# Guidelines for Conducting Research in Pinellas County Schools

## Department of Assessment, Accountability, and Research

### Introduction

Pinellas County Schools recognizes the value of educational research and its contribution to the field of education. The district also acknowledges the benefit of research in planning for the needs of students, measuring the effectiveness of programs and instruction, developing curriculum and instructional programs, and improving educational practice. Pinellas County Schools frequently receives requests from individuals and organizations to conduct research studies with students and/or their families, teachers, principals/administrators, and other school-based staff. While it is district policy to cooperate with researchers/study investigators whose projects might benefit education, all individuals and organizations interested in conducting research in the district must have their proposals reviewed by the Institutional Review Board (IRB) within the Department of Assessment, Accountability, and Research (AAR). Interested study investigators should contact the IRB prior to communication with district or school staff regarding study proposals or participation.

### Types of Research and Definitions

In order to be considered by the IRB, research must fit into one of four categories: 1) Academic Study, Presentation, or Publication (peer-reviewed journal or academic text); 2) MA Thesis or Ph.D./Ed.D. Dissertation/Degree Program; 3) State or National Study (other than reporting requirements mandated by the state or federal government); 4) Program Evaluation.

Research comprises various evaluation, measurement, and inquiry activities that include, but are not limited to:

- Systematic investigation (including, research development, testing and/or evaluation) designed to develop or contribute to general knowledge;
- Collecting and analyzing of information aimed at discovering new facts and their correct interpretation to draw conclusions;
- Quantitative and qualitative study activities such as observations, interviews, case studies, ethnographic analysis, analysis of written materials, secondary analysis of data, achievement testing, surveys, experimental designs to examine causal relationships, product testing, analysis of cost, and management records.

Researchers/Study Investigators include:

- Individuals not employed by PCS or agencies not contracted with PCS requesting to conduct research;
- Pinellas County Schools (PCS) staff requesting to conduct research for purposes or uses beyond their district role;
- Pinellas County Schools (PCS) staff planning to conducting research within their district role that involves collaboration with non-PCS partners or funding agencies.

Any research that involves human subjects requires IRB approval. A human subject is defined as: A living *individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual or 2) identifiable private information.*

*IRB approval does not guarantee that the research will be permitted within a particular school. Principals(s) of designated schools will ultimately accept or decline to participate in accordance with the procedure of the study. All research in schools must be done in cooperation with the principal or their appointed representative to ensure that the research is not disrupting existing school activities. Participation of teachers and students/families is voluntary.*

**Institutional Review Board and Research Proposals**
Research applicants are encouraged to contact AAR staff prior to finalizing the research plans to determine the feasibility of their proposed study in the district and to facilitate closer coordination between district requirements and their research efforts.

The IRB will review research proposals that meet the following approval criteria:

- The proposed research is compatible with PCS policy and must protect the privacy of all participants and ensure compliance with state and federal laws, including FERPA and PPRA;
- The research is consistent with district IRB policies.
- The proposed research has high value to a particular school or the school system as a whole, or will significantly contribute to the field of education, and/or benefits educators;
- The research design and methodology of the study including all data collection instruments is sound and uses valid and reliable techniques;
- The proposed research does not interfere with the educational programs of the district and is compatible with sound educational practice;
- The proposed research cannot be considered a burden to students, families, or staff. The benefits of the research must outweigh the costs, which include staff/student time and other resources. Evaluating whether the burden is considered excessive is the responsibility of the IRB. However, what is considered burdensome has very different values in different contexts, and ultimately participants will decide whether the cumulative burden on them is acceptable even if the study is IRB approved; The relative cost-benefit to the school district should be equitable.
- The district/school/staffs' tasks are clearly defined and delineated from the responsibilities of the researcher/study investigator. PCS staff, while serving as facilitators, will not assume responsibility for study recruitment, completion of any project, and/or for providing technical assistance;
- Subject/content is not considered to be controversial or inflammatory;
- The proposed research does not unduly interfere with instructional time or disrupt school activities, including local and state assessments. There must be minimal interference with school instruction/operations and relationships between students, parents, and school and district staff;
- The proposed research must document that the researcher or organization has the capacity and experience to successfully complete the project;

*These procedures and criteria are in place to protect students and staff of the district. While the district welcomes research studies, it is important to note that failure to adhere to district and IRB policy and procedures will result in denial of the application (proposal). Failure to abide by district and IRB policies will be sufficient cause for termination of any study previously approved.*

**Pinellas County School District Employees**

STUDENT/SCHOOL-BASED RESEARCH TO IMPROVE INSTRUCTIONAL PRACTICES:
Teachers may gather and analyze data at any time if the data are being used solely for the improvement of their own professional practice and if the collection of such data would be part of ordinary instructional procedures for their own students. Research of this nature should have the approval of the school principal, but does not require AAR IRB approval.

RESEARCH CONDUCTED AS PART OF A COLLEGE OR UNIVERSITY DEGREE PROGRAM OR CLASS:
Research conducted by PCS employees as part of a requirement for a class or degree program; involves a systematic investigation, including research development, testing and evaluation, designed to develop or to contribute to

generalizable knowledge; or is necessary to fulfill requirements for a master's thesis, doctoral dissertation, or other research requirements of a College or University requires AAR IRB approval.

ACADEMIC STUDY, PRESENTATION, OR PUBLICATION (PEER-REVIEWED JOURNAL OR ACADEMIC TEXT):
Research conducted by PCS employees that is not contracted, funded, or commissioned by Pinellas County Schools requires AAR IRB approval.

**Research Application**

Each research application must include:

- Abstract - please provide a brief, comprehensive summary of your research proposal indicating the purpose of the research, research questions, hypotheses (if applicable), description of research participants, research method(s), analytic approach, and implications.
- Rationale for the study - state clearly what you intend to accomplish with this research.
- Brief Literature Review/Theoretical Framework - please provide a brief statement of the theoretical basis for your study from prior published research (include reference citations in APA format) and what contribution your work is expected to make to your field.
- Research questions/hypotheses - please state briefly the research questions you plan to address, along with any necessary hypotheses.
- Sampling procedures - please describe, in detail, the target population (i.e. grade level, number of schools, specific schools, etc.), sampling frame, and selection procedures for the proposed research.
- Details of how study participants will be recruited for participation in the proposed research if applicable. To avoid any perceived coercion, any recruitment materials to participate in research/invitation to conduct research are to be printed on the researcher/study investigator's letterhead and may not indicate PCS sponsorship of the research study. Researchers may not ask principals to assist them in identifying and recruiting school staff to participate in their study. Researchers may request a meeting with school staff outside of instructional time, email school staff information about the study, or ask that recruitment materials be distributed in staff mailboxes with IRB approval and the principal's permission. School staff may choose not to participate in a research study, even though the study has been approved by the principal. Researchers may not ask administrators, teachers, or other school staff to assist them in identifying/recruiting students to participate in their study. Methods that can be used to recruit students include the distribution of materials for students to take home to review with their parent/guardian, scheduling meetings with student groups to describe the study, if instructional activities are not interrupted, and/or meeting with parent/guardian groups to describe the study. All of these approaches require IRB approval and the principal's permission.
- Attach draft copies of any forms, letters, and/or other documents that will be provided to participants or their parents/guardians.
- Attach draft copies of a letter of invitation to principals to conduct research in their schools (if applicable – this is for IRB review and should not be sent to principals prior to receiving preliminary determination).
- Data collection methodology (if applicable) - please describe the method of data collection and procedures you plan to use.
- Detailed secondary data request (if applicable) -please provide a detailed description of the variables you wish to include in your study, be as specific as possible. Please avoid broad or generic statements such as "demographic information" or "test results." Be sure to include schools, special programs, or departments, where applicable.
- Measures (if applicable) - please describe the instruments of measurement you plan to use. Please include results from pilot testing and/or other evidence for the validity of the instruments. For all research instruments that are not part of the district's existing assessment program, submit copies of the instruments.
- Analytic Plan - Please describe your anticipated analysis plan, including specifics regarding your treatment of the data, statistical or otherwise.

- Human subjects protections - Researchers/Study Investigators must provide detailed information explaining how the researcher will address privacy and confidentiality issues, any potential risks to participants, and how those risks will be mitigated.
- Please attach copies of informed consent forms that comply with Family Educational Rights and Privacy Act (FERPA) and Protection of Pupil Rights Amendment (PPRA) guidelines.
- Description of Incentives (if applicable) – please note that PCS does not permit the use of incentives with students or families (refreshments or token items such as a keychain are permitted). The use of drawings or a lottery system is prohibited for all research participants. Incentives for PCS staff are considered on a case-by-case basis (see pp 6-7 of this document for more information regarding incentives)
- Statement of Burden to the District - Please describe the burden that your research will have on the District – this applies for research with human subjects and secondary data requests. Depending on the research design, substantial time and effort may be required for staff to provide requested data with the appropriate selection and matching of records and concealment of personal identities. For proposals concerning human subjects research, the proposal will provide a clear rationale for the number of participants, the number of contacts, and the total time required by each participant. The research proposal will clearly state the number of participants, specifying the role of each group of participants. For example: Twenty math teachers in four schools will be observed, six principals will be interviewed, and forty students from five classrooms will be surveyed. The research proposal will clearly state the amount of time to be requested from each participant and when the interaction will occur. For example: Math teachers will be observed for four class sessions during the first two weeks in March.
- Statement of Benefit to the District - the proposal must identify the benefits that the research is expected to provide to the District.
- Data Procedures - please detail the data security and data disposal plan. Data security plans should outline how all hard copy and electronic data are securely stored to prevent unauthorized access, disclosure, or loss. Data disposal plans should outline when and how data collected in a study will be destroyed. Federal regulations require that research data and related documents such as consent forms be kept in a secure location for a minimum of three years.
- Submit PCS IRB forms - Form B if applicable and Form C (required). All forms requiring signatures are designed for electronic signatures. Directions for using electronic signatures are on the forms.
    - In most instances, the application should have a sponsor (Form B); a sponsor is someone who endorses the proposed research, deems it appropriate, believes it to be based on sound educational and research practices, and endorses its approval. The sponsor may be a college or university dean, the professor of record for a course, an agency director, or a Pinellas County Schools' administrator. University or Agency IRB approval is sufficient if the research applicant is a university faculty member or agency study investigator.
- Timeline of research - must include start and end date of all research activities and data collection and/or anticipated dates for delivery of secondary data. Researchers/study investigators should also clearly outline the amount of time necessary to complete data collection. Please note that if research activities exceed one year beyond date of proposal approval, an extension must be submitted to IRB.
- Current education on human subject research certificate (https://phrp.nihtraining.com/users/login.php)
- *Institutional review board (IRB) approval/exemption and a letter of support from the advisor or sponsor (if the proposal is associated with a college or university course or degree program) or authorization for the study (if it is associated with a government or private agency)

* Applicants may submit an initial application without University IRB approval attached to begin the review process; it is understood that a letter of support from PCS is needed to complete this process. The *Preliminary Determination Letter* will serve this purpose, however final PCS IRB approval will not be granted without this documentation on file.

**Consent**

The Federal Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA) are based on the premise that information about an individual student is private and confidential and generally may only be accessed with parent consent. Proposed research requiring student participation may require written parent/guardian consent prior to study activities commencing. Research requiring student participation may require written student assent in addition to written parent/guardian consent. Some research requiring staff participation may require written consent. The IRB will determine if consent/assent is required and whether passive or active is necessary.

Written consent is required in, but not limited to, the following circumstances:

- From active participants or from parents/guardians of students under the age of 18 years participating in research projects involving identified students or access to student records
- For student surveys or interviews if they include questions that reveal information referenced in Policy 2416 (see p. 4 for further information)
- From PCS staff, including teachers, who participate in research pursuant to PCS policies and or administrative procedures
- For studies that involve identified personnel or access to personnel records

If consent is required, all consent forms must:

- Use a conversational format that is easily understood by parents/guardians/participants;
- Identify the researcher(s) conducting the study (e.g., graduate student at a local University; National Evaluator, etc.) and include contact information so that the parent or participant may call if there are questions or concerns;
- The purpose(s) for collecting data;
- Information regarding confidentiality;
- A statement regarding participation being entirely voluntary and that participants may withdraw from the study at any time without consequence(s);
- The activities participants will be asked to complete (e.g., participate in a focus group with five other students, complete a survey online, complete a short reading assessment, etc.);
- If the participant will be audio- or video recorded and how privacy will be protected;
- The individual data requested of participants;
- The total amount of time required of the participant;
- Space for either consent or refusal to participate with signature line and date.
- Name, title, and telephone number of the Chair of the Institution's IRB, along with an invitation for participants to call regarding any concerns they have regarding participation in the research;
- Consent and assent forms may not indicate PCS sponsorship of the research study.

CONSENT FORM PROCEDURES - STUDENTS

- The researcher/study investigator will coordinate with school(s)/study site(s) and arrange for distribution and collection of parent/guardian consent forms;
- The parent/guardian consent form must be signed and collected prior to any involvement of a student in research;
- Failure to return the signed parent/guardian consent form will exclude the student from participating;
- Verification of parent/guardian signatures collected by the researcher or designated staff will be the responsibility of the school principal or research sponsor at study sites. The principal/sponsor will identify for PCS staff the students permitted to participate in the study;

- A copy of the signed parent/guardian consent form is to be filed in the student's cumulative folder;
- Parent/guardian consent forms must be made available in the parent's native language if the parent is not fluent in English. It is not acceptable to rely on the student to translate the information provided in the consent form to their parent/guardian(s).
- The researcher/study investigator will provide parent/guardian(s) with a copy of the signed consent form;
- The PCS IRB may request copies of signed consent forms from the researcher/study investigator at any time to ensure compliance

CONSENT FORM PROCEDURES – STAFF/FAMILIES

- The researcher/study investigator will coordinate with school(s)/study site(s) and arrange for distribution and collection of staff or family member consent forms;
- The consent form must be signed and collected prior to any involvement of staff or families in research;
- A copy of the signed consent form is to be filed with the principal/research sponsor;
- Parent/guardian consent forms must be made available in the parent's native language if the parent is not fluent in English. It is not acceptable to rely on the student to translate the information provided in the consent form to their parent/guardian(s);
- The researcher/study investigator will provide parent/guardian(s) with a copy of the signed consent form;
- The PCS IRB may request copies of signed consent forms from the researcher/study investigator at any time to ensure compliance.

Policy 2416

Researcher(s) must include in the application (proposal) a statement as to whether the research seeks to elicit information from students regarding any of the following eight areas specified in PCS Policy 2416. Written consent from parent/guardian must be obtained prior to eliciting the information for students under the age of 18. If the student is 18 years of age or older, the student may provide his/her own written consent before providing the information. Some studies may require parent/guardian consent and student assent.

- political affiliations or beliefs of the student or the student's parent;
- mental and psychological problems of the student or the student's family;
- sexual behavior or attitudes;
- illegal, anti-social, self-incriminating, or demeaning behavior;
- critical appraisals of other individuals with whom respondents have close family relationships;
- legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
- religious practices, affiliations, or beliefs of the student or student's parent;
- Income (other than that required by law to determined eligibility for participation in a program or before receiving financial assistance under such program).

Researchers/Study Investigators must include the following with their recruitment/consent materials if the proposed research seeks to elicit information from students regarding any of the eight areas specified in PCS Policy 2416.

*Participation Voluntary*

No student shall be required to participate in such a survey if the student (or the student's parent, if the student is less than eighteen (18) years of age), objects to participation.

*Right to Inspect*

A student (or the student's parent, if the student is less than eighteen (18) years of age), has the right to inspect any such survey instrument before the survey is administered or distributed to students if a request is made within a reasonable period of time. Parents also have the right to be advised of arrangements that will be made

to protect student privacy. Student survey instruments and teacher directions for administering the survey will be available at each participating school within a reasonable period of time prior to the survey administration.

*Failure to comply with all federal, state, and district policies around privacy and consent will result in an investigation by PCS and other appropriate authorities. The outcome of the investigation may lead to corrective action, suspension or termination of research, or other disciplinary actions.*

**Research Incentive Guidelines**

Students

Students may not receive direct compensation, rewards, or other incentives for participation in research conducted in Pinellas County Schools. Students may not earn extra credit or participation points for participation in research. Students may receive a small token foe their participation such as a keychain. Refreshments may be provided.

Parent/Guardian/Families

Parents, guardians, and family members of PCS students may not receive direct compensation, rewards, or other incentives for their participation in research conducted in Pinellas County Schools. Parents, guardians, and family members are permitted to receive a small token for participation such as a book. Refreshments may be provided.

Staff Members/Schools

PCS staff may receive incentives for their participation in research activities, amounts are considered on a case-by-case basis. The incentive must be offered to all persons recruited for the study. PCS teachers are not permitted to receive incentives for research participation during instructional time.

In-kind service to the school(s), or monetary donations to school funds are also acceptable forms of research incentives.

Compensation and/or incentives must be clearly stated in the research application and must be IRB approved prior to research activities being conducted.

*Methods used to recruit and compensate research participants must be free from coercion or undue influence, respect the privacy rights of prospective participants, and provide for their fair and unbiased selection. As with the informed consent process, research applicants/study investigators and the PCS IRB must consider the content, comprehensibility, and voluntariness of the methods used to recruit and compensate participants.*

**Letter of Invitation to Principals**

Approval by the PCS IRB does not guarantee access to any particular school, individual, or data source. Principal(s), or other PCS staff dependent on the research proposal, may choose that their school/program/staff/students not participate in the research, or may withdraw their school/program from participation at any time without any consequence. After the *Preliminary Determination Letter* has been issued, it is the researcher/study investigator's responsibility to reach out to principals or other appropriate PCS contacts to get required permissions before initiating a study. The AAR IRB committee will provide a PCS form (Form A) if applicable with the *Preliminary Determination Letter*. The researcher must provide the principal, or other relevant PCS staff, with a letter of invitation to participate in research and a copy of their *Preliminary Determination Letter*. Study investigators should not reach out to district staff until they have received preliminary determination.

The letter of invitation to the principal should outline the research design/methodology and provide enough information to assist the principal to make an informed decision about their school's participation. This would include what is most pertinent to the impact of the research on the school (including burden and benefits to students and staff), as well as the following:

- The researcher/study investigator's credentials;
- Rationale for selecting particular school(s);
- How research participants will be identified/recruited;
- Plan(s) for how to schedule data collection activities so as to not interfere with instructional time;
- Procedures for managing time commitment involved for staff and students;
- Detailed explanation regarding the use of school equipment (e.g., computers for taking surveys);
- Procedures for obtaining consent;
- Human subjects protections concerning confidentiality and anonymity and any possible risks/benefits of participation for research subjects;
- Intended uses of the research findings;
- If a study involves a randomized control trial (RCT), principal approval should be requested after randomization has taken place; principals should be informed of whether their school will be in the control or treatment group.

The letter of invitation should be included with the research application and will be reviewed by the AAR IRB committee as part of the review process.

*The principal is entitled to review the complete research application on file with AAR and to contact the department to discuss the proposed research.*

**Compliance**

Research conducted in PCS must comply with all federal, state, and district policies and procedures. All research activities, including data collection from or about individual students, parents, or staff, must comply with the following:

- The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of student education records. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. https://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html
- Protection of Pupil Rights Amendment (PPRA). The PPRA applies to the programs and activities of a State educational agency (SEA), local educational agency (LEA), or other recipient of funds under any program funded by the U.S. Department of Education. It governs the administration to students of a survey, analysis, or evaluation that concerns one or more of eight protected areas. https://www2.ed.gov/policy/gen/guid/fpco/ppra/modelnotification.html
- Florida Legislation regarding student records. See §§ 1002.22, 1002.221, and others, F.S. http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=1000-1099/1002/Sections/1002.22.html
- State Board Rules (6B-1.001 & 6B-1.006, F.A.C.) https://www.flrules.org/gateway/RuleNo.asp?ID=6B-1.001 https://www.flrules.org/gateway/ruleno.asp?id=6B-1.006
- Florida Department of Education Rules regarding the release of student records http://info.fldoe.org/docushare/dsweb/Get/Document-5134/releaserecords.pdf
- Florida Jessica Lunsford Act as described in Florida Statutes. See §§ 1012.465, .467, and .468, F.S. http://pcsb.schoolwires.net/Page/2781
- Pinellas County School Board Policy 2416 that is found in the "Code of Student Conduct."
- All researchers/study investigators must agree to maintain the anonymity of individual students, staff members and schools in any report(s) and in any presentations, publication(s), e.g., journal article(s), book(s), etc., which incorporate any information derived from the research conducted within Pinellas County Schools, unless expression permission from the Pinellas County School Board is otherwise provided.

**Application (Research Proposal) Submission Requirements**

The research applicant must submit a completed research application for review. The application is available online at www.pcsb.org/Page/2787 . The completed application and forms should be attached to an email addressed to Dr. Autumn Frei at freia@pcsb.org .

Completed applications and all requested documents must be received and approved by the IRB prior to any research being conducted. Any changes must be approved prior to being implemented. The researcher must provide a copy of all communication with principals, teachers, staff, families, and students throughout the study. Any adverse or unexpected events related to the research must be reported immediately to AAR (727-588-6253).

**APPLICATION REVIEW PROCESS**

All research proposals should be designed to answer informed research questions of educational importance using appropriate methodologies. Fundamentals of the research design, including the theoretical framework, hypotheses, sample selection, instruments, and proposed analyses are expected to support the goals of the research. It is the responsibility of the researcher to communicate these elements clearly in the proposal. Even research that imposes no risks may be rejected by the IRB if they judge it to be poorly designed, described, or justified.

The IRB reviews research proposals three times per calendar year. Applicants can expect a 4 to 6 week processing period after submission. Upon review of all submitted applications, applicants will be notified of next steps. Next steps could entail revisions, submission of additional documentation, and/or clarification of questions/concerns noted by the committee.

If the IRB committee approves the application, the committee will issue a *Preliminary Determination Letter*; this can be submitted to the applicant's university IRB (if applicable). The *Preliminary Determination Letter* will include the item(s) needed to complete the final approval process. No activities with human subjects (including, but not limited to, participant recruitment, pilot testing, surveys, etc.) may be conducted under the preliminary determination. Upon receipt of all items identified in the *Preliminary Determination Letter*, the PCS IRB committee will issue a *Final Approval Letter* that allows data collection for the study to begin.

An application should be submitted well in advance of the proposed research start date (see deadlines - https://www.pcsb.org/Page/2787 ). This ensures adequate time for review, possible modifications, contacting principals and/or other PCS staff, and obtaining final approvals from PCS and the research applicant's IRB. The proposed research start date, listed in the application, must allow for the IRB processing time.

Approval is valid for one year from the date of the approval letter. You may propose a multi-year study. Independent of how long your study takes to complete, you will be asked to submit an annual update. This update would consist of a summary of findings if the study is at completion or a request for an extension should the study need to continue beyond one year. So long as no substantive changes are made to the original proposal for a multi-year study, approval may be renewed via the annual update without the need for a revised proposal to be submitted each year. Form A will need to be completed each year.

*AAR IRB approval does not impose any obligation on any person, school, or office to cooperate with researchers/study investigators. An approval letter indicates that the proposal has met the IRB requirements; however, it does NOT commit school(s), staff, or students/families to participate. Principals(s) of designated schools will ultimately accept or decline to participate in accordance with the procedure of the study. All research in schools must be done in cooperation with the principal or their appointed representative to ensure that the research is not disrupting existing school activities. Participation of teachers and students/families is voluntary.*

Upon completion of the research study, researchers/study investigators are responsible for supplying the Office of Assessment, Accountability, and Research with a written summary of their findings. AAR reserves the right to provide input that the author will consider prior to dissemination of the results. In addition, if the anonymity of participant(s), school(s), or the district is compromised, AAR reserves the right to restrict dissemination of the results. Any publications resulting from the research including journal articles, book chapter, or dissertation must be submitted to AAR promptly. Researchers/study investigators may be requested to report detailed research findings to interested school personnel at a meeting arranged by AAR.

**Continuing Review Process**

The PCS IRB requires continuing review at intervals appropriate to the specific research, but at least once during the period of approval.

Revisions, modifications, and continuing review applications are reviewed on a rolling basis, in the order they are received. Applicants can expect a decision within 30 days after materials are received. Materials should be submitted at least 45 days prior to anticipated commencement of modified research activities, or 45 days before your current approval to conduct research expires.