DoDEA Administrative Instruction 1304.01

Research Request Program

Originating Division:	Performance and Accountability
Effective:	September 4, 2018
Releasability:	Cleared for public release. Available on the DoDEA Policy Webpage.
Incorporates and cancels:	DoDEA Administrative Instruction 2071.3, "Research Approval Process," June 27, 2008 DDESS Memorandum, "Data Collection Approval Process-Military Community Request," October 25, 2006
Approved by:	Thomas M. Brady, Director

Purpose: This Issuance establishes policy, assigns responsibilities, and provides directions for the approval and monitoring of research studies involving Department of Defense Education Activity (DoDEA) personnel, facilities, students, sponsors, and/or data. This Issuance is established in accordance with DoD Instruction 3210.7; DoD Instruction 3216.02; DoD Instruction 8910.01; Part 219 of Title 32, Code of Federal Regulations; Subparts B, C, and D of Part 46 of Title 45, Code of Federal Regulations; Executive Office of the President, "Federal Policy on Research Misconduct; Preamble for Research Misconduct Policy located in Federal Register at pages 76260-76264 of Volume 65; Section 980 of Title 10, United States Code; Sections 3501-3520 of Title 44, United States Code; and Section 552a of Title 5, United States Code.

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SECTION 1: GENERAL ISSUANCE INFORMATION

1.1. APPLICABILITY.

a. This Issuance applies to the Office of the Director, DoDEA; the Principal Deputy Director and Associate Director for Academics, DoDEA; the Associate Director for Financial and Business Operations, DoDEA; the Chief of Staff, DoDEA; the Director for Student Excellence, DoDEA Americas/Associate Director for Performance and Accountability (formerly the Director, Domestic Dependent Elementary and Secondary Schools, and Department of Defense Dependents Schools, Cuba (DDESS/DoDDS-Cuba)); the Director for Student Excellence, DoDEA Europe (formerly the Director, Department of Defense Dependents Schools, Europe (DoDDS-E)); the Director for Student Excellence, DoDEA Pacific (formerly the Director, Department of Defense Dependents Schools, Pacific, and Domestic Dependent Elementary and Secondary Schools, Guam (DoDDS-P/DDESS-Guam)); (referred to collectively in this issuance as "DoDEA Region Directors for Student Excellence"); and all DoDEA region, district, community, and school leaders and support staff.

b. This Issuance applies to any individual(s) or organization(s) who wish to propose data collection activities and/or research studies that involve DoDEA personnel, facilities, sponsors, students and/or data not publicly available.

1.2. POLICY.

a. The purpose of research in DoDEA is to improve the outcomes of DoDEA students.

b. All research conducted in the DoDEA school system shall adhere to recognized ethical standards of conduct.

c. All research involving human subjects shall comply with DoD Instruction 3216.02 and Part 219 of Title 32, Code of Federal Regulations.

d. DoDEA will only accept and support research studies that meet the criteria for exempt human subjects research in accordance with Part 219 of Title 32, Code of Federal Regulations, and Part 46 of Title 45, Code of Federal Regulations, as applicable.

e. All research conducted in the DoDEA school system by DoDEA employees, and/or by private organizations, individuals, or institutions, that is not being done on behalf of DoDEA (e.g., has not been assigned and is not being done as part of regular and expected job responsibilities), shall follow the approval procedures provided in this Issuance.

f. All research by DoDEA employees and/or individuals that is being conducted for the purpose of completing course work and/or other requirements related to degree attainment shall follow the approval procedures provided in this Issuance.

g. All research conducted in the DoDEA school system shall not unduly affect the students or employees of DoDEA as an organization by minimizing the research burden and disruption to instructional time.

h. All research conducted in DoDEA shall meet professional standards for research design and will produce information that is relevant and useful to DoDEA.

i. Permission to conduct research does not constitute the commitment of resources or endorsement of the study or its findings by DoDEA.

j. DoDEA has the right to request and inspect data sets and any supporting documentation that are generated by research projects approved under this Issuance as part of routine audits of approved research projects and/or to investigate suspected cases of research misconduct.

1.3. INFORMATION COLLECTION. This Issuance may result in the collection of information due to its policy and procedures. Any collection of information must follow all applicable Federal, DoD, and DoDEA regulations, policies, and guidance.

SECTION 2: RESPONSIBILITIES

2.1. DODEA DIRECTOR. The DoDEA Director:

a. Establishes and oversees DoDEA policies and procedures.

b. Suspends or terminates approval of research.

c. Establishes and maintains a Human Research Protection Program (HRPP) in compliance with DoD Instruction 3216.02 and Part 219 of Title 32, Code of Federal Regulations.

d. Establishes and maintains a Research Integrity and Misconduct Program in accordance with DoD Instruction 3210.7.

2.2. DODEA ASSOCIATE DIRECTOR FOR PERFORMANCE AND ACCOUNTABILITY. The DoDEA Associate Director for Performance and Accountability:

a. Oversees DoDEA's implementation of Federal assurances of compliance regarding the protection of human subjects.

b. Establishes procedures and standards related to the identification, investigation, and adjudication of reports of research misconduct in accordance with DoD Instruction 3210.7.

c. Reports promptly to the DoDEA Director any inquiries being made into reports or suspected incidences of research misconduct.

2.3. DODEA CHIEF OF RESEARCH, ACCOUNTABILITY, AND EVALUATION. The DoDEA Chief of Research, Accountability, and Evaluation:

a. Monitors and communicates policy, ethical standards, and approval processes for research conducted in DoDEA.

b. Oversees DoDEA's procedures concerning reports of research misconduct, the investigation of research misconduct, and the adjudication of research misconduct in accordance with DoD Instruction 3210.7.

c. Reports promptly to the Component Headquarters (CHQ), the Institutional Review Board (IRB) of record, and the DoDEA Associate Director for Performance and Accountability any inquiries being made into reports or suspected incidences of research misconduct.

d. Chairs and forms an appeals committee in order to review and respond to all letters of appeal relating to decisions to disapprove research proposals.

e. Appoints a DoDEA Human Research Protections Official.

2.4. DODEA HUMAN RESEARCH PROTECTIONS OFFICIAL. The DoDEA Human Research Protections Official (HRPO):

a. Monitors and communicates policy, ethical standards, and approval processes for research conducted in DoDEA.

b. Grants or denies permission for all research requests which are otherwise in compliance with this Issuance.

c. Ensures that researchers understand their responsibilities under this Issuance.

d. Coordinates and oversees a review committee to review all research requests.

e. Informs researchers in writing of the results of the review process.

f. Configures and maintains the DoDEA research request webpage and electronic submission system.

g. Reports promptly to the DoDEA Chief of Research, Accountability, and Evaluation and IRB of record any unanticipated problems involving risks to subjects or others, any serious or continuing noncompliance with this Issuance, the requirements or determinations of the IRB, or any suspension or termination of approvals to conduct research.

h. Reports promptly to the DoDEA Chief of Research, Accountability, and Evaluation any reports of or suspected incidences of research misconduct.

2.5. DODEA REGION DIRECTORS FOR STUDENT EXCELLENCE. The DoDEA Region Directors for Student Excellence:

a. Approve and deny the participation of their region in DoDEA HRPO approved research studies.

b. Report any suspected cases of research misconduct, unanticipated problems involving risks to subjects, or noncompliance with this Issuance to the DoDEA Chief of Research, Accountability, and Evaluation and the DoDEA HRPO.

2.6. DODEA DISTRICT SUPERINTENDENTS. The DoDEA District Superintendents:

a. Approve or deny the participation of their district in DoDEA HRPO approved research studies.

b. Report any suspected cases of research misconduct, unanticipated problems involving risks to subjects, or noncompliance with this Issuance to the DoDEA Chief of Research, Accountability, and Evaluation and the DoDEA HRPO.

2.7. DODEA PRINCIPALS. The DoDEA Principals:

a. Approve or deny the participation of their schools in DoDEA HRPO approved research studies.

b. Report any suspected cases of research misconduct, unanticipated problems involving risks to subjects, or noncompliance with this Issuance to the DoDEA Chief of Research, Accountability, and Evaluation and the DoDEA HRPO.

SECTION 3: RESEARCH REQUESTS

3.1. RESEARCH REQUESTS.

a. General Provisions. All individuals or organizations who wish to conduct research in the DoDEA school system must submit a research proposal application that will be reviewed by the DoDEA HRPO and the research review committee. Researchers must receive written authorization from the DoDEA HRPO to conduct research before beginning any data collection efforts.

(1) Research Request Prioritization: Research studies must demonstrate that they will be of benefit to DoDEA and that the research results will be useful for informing DoDEA priorities, goals, projects and/or policies. Research requests will be accepted and reviewed based on the following criteria:

(a) Adherence to ethical standards of research in accordance with DoD Instruction 3210.7; DoD Instruction 3216.02; DoD Instruction 8910.01; Part 219 of Title 32, Code of Federal Regulations; Subparts B, C, and D of Part 46 of Title 45, Code of Federal Regulations; Executive Office of President, "Federal Policy on Research Misconduct; Preamble for Research Misconduct Policy"; Section 980 of Title 10, United States Code; Sections 3501-3520 of Title 44, United States Code; and Section 552a of Title 5, United States Code.

(b) Alignment to research priorities established and posted on the DoDEA Research Requests website, updated annually on or by July 1.

(c) Minimization of disruption to instructional time, the time required for participants in participating in data collection activities, and the burden for staff in supporting or overseeing data collection activities.

(d) Methodological rigor, which includes:

1. An explanation of the questions and/or issues being investigated, to include background literature and/or context for why the study should address these questions and/or issues and how the results of the study will contribute to overall knowledge on the research topic.

2. Clear reasoning on why the research methods and analytical procedures used in the research study will result in producing the evidence necessary to answer the research questions and/or issues. This should include rationale for why the analytical methods being used are appropriate for the study and details on how data will be analyzed that will answer the research questions while removing potential confounding factors or bias. In addition, the analytical procedures should include a discussion of the research assumptions and limitations and should provide justification for collecting the data in support of the research study.

3. The rationale for selection of study participants, data sources and/or data collection instruments and details on research procedures that would allow other researchers to reproduce the research studies methods and results.

(2) Individuals or organizations that are given permission to conduct research studies in DoDEA shall abide by professional conduct at all time. Failure to do so will be sufficient cause for DoDEA to revoke permission to conduct research.

(3) Research that receives written Activity approval from the DoDEA HRPO only allows the researcher to proceed with the research as described and data collected may only be used for the approved purposes. The Activity approval of research studies is not an endorsement of the research by DoDEA and does not compel any personnel, students, or sponsors of the DoDEA system to participate in research studies. All participation in research studies is strictly voluntary.

(4) Researchers shall contact the DoDEA HRPO, in writing, if there are any changes to the study that was given Activity approval prior to continuing with the study. This includes changes to the study protocol, stopping the study for any reasons, adding or deleting parts of the study, requesting additional data, changes in participants, etc. Substantive changes to the research study will require a new research proposal submission and will necessitate an additional review of the research study by DoDEA HRPO, the research review committee, and the researchers IRB.

(5) Researchers may not contact any potential participants to discuss their research study or ask for consent for participation until after written authorization to conduct the research study is received from the DoDEA HRPO.

(6) All activities related to the collection of data from DoDEA employees or sponsors must occur outside of the normal duty day. Researchers may not collect data or conduct research while the researcher is being paid as part of their official duty day as a DoDEA employee. If approved to conduct research during the duty day, the researcher must be in non-pay (leave) status.

(7) Researchers shall provide the DoDEA HRPO with a draft copy of any written reports or other written products that result from the research ten (10) business days before they are to be finalized. The DoDEA HRPO will conduct a review of these documents to ensure that data reported in these documents are in compliance with this Issuance and the research approval granted.

(8) Researchers will be allowed to submit a research study for approval three (3) times. If, after the third submission, the research study is still not able to be granted approval, the researcher must wait one (1) year before submitting any research studies for approval.

(9) Research studies may be limited during the first or last two (2) weeks of the school year, or during the two (2) weeks before or after the winter break, for the specific school(s) or district(s) that are impacted by the research study. DoDEA has the right to make additional determinations about dates for when research studies may not be conducted.

b. Submission of Proposals. Research proposals will be submitted electronically, either by submitting approved research request forms via email or through use of an online submission system. Research request forms and/or directions on how to access to an electronic submission system and a research proposal submission checklist will be available on the DoDEA webpage.

A complete research proposal will include all research forms as well as any additional documentation as specified in this Issuance or otherwise requested by the DoDEA HRPO.

c. Collaborative Institutional Training Initiative Requirement. All individuals conducting research within DoD agencies are required to complete annual training in the protection of human subjects in accordance with the guidance in the August 16, 2012, Assistant Secretary of Defense Memorandum.

(1) Researchers shall complete training in the protection of human subjects appropriate for their role in the research study through the online Collaborative Institutional Training Initiative (CITI) by affiliating with the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)).

(2) The CITI training must be completed before submitting a research request to DoDEA and must have been completed within one (1) year before research proposal submission.

(3) The researcher must provide documentation of completion of the CITI training with his/her research proposal application.

(4) The DoDEA HRPO will verify that CITI training has been completed before processing a research request.

d. Research Sponsor for Student Research. All research and data collection activities that are being conducted for course credit or for completion of a degree require a research sponsor.

(1) Research Sponsor Requirements.

(a) The research sponsor must have demonstrated experience in conducting and overseeing research studies.

(b) DoDEA administrators, teachers, or other staff may serve as the research sponsor when appropriate.

(c) Research requests related to the completion of course work and/or other requirements related to completion of a degree program must have a College or University affiliated sponsor.

(2) Documentation of Research Sponsor.

(a) The researcher must submit a letter of support, signed by the research sponsor that includes:

1. The name of the researcher and the title of the proposed research study.

2. A statement of support for the research study.

3. Acknowledgement of what participation in the research study would entail.

4. A statement that the research proposal has been reviewed and the methodology is rigorous and appropriate.

5. Acknowledgement that the research sponsor has read DoDEA's research request policy and that the proposed study meets the requirements of this Issuance.

6. A statement that the research sponsor acknowledges and accepts responsibility for ensuring the security of data collected as part of the research study along with ensuring that the provisions of this Issuance are followed.

(b) The researcher must also submit a copy of their research sponsor's resume or curriculum vitae along with documentation of CITI training in the protection of human subjects with the letter of support. The research sponsor's resume or curriculum vitae must show that he or she has had experience in conducting and overseeing research studies.

e. Research Studies Not Considered for Approval. The following types of research studies or data collections will not be considered for approval:

(1) Any research study or data collection that has more than minimal risk.

(2) Any research study or data collection that violates ethical standards.

(3) Any research study or data collection that is not considered exempt human subjects research in accordance with Part 219 of Title 32, Code of Federal Regulations, and Part 46 of Title 45, Code of Federal Regulations, as applicable.

(4) Any research study or data collection that relies on an experimental design where a group of students is denied services.

(5) Research studies or data collections that intend to replace in whole, or in part, DoDEA's adopted curriculum for any subject area.

(6) Research studies or data collections that will not be of use to DoDEA for the purpose of providing data, information, and actionable insight about programs, policies or procedures through the rigorous examination of at least one (1) of DoDEA's specified research priorities.

(7) Research studies or data collections that do not meet the criteria for methodological rigor as specified in this Issuance.

(8) Research studies that duplicate data collection activities that are in process or have already been completed.

(9) Research studies that do not fully comply with the criteria set forth in this Issuance.

f. Identification of DoDEA. The identity of specific military installations, the names or locations of the schools, the names or locations of the districts, or the name of the school system (DoDEA, DoDEA Americas, DoDEA Europe, DoDEA Pacific) or any language that specifically

identifies DoDEA shall not be used in any written materials generated in relationship to research studies or data collection activities that are approved under this research Issuance.

3.2. INFORMED CONSENT AND ASSENT.

a. Consent Requirements. Informed consent and/or assent is required for all research studies conducted in DoDEA that involve human interaction between the researcher and/or the researcher's designee and research participants, where the research participants may be personally identified and/or where the research participants are actively engaged in the research study. Researchers shall obtain written consent from all research participants ages eighteen (18) and older. For research studies involving children under the age of eighteen (18) (student participants), researchers shall obtain written consent from a parent or legal guardian providing permission for their child to participate in the research study, along with written assent from the child to participate in the research. Informed consent and assent, at a minimum, must include the following elements:

(1) Purpose of the study.

(2) What participants are being asked to do as part of the study.

(3) Estimated amount of time required to participate in the study.

(4) Risks and benefits of participating in the study.

(5) Privacy and/or confidentiality statements.

(6) Statement of voluntary participation, including that participants may withdraw from the study at any time and instructions on how to withdraw from the study.

(7) Information about remuneration, if applicable.

(8) Contact information for questions about the research study.

b. Active Consent and/or Assent. DoDEA requires active consent for participation in research studies.

c. Passive Consent and/or Assent. DoDEA will not approve any research requests that employ passive consent for participation in research.

d. Informed Consent and Assent for Research Involving Students. Research studies involving student participants (children under the age of 18) shall obtain active consent from a parent or legal guardian providing permission for their child to participate in the research study. In addition, researchers shall obtain active child assent to participate in the research.

(1) Child assent forms must include all of the elements included in Section 3.2.(a) of this Issuance, and should be worded appropriately for the child's developmental level.

(2) Child assent will only be collected after parent consent has been granted.

(3) Child assent forms should indicate that the child's parent has provided permission for their participation in the study and that the child also has the right to decide if they do or do not want to take part in the research.

3.3. INSTITUTIONAL REVIEW BOARD. Documentation of IRB review and approval by the researcher's institution is required for all research activities covered under this Issuance.

a. General Provisions. The researcher shall ensure that an IRB review of the proposed research is conducted by his or her respective university or branch of the military prior to submitting the research proposal to DoDEA. If no university or military IRB review is available, the researcher will seek an IRB review through an independent IRB with an approved assurance.

(1) If the IRB requires conditional approval for the research project from the DoDEA HRPO before they will review the research project, documentation establishing this, in the form of official IRB guidance, or an official letter must be provided to the DoDEA HRPO as part of the research proposal package.

(2) A determination by the institutional IRB that the research study is exempt does not exempt the study from a full review by DoDEA. Research activities may not begin until the researcher has provided documentation of IRB review to the DoDEA HRPO and the DoDEA HRPO issues a letter providing authorization to begin research efforts.

b. IRB Documentation Requirements. The DoDEA HRPO must be provided the following IRB documents before a final letter of support for the research study will be issued.

(1) A copy of the IRB application that was submitted and approved, along with any requests for revisions and responses to those that were submitted to the IRB. The IRB application provided must include the data security plan and any forms that were submitted as part of the application.

(2) A certificate or letter that states that IRB approval for the proposed study has been granted and that includes contact information for the accredited research affiliate. The certificate or letter must be on official letterhead. The letter must include documentation of the type of review that was conducted and the human subject's research exemption category the study was approved under.

3.4. RESEARCH INVOLVING THE COLLECTION OF SURVEY, INTERVIEW, OR FOCUS GROUP DATA. In order to reduce the burden and to minimize participant response fatigue, research studies that intend to use survey, interview or focus group protocols, shall adhere to the following guidance in addition to the guidance otherwise specified in this Issuance:

a. General Requirements. Research studies that intend to use survey, interview, or focus group protocols must not place an undue burden upon research participants or significantly impact instructional time.

(1) Research studies that intend to use survey, interview, or focus group protocols involving DoDEA employees. Survey, interview, or focus group data collection activities requiring the participation of DoDEA employees must occur outside of the normal duty day. DoDEA employees may not use duty time to respond to surveys or to participate in interviews or focus groups. In general, surveys should be able to be completed in fifteen (15) minutes or less, and interviews and focus groups should take no more than thirty (30) minutes.

(2) Research studies that intend to use survey, interview, or focus group protocols involving DoDEA students:

(a) Survey, interview, or focus group protocols for use with student populations must be written at the appropriate developmental level for the student population that will be included in the research study.

(b) Student surveys should include no more than fifteen (15) items and may take no more than ten (10) minutes to complete.

(c) Interview and focus group research protocols involving students should not ask more than five (5) questions and should take no more than twenty (20) minutes to complete.

(3) Collection of Personal Identifiable Information should adhere to the following guidelines:

(a) Participants may not be audio or video recorded or their images otherwise captured when participating in surveys, interviews, and/or focus groups.

(b) Participants may not be asked to provide their name, school or duty location, email address, phone number, or other potentially personally identifiable information as part of any research study that uses survey, interview, or focus group protocols in order to preserve anonymity.

b. Sensitive Topics. Survey, interview, or focus group protocols that ask participants to respond to questions about sensitive topics, including questions asking about mental health, illegal or anti-social behaviors, and sexual orientation, are not permitted for use in research studies that are governed by this Issuance and will not be approved.

c. Duplication. Research studies that propose to collect survey, interview, or focus group data that duplicate data collected by existing research will not be approved.

d. Data Collection Tools for Survey Research. Surveys may be administered as either paper forms or electronically. Surveys that are conducted electronically must be administered through an application that supports participant anonymity. The use of DoDEA applications or programs may not be used to administer surveys since survey data may be linked to participant's names, email addresses, or other identifying information.

e. Additional Reviews for Survey, Interview, and Focus Group Research. Additional reviews and approvals, external to DoDEA, for survey, interview, or focus group research studies may be necessary depending on the population included in the research study.

Researchers will be informed, in writing, by the DoDEA HRPO if their research study requires external review and approval. External review and approval of survey, interview, and focus group research does not exempt the study from a full review by DoDEA. Survey, interview, or focus group research projects will not be approved and may not begin until the researcher has provided written approvals from the external reviewers to the DoDEA HRPO and the DoDEA HRPO issues a letter providing authorization to begin research efforts.

3.5. REMUNERATION FOR PARTICIPATION IN RESEARCH. Researchers may offer remuneration to research participants as long as the value of the remuneration offered does not unduly influence the participant's ability to decline to participate in the research study (e.g., the value of the remuneration creates an incentive to participate in the study). DoDEA employees can be offered remuneration for their participation in research as long as the research activities occur completely outside of their normal duty day.

3.6. RESEARCH INTEGRITY AND MISCONDUCT. DoDEA expects all researchers to adhere to ethical and professional research principals and standards. In addition, DoDEA will not tolerate intentional or reckless fabrication, falsification, or plagiarism when proposing, performing, and/or reporting research results. DoDEA will adhere to the research integrity and misconduct policy specified in DoD Instruction 3210.7 and with the procedures for how to implement and comply with DoD Instruction 3210.7, as specified in the January 29, 2018 OUSD(P&R) Memorandum.

SECTION 4: REVIEW AND APPROVAL PROCESS

4.1. RESEARCH PROPOSAL SUBMISSIONS. Individuals and organizations who wish to conduct research studies in DoDEA that are controlled by this Issuance must submit a research proposal application for review. Research and data collections activities are not allowed to begin until after the research documents have been reviewed and written authorization to begin research activities has been granted by the DoDEA HRPO.

a. Research Proposal Submission. All research requests must be submitted as specified in this Issuance. Incomplete proposals will not be reviewed.

b. Submission Deadline. All research requests must be submitted by the deadlines specified in this Issuance. There will be no exceptions made to the review schedule as specified in this Issuance.

4.2. RESEARCH REVIEW PROCESS.

a. Initial Review. The DoDEA HRPO will be the first to review research submissions for completeness and to ensure they are in compliance with the responsibilities outlined in this Issuance. The DoDEA HRPO will review research submissions for completeness and to ensure they are in compliance with this Issuance within five (5) business days of receipt of a research proposal submission. Incomplete submissions or submissions found to be out of compliance with this Issuance will be returned to the researcher without further action from DoDEA. The researcher may correct any deficiencies and resubmit their research proposal for review.

b. Approval Pathways. Upon receipt of a complete research proposal, the DoDEA HRPO will make a determination about the approval pathway for the research study and will inform the researcher, in writing, which pathway their study is in and when the review of their proposal will be conducted, per the schedule set forth in this Issuance. There will be no exceptions made to the review schedule as specified in this Issuance. Researchers will be informed of their review date within five (5) business days of receipt of a complete research package.

(1) Pathway One: Secondary data analysis. Research proposals that rely solely on the request of existing, de-identified, data for the completion of the research study shall be considered Pathway One research studies. The research committee will meet to review and evaluate Pathway One studies twelve (12) times annually, by the fifth business day of each month, assuming the submission deadline was met. Research proposals in this pathway may take two (2) to three (3) months for the review process to be completed and authorization to conduct research granted. Researchers who wish to only request existing, de-identified, data for their research project are encouraged to submit their proposal ninety (90) days before they intend to begin their research in order to allow for sufficient time for the review process.

(2) Pathway Two: Original data collection with no instructional impact. Research proposals that rely on original data collection and/or collection of data through the use of classroom observations, survey, interview, or focus group protocols shall be considered to be

Pathway Two research studies. The research committee will meet to review and evaluate Pathway Two studies four (4) times annually, by the fifth business day of February, May, August, and November, assuming the submission deadline was met. Research proposals in this pathway may take four (4) to six (6) months for the review process to be complete and authorization to conduct research granted. Researchers who wish to conduct a study in this pathway are encouraged to submit their proposal 150 (one hundred and fifty) days before they intend to begin their research in order to allow for sufficient time for the review process.

(3) Pathway Three: Original data collection impacting instructional time and/or involving student participation. Research proposals that rely on original data collection that includes a research design where there will be control and experimental groups established, where there will be a significant impact on instructional time, where DoDEA students or children under the age of 18 (eighteen) will be included in the research study, and/or where the research intends to study persons in a protected research population shall be considered to be Pathway Three research studies. The research committee will meet to review and evaluate Pathway Three studies two (2) times annually, by the fifth business day of June and December, assuming the submission deadline was met. Research proposals in this pathway may take six (6) to twelve (12) months for the review process to be complete and authorization to conduct research granted. Researchers who wish to conduct a study in this pathway are encouraged to submit their proposal at least 250 (two hundred and fifty) days before they intend to begin their research in order to allow for sufficient time for the review process.

(4) Additional or rescheduled review dates. The DoDEA HRPO may specify an additional review day in any given month if the volume of requests scheduled for review necessitates it. In addition, the DoDEA HRPO may specify that the regular review date be rescheduled if there are scheduling conflicts that prevent the review committee from meeting on the regular date of review. The additional or rescheduled review day will take place on or before the tenth business day of the month and researchers will be informed, in writing, of the specific date of review.

(5) Notification of review committee determination of research study. The researcher shall be informed, in writing, by the DoDEA HRPO of the results of the research committee review within five (5) business days of the research review meeting date. Researchers will be informed of the research committee's decision to either approve the proposal as submitted, require the researcher to clarify or modify the proposal, or not approve the proposal. If, upon review, the committee has determined that the research proposal cannot be approved, the researcher will be provided details on the questions and/or concerns the committee has with the proposed study in order to provide a response and amend the original research protocol.

(6) Re-review of research studies. Research studies that are denied permission to be conducted in DoDEA may be resubmitted for review by following the same submission guidelines as specified in Section 4.1.b.(1), of this Issuance. The review of proposal resubmissions will occur twelve (12) times a year, by the fifth business day of each month. Researchers may submit a proposal for review three (3) times. If, after the third review, the research proposal cannot be accepted, the researcher must wait one (1) year before submitting another research proposal for consideration.

c. Review Committee. The research review committee shall adhere to the following guidance:

(1) The research review committee shall be comprised of DoDEA employees who have had experience with conducting research studies, who have knowledge of research and methodological procedures, and/or who have the necessary content knowledge to review proposals for adequacy.

(2) The research review committee shall be comprised of at least three (3) members, including the DoDEA HRPO.

(3) The DoDEA HRPO may recuse committee members for participating in a review of a research proposal if it is found that reviewing the proposal might constitute a conflict of interests (e.g., committee member has a personal relationship with the researcher, the committee member has helped advise the research study in some form) that would prevent an unbiased review of the research proposal.

(4) If the DoDEA HRPO needs to be recused from the review of a study, the DoDEA Chief of Research, Accountability, and Evaluation will serve on the committee in his or her place.

4.3. CONTINUING REVIEW OF APPROVED RESEARCH PROJECTS. Approved research projects that are still in process will be subject to continuing review by the DoDEA HRPO and the research review committee at the time of expiration of IRB approval of the research study. Continuing review meetings of research projects will occur twelve (12) times annually, by the tenth business day of each month, as necessary. Researchers will be notified by the DoDEA HRPO, in writing, of the date their research project will be subject to a continuing review, and will be provided with a list of materials and information necessary for the review, at least six (6) weeks prior to the scheduled continuing review meeting. Researchers are responsible for submitting all requested materials and information for continuing review two (2) weeks prior to the scheduled continuing review meeting.

4.4. APPEALS. Researchers have the right to request reconsideration of a research review committee's decision to deny a research project. Exceptions to the appeals process as specified in this Issuance will not be granted.

a. Basis for Appeals. Reconsideration of a research review committee's decision will be made if the researcher can provide evidence that the review process did not occur in accordance with this Issuance and/or that the decision to deny the research project is not supported by the standards set forth in this Issuance.

b. Appeals Process.

(1) Appeals Submission. Appeals must be made, in writing, to the DoDEA Chief of Education Research, Evaluation, and Accountability within twenty (20) business days of receipt of the final decision letter from the DoDEA HRPO. The appeal must clearly state the grounds

upon which the appeal is being filed. It is the sole responsibility of the researcher to include all evidence and supporting documentation that forms the basis of the request for reconsideration at the time of submission. The appeals package must include a written letter of support for the appeal from the research sponsor.

(2) Appeals Committee. The appeals committee will consist of three (3) DoDEA employees, including the DoDEA Chief of Education Research, Evaluation, and Accountability, who have had experience with conducting research studies, who have knowledge of research and methodological procedures, and/or who have the necessary content knowledge to review research proposals for adequacy. The appeals committee members may not include members of the original research review committee. The DoDEA HRPO will be required to participate in appeals reviews for the purpose of providing details or evidence about the review process and communication with the researcher. However, the DoDEA HRPO may not provide any input into the final decision made by the appeals committee.

(3) Review Process. The DoDEA Chief of Education, Research, Evaluation, and Accountability will form the appeals committee within two (2) business days of receiving a complete appeal package. The appeals committee with have twenty (20) business days from being notified that they are serving on the committee to review the appeals package. The DoDEA Chief of Education, Research, Evaluation, and Accountability will schedule an appeals committee meeting to occur within five (5) days of the end of the review period so that the appeals committee can arrive at a decision.

(a) Researchers will be notified, in writing, of the date scheduled for the appeals committee to meet to make a determination about their appeal.

(b) The DoDEA Chief of Education Research, Evaluation, and Accountability shall inform the researcher, in writing, of the appeals committee's decision within two (2) working days of the meeting date.

(c) The decision of the appeals committee is final.

4.5. PROTOCOL VIOLATIONS AND UNANTICIPATED PROBLEMS. Violations to research protocols and/or unanticipated problems related to research participation are required to be reported, in writing, to the DoDEA HRPO within forty-eight (48) hours of knowledge of the event occurring. Depending on the nature of the event, additional documentation may be requested and further reporting of the event may be required. Serious violations and unanticipated problems will result in all research activities being permanently ended.

4.6. CLOSING OF RESEARCH STUDIES. The completion or early termination of a research study is a change of activity that must be reported to the DoDEA HRPO in writing within five (5) days of the termination of the research study. Research studies may be closed when human subjects are no longer involved in the research study, the analysis of data has been completed, and publications related to the research approval have been submitted. Closure submissions must include a summary of the data collection activities and copies of final written products that report on the results of the research project. A research project closure will be

considered effective at the time it is submitted. Once a research study is closed no further research related activity can occur, including collection of additional data and/or using the data collected for other research purposes. If a researcher wishes to continue a research study after study closure, he/she must submit a new research request application and obtain approval before research may continue.

4.7. DATA DESTRUCTION. Researchers may maintain the data collected as is consistent with approvals granted under this Issuance. Researchers must continue to protect the confidentiality of the data as specified in the approved research application and to honor any other commitments that were agreed to as part of the approved research. The DoDEA HRPO must be provided a certified letter indicating all data has been destroyed and the date of destruction by or before the end of the period of time that specified in the approval.

GLOSSARY

G.1. ACRONYMS.

CITI	Collaborative Institutional Training Initiative
CHQ	Component Headquarters
HRPO	Human Research Protections Official
HRPP	Human Research Protection Program
IRB	Institutional Review Board
OUSD(P&R)	Office of the Undersecretary of Defense for Personnel and Readiness

G.2. DEFINITIONS. Unless otherwise noted, these terms and their definitions are for the purpose of this Issuance.

active consent. A method of obtaining consent for participation in research that provides participants the ability to actively agree and document permission to participate in a research study.

bias. Bias in research studies occurs when the collection, analysis, and/or interpretation of the data results in conclusions that are distorted or inaccurate.

child assent. The process by which consent to participate in a research study is obtained from a minor under the age of 18 (eighteen). Child assent to participate in research must be accompanied by parent or guardian consent for their child to participate in the research study.

methodological rigor. As related to research studies, this is the process by which appropriate tools for data collection and the correct analytical techniques are used in order to minimize bias, answer research questions and arrive at conclusions that are valid.

minimal risk. As related to research studies, this is the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life.

passive consent. A method of obtaining consent for participation in research that does not require the documentation of consent or permission to participate in a research study. For example, a passive consent form might indicate that the form only need to be returned if the research participant does not want to participate in the research study, if the form is not returned, or no action is taken, it implies that the participant has provided their consent to participate in the research study.

protocol violation. Failure to conduct the research in accordance with institutional and/or DoDEA policy or failure to comply with the study protocol as approved by the IRB and DoDEA HRPO.

research. Any activity that is a systematic investigation designed to develop or contribute to generalizable knowledge, to solve a problem, or contribute to program or process improvements.

research integrity. The adherence of researchers to ethical and professional research principles and standards, including intellectual honesty, and objective data evaluation and reporting.

research involving human subjects. Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge, to solve a problem, or contribute to program or process improvements and involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

research misconduct. Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

unanticipated problems. Any incident, experience, or outcome that is unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in protocol-related documents and the characteristics of the subject population being studied; related or possible related to participation in the research; and suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.

REFERENCES

Code of Federal Regulations, Title 32, Part 219

Code of Federal Regulations, Title 45

DoD Instruction 3210.7, "Research Integrity and Misconduct," May 14, 2004

DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," November 8, 2011

DoD Instruction 8910.01, "Information Collection and Reporting," May 19, 2014

Executive Office of the President, "Federal Policy on Research Misconduct; Preamble for Research Misconduct Policy," December 6, 2000, located in Federal Register, Volume 65, Pages 76260-76264

Office of the Assistant Secretary of Defense Memorandum, "Minimum Education Requirements for DoD Personnel Involved in Human Research Protection," August 16, 2012

Office of the Undersecretary of Defense for Personnel and Readiness Research Regulatory Oversight Office Memorandum, "Research Integrity and Misconduct Operating Instruction," January 29, 2018

United States Code, Title 5, Section 552a

United States Code, Title 10, Section 980

United States Code, Title 44, Sections 3501-3520