectations of the Every Student Succeeds Act (ESSA).	Involves random assignment of schools and students.
Assists with meeting requirements in State law or developed by the Kentucky Department of Education (KDE).	Adds burden to school processes, especially for schools identified as Targeted or Comprehensive Support and Improvement (TSI and CSI) schools.
Enhances equitable opportunities for at-risk students.	Conflicts with current JCPS initiatives and expectations for schools.
Enhances the successful implementation of current JCPS initiatives	Violates State law or contradicts KDE requirements.
	Provides no real benefit to JCPS.

Figure 1. JCPS Preferences for Supporting Research Activities.

Regarding ESSA, the U.S. Department of Education holds schools accountable for implementing programs and interventions that are evidence-based, not simply research-based. Thus, the priority for JCPS implementation of any programs or interventions in schools is that these activities meet the ESSA threshold for being labeled as evidence-based. Refer to the Non-Regulatory Guidance: Using Evidence to Strengthen Education Investments, the KDE ESSA Evidence Levels Chart , or the JCPS fact sheet Evidence-Based Interventions for more information on ESSA tiers for evidence-based quality.

Activities Needing IRB Approval

Any activity or intervention defined as a research activity pursuant to 45 CFR 46.102 (l) must be submitted for review to the JCPS IRB through the JCPS DRMS platform. The following categories of requests qualify as research (45 CFR 46.102 (l)). These categories apply to requests from external researchers, vendors, and JCPS employees using information outside the normal scope of their job responsibilities. This includes requests to:

1. access existing non-public identifiable JCPS data to evaluate program or technology effectiveness, or
2. access existing non-public identifiable JCPS data to address a research question or a question for which the data were not collected originally, or
3. implement a new program or technology in JCPS that requires some level of monitoring and evaluation to determine fidelity or impact, or
4. collect your own data with JCPS students or staff through surveys, focus groups, or observations/walkthroughs for use beyond standard operational and educational decisions made by JCPS staff.

Obtaining Informed Consent from Students, Families, and Staff

All four categories of activities listed under Activities Needing Approval require Informed Consent from participants. Please refer to the Informed Consent Checklist (Appendix A) to include required statements to address federal law (45 CFR 46.109 (b) and (c)) and JCPS policies.

Any external entity should use informed consent forms describing what they intend to do and how they will maintain privacy with the subjects' (students, families, and/or staff) information. Informed consent forms should provide participants with a full picture of the planned activities. Per federal law, any JCPS employee requesting access to non-public JCPS data MAY require informed consent or an Open Records Request, if the request extends beyond their normal job responsibilities and/or the information or data is used to answer questions for which the data were not collected originally.

Compliance with JCPS IRB Requirements and Conditions for Informed Consent

The JCPS IRB committee is more than happy to assist prospective researchers and partner organizations in navigating the application process. Pursuant to federal law, research activities may not begin prior to receipt of approval by the authorized IRB or collection of signed informed consent forms from participants. Non-compliance by applicants with 45 CFR 46 can result in suspension or termination of activities by the JCPS IRB.

Individuals or groups who have obtained approval from their own institutional IRB still must submit an application to the JCPS IRB for approval. The JCPS IRB requires receipt of the external IRB approval letter documenting that the institution is supportive of the applicant's activities and the applicant is affiliated with the institution.

Types of IRB Reviews

Applications to the JCPS IRB will be reviewed according to one of three procedural methods outlined in 45 CFR 46.

1. Full Review

   Applicants should anticipate that many requests require a full IRB committee review, particularly if the request involves access to students and their personal information, to comply with 45 CFR 46 Subpart D – Additional Protections for Children Involved as Subjects in Research. A full review of an IRB application involves the following requirements pursuant to 45 CFR 46.110

   - An in-person meeting
   - Majority of members present
   - A quorum decision by the majority present relative to 45 CFR 46 requirements and institutional policies.
   - Documentation and rationale for the application decision

   The JCPS IRB conducts full reviews on a quarterly schedule: October, January, April, and July. Applicants must submit completed applications for a quarterly review a minimum of two weeks prior to the review date.

   If JCPS provides services supported by HHS that requires research, these studies will be subject to full JCPS IRB review. The JCPS IRB will determine during this review if the research can be exempt from any portions of the HHS regulations.

2. Exempt Review

   A limited number of research activities can be *exempt* from some or all requirements of 45 CFR 46. However, this does not imply that the application is exempt from review entirely by the IRB. Rather, the JCPS IRB must decide whether the proposed activities are exempt from federal requirements or from JCPS policies and procedures.

   Examples of activities that may be exempt from portions of 45 CFR 46 include (104, Subpart D):

- Normal educational classroom practices that are not likely to adversely impact students' opportunity to learn required educational content.
- Regular and special education instructional strategies.
- Identities cannot readily be ascertained either directly or through identifiers linked to the participants.

The JCPS IRB, in conjunction with the General Counsel representing JCPS, will determine whether the research can be exempt from any JCPS policies and procedures.

Individuals or groups who have obtained approval from their own institutional IRB, including an exemption, still must submit an application to the JCPS IRB for approval. Additionally, it is possible that the application will not qualify for exemption with the JCPS IRB if it fails to meet criteria for JCPS policies and procedures.

3. Expedited Review

   Activities, programs, interventions, or technologies determined by the JCPS IRB Chair and consulting members to involve no more than minimal risk to participants, or that requires minor change to previously approved applications, may qualify for an expedited review process. An expedited review can occur between the regular quarterly committee meeting dates. However, applicants still should expect a minimum of one week for review and approval after the JCPS IRB Chair determines the completed application qualifies for an expedited review.

Materials Required for Submission

Table 1 identifies materials and documents that should be submitted with a research application to the JCPS IRB along with the circumstances for when these documents are required. All required documentation must be received with the application before the JCPS IRB will review.

Table 1. Documentation Requirements for JCPS IRB Application.

Documentation	When To Submit
Completed JCPS IRB Request Online Form	Required for all requests via the DRMS platform.
JCPS letter of support	Required for all requests with the following guidance: 1. *Multiple school sites*. Requests that involve program or intervention implementation at multiple school sites or departments, or that may conflict with current JCPS priorities or initiatives, require a letter or support from a JCPS Chief. 2. *Individual school or JCPS department*. Requests involving individual schools or JCPS departments require a Supervisor letter of support. The Supervisor may request a Chief letter of support.
IRB approval (separate institution)	Required for requests from researchers or project leads affiliated with an organization with an authorized IRB or Human Subjects Protection Program.
Informed Consent Forms and/or Student Assent Form	1. Required for all requests involving direct collection of new data during school hours in a JCPS site from students, families, or staff. a. Informed Parent Consent (students under age 18 and families) and Student Assent (students under age 18) b. Informed Student Consent (students 18 years of age or older) c. Informed Staff Consent 2. Required for all requests involving the use of existing non-public identifiable student or staff data for purposes other than those for which the data were originally collected. a. Informed Parent Consent (students under age 18 and families) b. Informed Student Consent (students 18 years of age or older) c. Informed Staff Consent 3. Required documentation with all informed consent forms: Completed JCPS Informed Consent Checklist (see link or Appendix A). Applicants must denote where each element can be found in their consent form. The consent form and the JCPS Checklist for Informed Consent must be submitted with the IRB application through the JCPS DRMS online platform.
Instruments (e.g., surveys, protocols, focus group questions, walkthrough tools)	Required for all requests for which applicants will be using these methods to collect new information from participants.
Criminal Records Check [a]	Required for requests to work directly with students and staff in any JCPS or affiliate (e.g., YMCA) school site. Pursuant to Kentucky laws, these individuals must have: 1. Kentucky state criminal records check, and 2. A Child Abuse and Neglect (CAN) check from the Kentucky Cabinet for Health and Family Services.
Contract [b]	Required for IRB requests being submitted pursuant to, or in conjunction with, an MOU, MOA, or a contract with JCPS.
Data Sharing Agreement [c]	Required for requests to access JCPS existing non-public student level identifiable data for research or evaluation purposes.

[a] If the applicant does not have a completed criminal records check at the time the request is submitted, the documentation must be on file with the JCPS General Counsel's Office before the first day the study begins at the school site.

[b and c] Contracts and agreements involve separate procedures from the IRB process, which are managed by the JCPS General Counsel's office. The JCPS IRB will assist in directing applicants to General Counsel should these legal processes be required and if not already established.

Communication Procedures for Applicants and JCPS on Questions and Decisions

All communication about submitted applications from an applicant to the JCPS IRB and to the applicant from the JCPS IRB must go through the secure DRMS platform in the communication section of the application portal. Applicants should check their DRMS account regularly to monitor response from the JCPS IRB. This process fulfills 45 CCR 46.115(a) (4) "[An IRB] shall prepare and maintain adequate documentation of IRB activities, including the following: Copies of all correspondence between the IRB and the investigators". Furthermore, this process allows the JCPS IRB Chair to document correspondence and share with Committee members as needed securely and efficiently.

Questions about general IRB procedures not related to a specific, submitted application can be communicated by email to the JCPS IRB (jcps.irb@jefferson.kyschools.us).

Approval/Denial

Applicants will receive communication about the results of the review in writing via the JCPS DRMS platform with the decision and rationale from the JCPS IRB Committee. Applicants are responsible for monitoring the DRMS for any communication from the JCPS IRB.

Applicants should be aware that approval of research does not include the following circumstances: (1) changes to the protocols, methods, programming components, or assigned primary project manager/investigator, and (2) formal publication or presentation of results. These circumstances must be approved separately by the JCPS IRB.

Renewal and Continuing Reviews

Applicants should advise JCPS of the intent to conduct activities across multiple years at the onset of the application process (e.g., grants requiring multiple years of data collection and reporting). Any request for multiple years of data collection are subject to a Continuing Review process and documentation requirements upon approval from the JCPS IRB pursuant to 45 CFR 46.109 (e). This status will be documented in the DRMS platform. However, the JCPS IRB retains authority to: (1) adjust the request to a one-year review as a condition for initial approval, or (2) terminate continued activities approved previously by the JCPS IRB, if the committee determines that the approved study "is not being conducted in accordance with the IRB's requirements" (45 CFR 46.113).

Applicants under Continuing Review status must submit a report and supporting documentation to the JCPS IRB through the secure DRMS platform at the end of each review cycle (one year from the date of initial approval). This information should provide a summary of activities to date and alert the JCPS IRB to any potential upcoming changes to methods with a clear rationale. The JCPS IRB will review the report and documentation and notify the project manager of the approval status before the next phase can begin.

If the JCPS IRB finds the project to be out of compliance with the conditions for previous approval, the activities will be halted and reviewed for possible suspension or termination. This status will be communicated to the project director in writing via the DRMS, and the appropriate JCPS Chief sponsor and the General Counsel also will be notified. Once a joint decision has been made between the JCPS IRB, Chiefs, and General Counsel on a course of action, the project director will be notified and must respond within three days to address the decision.

Finally, applicants should be aware that contractual agreements with JCPS, including MOUs, MOAs, and DSAs, must be renegotiated and approved by the JCPS General Counsel's office separately from the IRB process every year. JCPS does not approve multi-year contracts to ensure agreements are up-to-date and comply with any potential changes to State and federal laws.

Completion of Research

Project managers and investigators must notify JCPS officially when the approved project has been completed. In addition, the project manager must submit a final report via the DRMS platform, including a list of project activities and findings. A formal research report is preferred that cites the: (1) purpose, (2) methods, (3) analyzed findings, and (4) conclusions.

Amendments to Approved Projects

Changes to the approved project must be communicated to the IRB before those activities can be implemented, and the JCPS IRB must first review and approve (45 CFR 46.109(d)). The types of activities that require review and approval include changes to the protocols, methods, programming components, study length, or assigned primary project manager/investigator.

Complaints, Problems, Concerns, and Reportable Events

At times, unanticipated problems occur with approved activities. The JCPS IRB Chair must be consulted about unanticipated problems or changes to determine if a formal Committee review is required. These events should be documented to the JCPS IRB Chair in writing using the secure DRMS portal.

If the JCPS IRB Committee receives a complaint or concern about activities for an approved project, the JCPS IRB Chair will notify the primary investigator in writing and request a written response about the subject of the complaint and how it may be resolved. If the complaint or concern seems to exceed minimal risk for study participants, the full IRB Committee will review the circumstances and decide on a course of action (e.g., recommend a correction; suspend or terminate the study activities).

All activities related to JCPS IRB approved activities are subject to Kentucky laws on reportable events, including criminal activity and cases of child abuse and neglect. Thus, investigators and JCPS staff shall report these circumstances to authorities (i.e., Child Protective Services in cases of suspected child abuse and neglect) as required by State law. Failure to comply with Kentucky state law will result in immediate termination of research activities and disclosure to authorities for legal response.

Procedures and Guidance Specific to JCPS District and School Staff

Is it part of your job or considered research?

Often, district and school staff use methods in Table 2 to gather information on their own students, families, and employees to assess immediate needs, communication strategies, or future programming or staffing decisions. Table 2 describes when these activities are acceptable and when they qualify as research and require informed consent from parents, students, and staff.

Table 2. Research vs Operational and Educational Activities for Current JCPS Employees.

Method	Acceptable Use	Submit to JCPS IRB
Surveys, Focus Groups, and Observations/Walkthroughs	• To make daily operational and educational decisions by JCPS employees.	• To fulfill requirements for their own coursework, thesis, or dissertation. • To distribute a survey or collect data on students or staff on behalf of another individual (e.g., external partner). • To evaluate the effectiveness of interventions or programs beyond routine school services to students.
Access and Analysis of Existing Non-Public Data	• To execute normal job responsibilities by school or district staff with permissions to access student and/or employee information as part of their job description.	• To assess effectiveness of programs using existing identifiable data collected originally for a different purpose and without student/parent or employee consent.

It is a violation of the Protection of Human Subjects (45 CFR 46) regulation and of the Family Educational Rights and Privacy Act (FERPA) for JCPS employees to engage in activities without prior IRB approval. Furthermore, JCPS staff must adhere to requirements under FERPA regardless of whether data are used as part of normal job responsibilities. Any identifiable student and personnel information must be secured and cannot be shared with others who do not have authorization. You can access the JCPS training on FERPA by downloading the Powerpoint.

Notifying JCPS IRB of Potential Requests

If a JCPS employee becomes aware of a potential project that may involve information sharing or access to students or staff by non-JCPS employees, the employee should consult the JCPS IRB before agreeing to work with any vendors, accept grant relationships, or support community partner programs. In addition, JCPS employees wanting to use existing non-public JCPS data, or collect new data, for their own research purposes to fulfill requirements of their programs of study or courses must secure agreements from the relevant Chief(s) and notify the JCPS IRB before committing to any activities in order to ensure the district can support the research. Refer to Table 1 for more information.

Instructions for IRB Reviewers

Members of the JCPS IRB Committee are expected to familiarize themselves with the requirements of 45 CFR 46. In addition, the JCPS IRB members will follow the methods described in the IRB Review Procedures section of this document.

IRB Records

The JCPS IRB retains all records related to each application for at least three years as required by 45 CFR 46.115. All materials are stored through secure online platforms, including communication on potential and approved applications and on decisions and rationale, aligned with federal law and JCPS policy and priorities.

The secure platforms are managed by the JCPS Accountability, Research, and Systems Improvement (ARSI) division. This documentation is subject to federal privacy laws.

IRB Review Procedures

General Procedures for All Reviews

The JCPS IRB chairperson, or designated IRB member, first determines whether the application meets the three JCPS criteria for review upon receipt of the application. If the application does not meet one or more criteria, the JCPS IRB Chair notifies the primary project manager/investigator that the application will be not be reviewed by the Committee for these reasons via the secure DRMS system. The applicant may appeal the denied review if issues can be resolved in a way that will lead to the criteria being met.

If the application meets all three criteria for review, the JCPS IRB Chair determines whether the application qualifies for an Exempt Review process with limited IRB review pursuant to 45 CFR 46.104 (3) Subpart D or for or an Expedited Review process pursuant to 46.110. If neither an Exempt Review or an Expedited Review process is appropriate, the JCPS IRB must conduct a full review (46.108 (b)).

The JCPS IRB Committee uses two checklists to evaluate applications. For all review processes, the Committee determines whether applications meet federal, state, and district requirements using the JCPS Checklist for IRB Approval of Research (Appendix B). The Committee evaluates the applicant-completed JCPS Checklist for Informed Consent with the submitted informed consent forms (Appendix A). Applicants must submit the completed Checklist for Informed Consent denoting where each element can be found in their consent form. The consent form and the Checklist for Informed Consent must be submitted with the application through the JCPS DRMS online form.

Full Review Procedures

To hold a full review, the JCPS IRB "must review proposed research at convened meetings at which a majority of the members of the IRB are present" (46.108 (b)). The JCPS IRB only conducts full reviews of applications on a quarterly schedule: October, January, April, and July.

Many applications to the JCPS IRB are subject to 45 CFR 46 Subpart D – Additional Protections for Children Involved as Subjects in Research, which requires consideration of additional safeguards. The JCPS IRB applies full review procedures to most applications requesting access to students and their personal information.

Under special circumstances, an IRB may conduct a full review outside of the regular posted schedule. For example, time-sensitive research opportunities (e.g., federal grants; environmental circumstances that can't be replicated) with substantial benefit to participants and the field, and that do not qualify for an expedited review, may warrant a separate IRB convening. The same full review procedures apply, and the JCPS IRB still retains final authority to determine whether the study meets requirements of the Protection of Human Subjects regulation for approval.

The Chair and committee members will apply the following procedures in Figure 2 for full reviews.

Pre-Meeting

2 weeks

Chair: Determines which completed applications meet the three criteria for review. Notifies members of completed new applications that are eligible for review in DRMS. Identifies any initial issues for attention. Notifies JCPS sponsor (i.e., Chief) of intent to review. If no JCPS sponsor has been identified, the request will not be reviewed until we receive confirmation that the relevant JCPS division is willing to support the research; or, the relevant JCPS division will be notified if the request is required by law or by regulating agencies governing JCPS.

Members: Ensure access to relevant applications and their attached materials in DRMS.

1 week

Members: Notify Chair if additional documents are required, or questions answered, from submitters for adequate review.

Chair: Post agenda and other relevant materials on secure Committee site. Provide members with a summary of completed applications for review in a Review Record template, and include any outstanding issues identified. Communicate with applicants if additional information is requested via DRMS.

During Meeting

Chair: Provides paper copies as needed. Reviews any outstanding Action Items. Provides an update on any eligible applications reviewed using the Exempt or Expedited Review procedures. Moderates and documents discussion and decisions on each application reviewed.

Members: (1) Review/discuss critical issues related to federal policy (minimum requirements) and to district policy/priorities for each application reviewed, (2) determine whether a vote can occur, and (3) establish majority agreement and rationale on each reviewed application when a vote is conducted.

Post Meeting

Chair: Notify applicants of decisions and rationale via DRMS three days after meeting. Or, request further information from submitters, if a vote was not possible due to questions. Confirm decision with JCPS sponsor. Finalize Meeting Minutes and Action Items, document outcomes in using Review Records template, and post to secure Committee materials site.

Members: Review meeting minutes for accuracy and respond within three days after receipt. Review any outstanding applications and vote in DRMS, if applicable, within three days from application update.

Figure 2. JCPS IRB Procedures for Preparing, Conducting, and Finalizing Full Reviews.

Exempt Review Procedures

The JCPS IRB chairperson, in consultation with committee members as needed, will determine whether the proposed activities are exempt from any regulation or policy. In such cases, an exempt review can be conducted by the JCPS IRB Chair between the regular quarterly committee meeting dates. If applicants qualify for exemptions, they are notified of a decision with a list of any expectations that they must agree to before they can begin the activities.

If either the chairperson OR an additional committee member(s) determines that the application cannot be exempt, applicants are automatically moved into expedited or full review processes and notified of the decision.

The JCPS IRB chair is responsible for documenting the review and approval of any applications with exempt procedures and communicating these results to the full Committee.

Expedited Review Procedures

The JCPS IRB chairperson and at least one additional committee member will conduct an expedited review instead of the full committee. Thus, an expedited review can occur between the regular quarterly committee meeting dates. If either the chairperson OR additional committee member(s) determines that the application may be denied, the application must then go to the JCPS IRB committee for a full review pursuant to 45 CFR §46.110 (b) (2).

Applications accepted for Continuing Review qualify for an expedited review process annually. However, if upon review, the JCPS IRB Chair or other expedited reviewer determine that the study is non-compliant, the report and documentation submitted by the project manager must go to the full JCPS IRB committee to determine the status.

The JCPS IRB chair is responsible for documenting the review and approval of any applications with expedited procedures and communicating these results to the full Committee.

Suspension or Termination of Approval

Activities previously approved by the JCPS IRB and found to be out of compliance with the conditions of approval will be halted and reviewed. Activities that could lead to suspension or termination include failure to: (1) comply with stated conditions for JCPS IRB approval, (2) report unanticipated problems or changes to research activities, or (3) comply with federal or state laws or JCPS policies.

In these cases, the JCPS IRB Chair will consult the JCPS IRB full Committee to determine a course of action. The JCPS Chair then will communicate the Committee decision, the rationale, and any required next steps by JCPS or of the primary investigator in writing via the JCPS DRMS. The primary investigator will have three days to acknowledge receipt of the suspension or termination, including a plan for rectifying the identified issues if suspended or for ending the research activities and notifying the participants if terminated. The JCPS IRB may require additional steps for ending activities and notifying the participants if the proposed plan is insufficient or the primary investigator does not respond in a timely manner. These steps will be coordinated with General Counsel.

Activities that SHOULD have been reviewed and approved by the JCPS IRB, but were not, also will be halted. The IRB Chair and consulting members will review the circumstances with the JCPS General Counsel and the JCPS Chief(s) who oversees the work to determine whether the project aligns with JCPS priorities and policies. The JCPS Chiefs and General Counsel are responsible for negotiating any programmatic adjustments needed to continue project implementation. The JCPS IRB will determine whether the activities meet federal regulation, or can be brought into, compliance with these regulations. If all criteria can be met, the JCPS IRB will communicate approval and any associated conditions to the project director. If any criteria cannot be met, the JCPS IRB, in conjunction with General Counsel, will communicate that the project has been denied and any specific steps expected to end the work in ways that will be least disruptive to students, families, or staff affected. These steps will be monitored by General Counsel.

Cooperative IRB review arrangements

The JCPS IRB does not hold cooperative review arrangements with IRBs of other institutions. While the JCPS IRB requires that applicants affiliated with an external institution with an established IRB submit evidence of their approval, this evidence will not substitute for the approval of the JCPS IRB. The JCPS IRB is responsible for determining whether the activities align with JCPS policies as well as confirming that the activities fully comply with 45 CFR 46 Subpart D – Additional Protections for Children Involved as Subjects in Research.

APPENDIX A: Informed Consent Checklist

Applicants to the JCPS Institutional Review Board (IRB) must use and complete the following checklist to develop your Informed Consent Form. The completed checklist must be uploaded with the Informed Consent Form(s) in the DRMS.

Statements Required in Informed Consent Form

Column 3 denotes mandatory components for inclusion in your Informed Consent Form. If applicable to your particular research, please include statements marked under column 4. These statements are required by federal policy 45 CFR 46 Protection of Human Subjects, subpart 116. Other statements are required by Kentucky State law or by JCPS to meet district policy. In column 1, indicate the section where the requirement can be located in your Informed Consent Form (e.g., page, paragraph, sentence).

Cite Section	Components to address in Informed Consent Form		Mandatory statements	Include statement if appropriate to your research.
§46.116 General requirements for informed consent.				
	(a) (5) (i)	**Summary**. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.	✓	
	(a) (5) (ii)	**Detail and organization**. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.	✓	
	(b) (1)	**Description of Research and Procedures.** A statement that the study involves research, an explanation of the purposes 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.	✓	
	* (b) (8)	**Voluntary**. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.	✓	
	(b) (2)	**Identified Risks**. A description of any reasonably foreseeable risks or discomforts to the subject.	✓	
	(b) (3)	**Benefits**. A description of any benefits to the subject or to others that may reasonably be expected from the research	✓	
	(b) (4)	**Alternative Procedures**. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. NOTE: Non-participation does not qualify as an alternative and should not be listed as such.		✓
	(b) (5)	**Confidentiality**. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.	✓	

Cite Section	Components to address in Informed Consent Form		Mandatory statements	Include statement if appropriate to your research.
	(b) (6)	**Compensation for Risk**. For research involving more than minimal risk, an explanation as to whether any compensation is available and, if so, what they consist of, or where further information may be obtained.		✓
	(b) (7)	**Contact for Questions**. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.	✓	
	** (b) (9) (i) ***OR*** (b) (9) (ii)	**Future Use and Data Sharing**. A statement that identifiers might be removed from the identifiable private information … and that, after such removal, the information … could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; ***OR*** **Non-Disclosure Agreement**. A statement that the subject's information … collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.		✓
	(c) (1)	**Unforeseeable Risks.** A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.		✓
	(c) (2)	**Termination of Participation**. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent		✓
	(c) (3)	**Costs to Participant**. Any additional costs to the subject that may result from participation in the research.		✓
	(c) (4)	**Consequences for Withdrawal**. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	✓	
	(c) (5)	**Notifications for Continued Participation**. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.		✓
	(c) (6)	**Sample Size**. The approximate number of subjects involved in the study.	✓	
	(c) (8)	**Clinical Findings**. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.		✓

Cite Section	Components to address in Informed Consent Form		Mandatory statements	Include statement if appropriate to your research.
Kentucky Law on Reporting Abuse, Neglect, and Exploitation				
	Kentucky Unified Juvenile Code	**Child Abuse and Neglect Reporting**. Include a statement notifying students or parents/guardians that Kentucky law requires that abuse, neglect, and exploitation be reported when the victim is (1) a child, (2) the spouse of the offender, or (3) an adult with a disability who is unable to protect him or herself. Thus, the researchers and JCPS are required to report any information about abuse or neglect reported during the course of the study to Child Protective Services (CPS). Additionally, participant information may be disclosed to CPS. This statement MUST be included for any studies in which students or staff have a reasonable opportunity to report this information.		✓
JCPS Required				
	Limited English Proficiency. For students or families with limited English proficiency, the informed consent form must be written in the native language of the student or guardian.		✓	
	Student Assent. As developmentally appropriate, student assent should be sought in addition to guardian consent (for students under 18 years of age). For studies, activities, and projects involving the entire class, a description of how opting out will impact the student should be included.		✓	
	Photo/Videotape Release and Use. Include descriptions of: (1) the use of any photographs or video recordings collected as part of the project, (2) all potential locations where the pictures or recordings will be published or groups with whom they will be shared, and (3) a statement describing the extent, if any, to which confidentiality of the subject's likeness will be securely maintained.			✓
	Media or Performance Expectations. Include statements about any performance expected of the individual as part of the program or study (e.g., writing; performance piece; artwork).		✓	
	Coercion. A statement that, as a voluntary activity, the subject will not be rewarded with, or penalized by withholding, educational or professional opportunities or credit (e.g., grades; field trips; promotions; trainings) as a condition for participation in the activities/methods (e.g., surveys; interviews) identified in this informed consent form.		✓	
	Staff Participation. Include a statement addressing the following district contractual agreement: Due to collective bargaining agreements for JCPS certified staff, any request for participation in research-related activities outside of the scope of their regular job responsibilities must be voluntary during or outside of contracted hours.			✓
	Staff Compensation. Be advised that JCPS does not permit employees to collect individual monetary benefits if research-related activities occur during contracted hours. However, JCPS employees can receive monetary benefit for their research-related participation outside of contracted hours. Plans for staff compensation should be developed and described according to this policy.			✓
	Study Approval. Include a statement indicating that your project has been reviewed and approved by the JCPS IRB. In addition to your contact information for questions about the study, include the contact information for JCPS IRB chair for any additional questions for JCPS.		✓	

*** Statement about voluntary participation must be written before describing risks, benefits, etc.**

**** Either statement (b) (9) (i) <u>OR</u> statement (b) (9) (ii) must be included in the form, whichever is accurate.**

Conditions for Obtaining Informed Consent

The chart below lists conditions in federal and Kentucky state regulations for collecting informed consent and participant information related the extent of confidentiality permissible. Please check boxes to indicate you understand and will follow the policy requirements for obtaining consent from study participants and reporting information.

Mark a check to confirm	Conditions Required for Consent	
§46.116 General requirements for informed consent.		
	(a) (1)	**Prior to Project Start**. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
	(a) (2)	**Participant Questions and Coercion**. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
	(a) (3)	**Plain Language**. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
	(a) (4)	**Reasonable Explanation**. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
	(a) (6)	**Negligence**. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
§46.117 Documentation of informed consent.		
	(a)	**Signed Consent**. A written informed consent form that meets the requirements of §46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.
(If not applicable, indicate N/A)	(b) (1) and JCPS	**Students and/or Guardians with limited English Proficiency or cognitive capacity**. A short form stating that the elements of informed consent (required by §46.116) have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's legally authorized representative, in addition to a copy of the short form. ***AND*** Oral presentation of consent information is required in cases where participants (students and/or guardians) are limited in English proficiency or in cognitive capacity. In the case of limited English proficiency, informed consent must be obtained in the native language of the participant (or guardian), and the short written informed consent form must be written in the native language of the student or guardian (see ***Statements Required in Informed Consent Form)***

Informed Consent Form

TEMPLATE

JCPS Institutional Review Board (IRB)

TEMPLATE GUIDANCE

This document serves as a template for developing an informed consent form, if your organization does not already use a template. This form provides structure and guidance for development, including the basic components required for consent under §46.116, Kentucky State statute, and JCPS policies and procedures. Please adjust the document to reference organizations, personnel contacts, methods, descriptions or your plans and methods, and conditions as appropriate.

Guidance within the template is noted in italics.

Please delete the italicized guidance throughout this document, including this page, when your informed consent form is complete and before submitting your application.

NOTE: JCPS enrolls a substantial number of English as a Second Language (ESL) families. As such, JCPS requires that applicants translate this document into the native language of students and their families of Limited English Proficiency to fully meet 45 CFR 46.116 (a) (3): The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

Adapted from the National Institutes of Health-National Center for Complementary and Integrated Health (NIH-NCCIH).

INFORMED CONSENT FORM

(Name of Institution)

Title of Project: *(complete title of the project as it appears on the protocol and abstract)*

Principal Investigator: *(only one person may be named as principal investigator)*

Other Investigators: *(names)*

INTRODUCTION

Example Introductory Paragraph

We invite you (*your child, if parent/guardian form*) to take part in a research study *(title)* at *(location/institution)* which seeks to *(research question)*.

Taking part in this study is entirely voluntary. That means that you (*your child, if parent/guardian form*) are not obligated to participate in this research. We urge you to discuss any questions you may have about this study with our staff members before agreeing to participate. Take your time to make your decision. If you decide to participate, you must sign this form to show that you want to take part.

PURPOSE OF THE RESEARCH

This section focuses on explaining to the participant why they were asked to participate in the study and the purpose of the research study.

Examples: Purpose of the Research

You are being offered the opportunity to take part in this research study because *(state why the individual was selected, e.g., condition, age, or healthy volunteer)*. This research study is being done to (*detailed research description in layman's terms*).

OR

The purpose of this research study is to obtain information on the effectiveness and safety of *(name of intervention, program, device, etc.)* Approximately *(number)* people will take part in this research (*schoolwide, districtwide, nationwide*) and about *(number)* people are expected to take part at *(location/institution)*.

VOLUNTARY PARTICIPATION

Example Voluntary Participation Section

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include (*briefly list major responsibilities. NOTE: Do not include this sentence if there are no major responsibilities for the participant)*. You do not have to participate in this research.

If you choose to take part, you have the right to stop at any time. If you decide not to participate, or if you decide to stop taking part in the research at a later date, there will be no penalty to (*give examples for relevant role groups; student – grades, school; teachers – position, school)* or loss of benefits to which you are otherwise entitled (*remove statement on benefits here if there are none*).

(Optional, if appropriate) Your investigator may remove you from the research study without your permission. Some possible reasons for this are: *(list possible reasons, for example: the research may end early; you did not follow the study instructions, etc.)*.

PROCEDURES

This section outlines in clear, concise language how the study or program and related activities will be conducted, including any methods or materials, and it explains exactly what will happen should the individual choose to take part in the study. It should clearly identify all activities in which individuals may be asked to engage over the full course of the study/program, including parts of the procedure (if any) that are experimental. References to any (1) audio, (2) video, (3) photography of the participants, (4) performance requirements, and/or (5) tasks completed online or through a database platform should be described here.

TIME DURATON OF THE PROCEDURES AND STUDY

The purpose of this section is to clearly outline the time commitment a participant is agreeing to in choosing to take part in the study.

Example of a Time Duration Section

If you agree to take part in this study, your involvement will last approximately *(give length of time of participation).* You will be asked to return for evaluation (*number)* times. Each visit will take approximately (*number)* minutes.

OR

If you agree to take part in this study, your involvement will last approximately *(give length of time of participation).* This is the only time you will be asked to commit to this research.

RISKS OR DISCOMFORTS

This section is required in all informed consent forms. In most studies, this section will outline in lay terms what risks or discomforts may be associated with each procedure, even if risks are minimal. However, for some research studies, it may suffice to say that there are no known risks associated with the research. List by regimen the physical and nonphysical risks of participating in the study in percentages and numbers whenever possible. Nonphysical risks may include such things as the inability to work, potential anxiety related to the sensitive nature of the questions asked, etc. List the known human experiences related to the treatment and procedures involved, if the current study has precedent. Highlight or otherwise identify any potential side effects. The use of lists or a table format is recommended.

POTENTIAL BENEFITS

This section must be in all informed consent forms. However, the way it is included may vary depending on the type of research. The purpose of this section is to describe the benefits of participating for the subject and for others that may be impacted by the research. The following should be included in this section:

- *This section should address two parts: 1) potential benefits to the participant, and 2) potential benefits to others. The two ideas can be integrated, but for the purposes of the example below, they have been separated into two subsections.*
- *NOTE: Payment given to the subject for participation in the study is <u>not</u> a benefit and should not be addressed in this section; it is a compensation for the subject's time and any expenses incurred as a result of participation in the study and should not be included in this section. See Compensation for Participation to address.*

Example of Possible Benefits Section

Possible Benefits to the Participant

The possible benefit you may experience from the (*procedure, intervention, program*) described in this research includes (*list any benefits that may be reasonably expected*). However, there is no guarantee that you personally will benefit from being in this research.

(*For research with no direct benefit*) You personally will not benefit directly from taking part in this research study.

Possible Benefits to Others

(*Address potential benefits to others*) The results of this research may guide future (*interventions, programs, procedures*) or lead to benefits to future (*students, staff, etc*).

CONFIDENTIALITY AND SECURITY

This section must outline the methods that will be used to protect the privacy of participants, including all confidential and private identifiable information and/or materials. This section also will address how participant information and materials will be treated, stored, and maintained and for what lengths of time, as well as how materials will be disposed of at the end of the study period. Privacy and confidentiality measures must be addressed in this section as outlined below.

1. Privacy and Confidentiality Measures

Example Statement of Confidentiality

Your research records that are reviewed, stored, and analyzed at *(location/institution)* will be kept in a secured area in (*list where records are stored*). (*If research will use indirect identifiers linked to individuals, such as pseudonym or codes, describe methods that will be used to ensure anonymity and*

confidentiality). The records may include (*list all that apply: a code number, your initials, date of birth, etc.)*. The list that matches your name with the code number will be kept in a locked file in *(note location, such as PI's office)*.

(If research records are sent outside your institution, describe methods that will be used to ensure confidentiality.) For research records sent to *(outside entity)*, you will not be identified by name, Social Security number, address, or phone number.

OR

For research records *(and specimens)* sent to *(outside entity)*, you will be identified by *(list all that apply: name, Social Security number, address, phone number, date of birth, any other direct personal identifier or code number, etc.)*. The list that matches your name with the code number will be kept in a locked file in *(note location, such as PI's office)*.

AND/OR

(audio, video, or photography) records of you will be reviewed by (*your institution and/or list any other external entities by name*). *Identify and describe how they will be used.*

(Remember to include separate descriptions for records if they are labeled differently, stored differently, or sent to separate entities.)

The following statement is considered mandatory for all research studies:

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

The following statement is for those studies that <u>do not</u> include section 2. The Use of Private Health Information.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, the following people or groups may inspect and copy records pertaining to this research to ensure compliance with human subjects research requirements:

- The JCPS Institutional Review Board.
- The Office of Human Research Protections in the U. S. Department of Health and Human Services *(for drug/device studies, add the U.S. Food and Drug Administration)* The *(location/institution)* Institutional Review Board *(a committee that reviews and approves research studies)*
- The *(location/institution)* Human Subjects Protection Office

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

If during the course of the study, *(you or your child)* disclose allegations of abuse or neglect, the researchers are legally obligated by Kentucky law to report those allegations to the Kentucky Cabinet for Health and Family Services.

2. The Use of Private Health Information

*This section is mandatory IF the research creates, obtains, uses, and/or discloses **identifiable** health information about the research participants. The 18 identifiers are listed under HIPAA regulations. Do not include any part of section 2. The Use of Private Health Information, unless the research fits the above criteria.*

Example Statement of Use of Private Health Information

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law, as explained in the (location/institution) Privacy Notice. If you have not received this notice, please request a copy from the investigator. At (location/institution) your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people or groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research, you must allow the study team to use your health information *(e.g., 504 plan*). If you do not want us to use your protected health information, you may not participate in this study. *(When specific therapy is only available through the research, include the following sentence.)* The research-related therapy is investigational; therefore, it is not available unless you allow the use of your health information that is collected during this research study.
(For blinded studies) People usually have a right to access their medical records. However, while the research is in progress, you may not be allowed to see or copy certain information that is related to this research study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

Your permission for the use, retention, and sharing of your identifiable health information will (*Describe the date or event that will trigger the expiration of this authorization, e.g., "expire upon completion of the research study" or "expire when FDA approval of the study drug is obtained" or "will continue for the period of time necessary for the preparation of a related follow-up research study" or "continue indefinitely" or "will continue until the NCCIH notifies the investigator that the information is no longer needed.").* At that time, the research information not already in your medical record will be destroyed (*or "will be retained until ___ in order to ___" or "information identifying you will be removed from such research results at (location/institution)").* Any research information already in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information at any time. You must do this in writing. Write to Dr. *(PI)* and let *(him/her)* know that you are withdrawing from the research study. *(His/Her)* mailing address (*or email address*) is *(address)*.

If you withdraw your permission:

- We will no longer use or share medical information about you *(if applicable, add the following:* or your samples) for this research study, except when the law allows us to do so
- We are unable to take back anything we have already done or any information we have already shared with your permission
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information:

- *(List any and all medical information collected from or about the participant in connection with this research study, e.g., blood and other tissue samples and related tests, your medical history as it relates to the research study, x-rays, MRIs, questionnaires, etc.)*
- *(Indicate the span of time from which the records are pulled, e.g., "since your asthma was diagnosed," "the last 5 years," or "only during the time span of the research study".)*

Representatives of the following people or groups within *(location/institution)* may use your health information and share it with other specific groups in connection with this research study.

- The principal investigator, *(Principal Investigator)*
- The *(location/institution)* Institutional Review Board
- The *(location/institution)* Human Subjects Protection Office
- *(If using the Investigational Drug Pharmacy)* The *(location/institution)* Pharmacy
- *(If applicable)* The *(location/institution)* Financial Analyst for Clinical Research
- *(List every other class of persons or groups **affiliated with** (location/institution) (e.g., the research team, the study coordinators, etc.) who might need to use and/or disclose the participant's information in connection with this study.)*

The above people or groups may share your health information with the following people or groups outside *(location/institution)* for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original *(location/institution)* records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- *(List every other class of persons or group **NOT affiliated with** your institution (e.g. fellow researchers in this study at (list other institutions), outside data analysts appointed for this study, the Data Safety Monitoring Board appointed for this study, the National Institutes of Health, the Food and Drug Administration, etc., to whom the participant's information might be disclosed.)*

- *(If the study is international)* Representatives from regulatory agencies in other countries may also review your research record, including research-related medical reports and information, along with NCCIH and/or the FDA.

If during the course of the study, (you or your child) disclose allegations of abuse or neglect, the researchers are legally obligated by Kentucky law to report those allegations to the Kentucky Cabinet for Health and Family Services.

COSTS FOR PARTICIPATION

This section discusses participants' research-related costs incurred and their compensation. If the participant incurs costs that may result from participation in the research, include a statement describing any additional costs associated with study participation.

Example Costs for Participation Section

To participate in this study, you may need to purchase basic supplies *(e.g., paper, pens*). The researcher, or supporting agency, will reimburse you for your costs based on standard rates for these expenditures not to exceed *($x.xx).*

(If the investigator institution has <u>not</u> agreed to cover costs of research-related expenses incurred by the participant, include this statement as a separate paragraph.) If you incur costs as a result of participating in this study (e.*g., paper, pens*), you will assume responsibility for these costs as a condition of your participation. You will not be reimbursed.

(End this section with the following statement.) You will not lose any legal rights by signing this form.

COMPENSATION FOR PARTICIPATION

This section should clearly describe any monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.).NOTE: JCPS policies and collective bargaining agreements may preclude staff from receiving monetary benefits in some circumstances. Refer to the JCPS Informed Consent Checklist for conditions.

Example of Compensation for Participation Section

You will be given $_____ on each visit to compensate you for time and expenses for participating in this study.

(Add this if participants do not receive any reimbursement for participation.) You will not receive any compensation for being in this research study.

RESEARCH FUNDING

This section discloses what grantors, institutions (e.g., SAMSHA, NIH), or companies are involved in the research through funding or grants (if none, say so). It also includes information about conflicts of interest, including any consultative or financial relationships the investigators may have with the

researcher or JCPS.

Example Research Funding Section

The institution and investigators are receiving a grant from *(list any grantors)* to support this project.

(For funding disclosure) The institution will be reimbursed by (*grantor*) for use of this site's facilities and for the work the research staff does for this research.

CONTACT INFORMATION FOR QUESTIONS OR CONCERNS

This section clarifies the participant's right to have questions answered. It also indicates a contact person in case of further questions about the research or to report a research-related issue, along with someone to contact regarding questions about participant rights and privacy issues.

Example Contact Information for Questions or Concerns Section

You have the right to ask any questions you may have about this research. If you have questions, complaints, or concerns or believe you may have developed an issue related to this research, contact *(Principal Investigator)* at *(phone number)*.

(All informed consent forms should include this paragraph). If you have questions regarding your rights as a research participant or you have concerns or general questions about the research *(add the next phrase if using identifiable health information:* or about your privacy and the use of your personal health information*)*, contact the research subjects protection advocate in the *(location/institution)* Subjects Protection Office at *(phone number)*. You may also call the JCPS IRB Chairperson at (502) 485-3036 if you cannot reach the research team or wish to talk to someone else.

For more information about participation in a research study and about your institutional review board (IRB), which is a group of people who review the research to protect your rights, please visit the JCPS IRB's website. You can access more information about your rights as a participant and the protection of human research participants here. If you do not have access to the Internet, copies of these Federal regulations are available by calling JCPS at 502-485-3036.

SIGNATURE AND CONSENT/PERMISSION TO BE IN THE RESEARCH

This section is required in all informed consent forms. It ensures that the participant has freely chosen to participate in the research and is free to withdraw at any time, without penalty. It also ensures that appropriate staff has thoroughly explained the research to the participant.

Example Signature and Consent/Permission To Be in the Research Section

Before making the decision regarding enrollment in this research, you should have:

- Discussed this study with an investigator
- Reviewed the information in this form
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research, and have received answers to those questions. You will receive a copy of the signed and dated form to keep for future reference.

Participant: By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

_____	_____	_____	_____
Signature of Participant	Date	Time	Printed Name

Participant's Legally Authorized Representative: By signing below, you indicate that you give permission for the student under 18 years of age to take part in this research.

_____	_____	_____	_____
Signature of Participant's Legally Authorized Representative	Date	Time	Printed Name

The signature of the participant's legally authorized representative is required for people unable to give consent for themselves.

Person Explaining the Research: Your signature below means that you have explained the research to the participant or participant representative and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

Only approved investigators for this research who fully understand the research and are authorized to explain the research and obtain informed consent.

A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.