Frequently Asked Questions (FAQs)
Human Subject Research Grants and the COVID-19 Pandemic
Grants Administration

GRANTS ADMINISTRATION

The U.S. Department of Education (ED) has received several questions related to the COVID-19 pandemic's impact on the day-to-day administration of grants and contracts involving Human Subjects Research. Regarding contractor questions (e.g., concerning performance, modification, payment, or any other aspect of the contract's terms and conditions), the contractor must contact their ED Contracting Officer. Regarding grants, the following frequently asked questions (FAQs) and responses address flexibilities that are meant to aid grantees in the implementation of their grant projects during the COVID 19 pandemic.

The grantee organization's administration must be apprised of any changes to research or a study funded by ED resulting from the questions and answers that follow. Additionally, budget changes resulting from the questions and answers that follow must also be captured in the grantee's required financial reports.

1. **Will the U.S. Department of Education (ED) allow a grant extension when planned human subjects research activities are disrupted by COVID-19?**

   Unless otherwise stated in a grant program's statute or regulations, or other superseding regulation, ED's current no-cost extension policy continues to apply during the COVID-19 pandemic accordingly:

   First no-cost extension –

   - Grantees may initiate a one-time no-cost extension, without prior approval, as authorized in EDGAR § 75.261(a) in accordance with the following:

     1. Grantees (and their sub-recipients)[1] may request to initiate a one-time extension of the final budget period without the obligation of additional funds by the Federal government (i.e., a no-cost extension).

     2. Grantees notify ED in writing with the supporting reasons for the one-time no-cost extension (e.g., COVID-19 related delays), and the revised expiration date at least ten days before the project period end date. However, ED may waive the ten day notification requirement on a case-

[1] Grantees may approve no-cost extensions to sub-recipients (i.e., subgrantees). The sub-grantee would submit their request to the grantee and the grantee has the authority to approve a no-cost extension. Grantees must maintain documentation of the no-cost extension approval.

by-case basis (e.g., for COVID-19 related reasons) in accordance with EDGAR § 75.261(a) if the extension is otherwise appropriate.

3. In identifying a revised expiration date, the grantee must identify the actual time (months) needed to complete the work.

Subsequent no-cost extensions –

- After grantees have initiated the first no-cost extensions addressed above, and they find they need additional time beyond the original one-time no-cost extension period due to COVID-19 related delays, they must submit a request to ED for prior approval (see EDGAR § 75.261(c)).

  1. For subsequent no-cost extensions, the grantee submits a request for prior approval at least 45 calendar days before the end of the project period in accordance with EDGAR § 75.261(c)(4)(b). However, when necessary ED may waive the requirement to request such extensions 45 calendar days in advance due to COVID-19 related reasons in accordance with EDGAR § 75.261(d).

  2. A grantee's prior approval request for a subsequent no-cost extension must justify the need for the additional time, provide updated timelines with completion dates, list remaining activities to be completed, and identify the amount of unobligated grant funds.

For grants that received funding for an entire 60-month grant period in their initial grant award (i.e., frontloaded grants), extensions may not be feasible because this unspent funding will revert to the United States Treasury five years after the end of the fiscal year in which the funds were obligated.[2] However, if any such grant is awarded supplement funding after the first year, an extension that meets the requirements under EDGAR § 75.261 may be initiated for amounts awarded under the supplement to accomplish activities authorized by the supplement.

[2] For example, if a grantee receives a fully frontloaded 60-month award on September 30, 2018 for funds that ED had to have awarded by that date, the funds revert to Treasury at the same time the project ends. However, if a grantee receives a fully frontloaded 60-month award at any other time during the fiscal year, the grantee could receive a one-time no-cost extension through the end of the fifth fiscal year of the grant (e.g., if the grantee received its frontloaded award on June 1, 2018, it would complete its project on May 31, 2023, and would have several months before the end of the fiscal year in which the funds revert to Treasury).

Grantees are encouraged to engage with ED (i.e., their ED Program Contact identified on their Grant Award Notification, or other ED official as established by ED) as soon as they foresee a need for a no-cost extension.

2. **When a planned meeting or training that was to be hosted by the grantee is cancelled due to COVID-19 related reasons, who does the grantee contact to address the cancellation's impact on the award?**

   Grantees should contact their ED Program Contact reflected on their Grant Award Notification, or other ED official as established by ED about this circumstance, and to address rescheduling the meeting or training, or using the funds for a future meeting that is consistent with the original scope and objectives of the award. Additionally, considering the COVID-19 public health threat and the fact that many institutions, cities, communities, and States are restricting non-essential travel, the grantee may wish to consider options for virtual meeting and training participation.

3. **How should grantees treat refunds for an airline ticket for a conference that was canceled? Are there restrictions on how a grantee may use an airline credit moving forward?**

   If a grantee receives a refund on an airline ticket that was canceled, those funds should be treated as program income and used for grant-related costs. If a grantee receives an airline credit, that credit should be used to support grant-related activities.

4. **Will APR and FPR extensions be granted due to award-related delays pertaining to COVID-19?**

   Grantees may request to delay the submission of their Annual Performance Report (APR)—including both the financial and Research Progress Performance Reports (RPPR)—due to COVID-19 related reasons by submitting a written notice to the program contact in the form of an email from the grantees' official email account. The ED program contact will then work with the grantee to identify a new report due date.

5. **Where can a grantee find additional information related to travel cancelation due to COVID-19 for Pathway Fellows?**

   Airlines have announced flexible cancellation policies (see AERA's travel resource page for details), and many are not charging for flights that have been cancelled due to COVID-19 related reasons.

For each fellow who had travel canceled or postponed due to COVID-19 related reasons, grantees must document, in a request to the ED program contact, the initial travel costs, the non-recoverable amount, the amount refunded, and proposed plans to reapply the refunded amounts. Additionally, grantees should request approval to let Pathways fellows who have already completed the program to reapply travel funds to future meetings.

6. **May a grantee or subgrantee continue to pay the compensation of an employee paid with grant funds during the period the employee is unable to work on the grant because his or her organization is closed due to the COVID-19 pandemic?**

Yes. Generally, a grantee or subgrantee may continue to charge the compensation (including but not necessarily limited to salaries, wages, and fringe benefits) of its employees who are paid by a currently active grant funded by ED to that grant, consistent with the organization's policies and procedures for paying compensation from all funding sources, Federal and non-Federal, under unexpected or extraordinary circumstances, such as a public health emergency like COVID-19. Thus, if the organization pays, consistent with its policies and procedures, similarly situated employees whose compensation is paid with non-Federal funds during an extended closure, those paid with grant funds from ED may also continue to be paid. However, an employee who is being paid with ED grant funds while the program grant activities are closed in whole or in part due to the COVID-19 pandemic may not also be paid for the time during which the program is closed by the organization or another organization for working on other activities that are not closed down."

If a grantee or subgrantee does not currently have in place a policy that addresses extraordinary circumstances such as those caused by COVID-19, the grantee or subgrantee may amend or create a policy in order to put emergency contingencies in place for Federal and non-Federal similarly situated employees. If the conditions exist for charges to be made to the Federal grant, charges may also be made to any non-Federal sources that are used by a grantee or subgrantee to meet a matching requirement.

A grantee and subgrantee must maintain appropriate records and cost documentation as required by 2 CFR § 200.302 (financial management), 2 CFR § 200.430(i) (standards for documenting personnel expenses), and 2 CFR § 200.333 (retention requirements for records) to substantiate the charging of any compensation costs related to the interruption of operations or services.

At the same time, grantees should consider ways that employees paid with grant funds

can support continuing activities, including distance learning opportunities for students served by the grant.

7. **May a grantee re-budget funds and tasks to ensure that its students and staff who were going to be collecting data continue getting paid?**

   A grantee may be able to re-budget funds consistent with its current policy of paying salaries (under unexpected or extraordinary circumstances) from all funding sources, Federal and non-Federal. However, grantees should consult with their ED program contact for allowability prior to re-budgeting.

8. **May a grantee re-budget for necessary equipment or IT support if it needs to change meetings or data collections into virtual experiences (for example, qualitative videos online).**

   A grantee may be able to re-budget funds for this purpose, if doing so is consistent with its current project plan. However, grantees should consult with their ED program contact for allowability prior to re-budgeting.

9. **May a grantee reschedule travel to sites to collect data to next fall?**

   A grantee may be able to make these types of changes to its project plan; however, it should first discuss these changes with its ED program contact.

CONDUCT OF RESEARCH

ED has received questions regarding how human subject protections regulations (34 CFR 97) apply to the activities of institutions and investigators in response to the COVID-19 pandemic. ED understands that for many studies, the conditions and timeline for conducting human subjects research have become unpredictable, and ED offers the following clarification to the research community.

A major concern is whether the research can go forward without in-person interaction. In other words, can the grant objectives (including valid and reliable research) be met without in-person interaction.

ED grantees should check with their project officers on proposed changes to the research. If the research can proceed without its quality or effectiveness being hurt, then the change from in-person interaction can be approved by the ED project officer. If it cannot, then the project timeline may have to be altered until in-person research can be resumed, assuming the delay does not cause other problems. ED will defer to grantee policies on in-person activities, but those policies might have an impact on a grantee's ability to carry out its project which will have to be addressed.

ED typically requires that all projects involving human subjects must either have approval from an Institutional Review Board (IRB) before issuance of an ED award, or a determination that the project is exempt from review. ED understands that given the current COVID-19 pandemic, many IRBs have suspended their activities. Accordingly, ED will accept a review pending determination notice in place of an approval or exemption determination. ED will be flexible with the form that this notice takes, if the notice makes clear that no work involving human subjects, including recruitment, will be conducted until a full IRB approval is obtained.

The project's Principle Investigator (PI) may conduct preliminary or conceptual work that does not involve human subjects while the protocol is being developed or under review, consistent with institution guidelines. In such cases, ED will add conditions to the grant that prevent any research involving human subjects from being carried out until IRB approval has been obtained. IRBs, institutions, and individual researchers may wish to consult the U.S. Department of Health and Human Services, Office of Human Research Protections' (OHRP) guidance on COVID-19 at: OHRP Guidance on COVID-19.

The grantee organization's administration must be apprised of any changes to research or a study funded by ED resulting from the questions and answers that follow. Additionally, budget changes resulting from the questions and answers that follow must also be captured in the grant's required financial reports.

10. Where can a grantee find helpful information related to COVID-19's potential impact on its research project, project-related travel, or field work?

The grantee organization that was awarded the ED grant is an ideal starting point. For example, many colleges and universities have created websites offering helpful COVID-19 related information. Beyond that, grantees are encouraged to consult the following resources:

- For information about COVID-19, see the Centers for Disease Control (CDC) and World Health Organization (WHO) websites, and also refer to the grantee's State or local health departments.
- For information about international travel and quarantine information in foreign countries, see the State Department Travel Advisory website.
- For COVID-19 information and resources for schools and school personnel, see the COVID-19 ("Coronavirus") Information and Resources for Schools and School Personnel website.
- For grantees awarded grants by the Institute of Educational Sciences (IES), see the featured resources addressing COVID-19 at the IES website.

11. A school district will be closed until the end of the school year and that will affect a grantee's research project. What can the grantee do?

The grantee may be able to make changes to its project plan; however, it should discuss the need for changes with its ED program contact. The grantee should refrain from making any changes to its project plan until it has consulted with its ED program contact and has received guidance addressing the need for changes.

12. If schools stay closed, a grantee could lose its research sample. Under such circumstances, the grantee may not have enough funding to regroup a sample, even if it is awarded a no-cost extension. What should the grantee do?

Grantees experiencing this issue should seek guidance from their ED program contact; however, ED may not be able to award supplemental funds under every scenario presented. Grantees should therefore not make any plans or take any actions that assume such funds will be available until they have consulted with their ED program contact and have received guidance resulting from that consultation.

13. Can a grantee place a hold on its research due to COVID-19 related reasons?

A grantee may consider whether its study or parts of its study should be placed on hold during the COVID-19 pandemic. This hold may be necessary for all research procedures, or perhaps placing a hold on enrollment, study visits, data collection, or data analysis separately is reasonable. It is recognized that discontinuing a participant's involvement during this time may not be safe or may dramatically jeopardize the results of the research project. The decision to place a hold on a study or research is to be made on a case by case basis, and in consultation with the ED program contact to ensure that Federal and participant needs will be met. A grantee is not required to report study holds to the IRB; however, it must document the holds in its research records and report them to sponsors, as necessary.

14. **Will ED (e.g. IES) extend a project's timeline given that data collection has been interrupted?**

    ED may afford grantees the flexibility to extend their project timelines; however, grantees must consult with their ED program contact and refrain from making any changes until such time as guidance in provided. In regard to extending a grant project period, see our answer to question 1 which addresses ED's no-cost extension policy.

Deviations from Protocol:

There may be an urgency to deviate from the protocol or the conduct of research procedures before an amendment can be approved by the IRB. Some deviations will be minor. Some may have major effects on the welfare of participants and/or study validity. All deviations must be reported according to the IRB's reporting policy.

COVID-19 outbreak and isolation/quarantine requirements may result in deviations that are intended to eliminate apparent immediate hazards to a research participant. The IRB recognizes that some deviations pose little to no threat to participant safety or scientific integrity. For example, when the subject misses a clinic visit and the only available re-schedule date is outside the study visit window, but no study procedures or medication doses are missed. In this case, the subject may not incur possible harm from a missed dose or missed procedures meant to maintain or evaluate the subject's safety and welfare. As such, reporting is left to the discretion of the PI within the context of the IRB's reporting policy.

Though a deviation may not pose a conceivable threat or possible harm, it may represent possible continuing non-compliance if an amendment is not pursued with the IRB. All deviations must be documented in the research record, regardless of whether they meet the IRB's reporting criteria.

The IRB may support the use of home visits and phone calls for participant data collection and monitoring, so long as no procedures would be performed that are unsafe in this setting. Home visits and phone calls need to be conducted by a member of the study team that is approved in the IRB application. A grantee's IRB application should be amended to include these methods if it chooses to use them.

15. How may a grantee propose study changes and how are they reviewed?

PIs may submit any proposed changes to previously approved research to the IRB at any time. The IRB may use an expedited review procedure to review and approve those changes if the changes are minor (see 34 CFR 97.110(b)(1)(ii) under the 2018 Requirements and 34 CFR 97.110(b)(2) under the pre-2018 Requirements).

16. Must suspensions of research be reported?

Please note that only IRB suspensions or terminations of approved research are required to be reported to ED and OHRP. If a PI or an institutional official suspends or terminates approved research, such actions are not required to be reported to ED and OHRP under 34 CFR 97.113, but are to be reported to the ED as part of grant-related activities in accordance with grant terms and conditions.

17. How may grantees make research changes to eliminate apparent immediate hazards

PIs may implement changes to approved research prior to IRB review and approval, if the changes are necessary to eliminate apparent immediate hazards to the subject (see 34 CFR 97.108(a)(3)(iii) under the 2018 Requirements and 34 CFR 97.103(b)(4)(iii) under the pre-2018 Requirements). For example, ED expects that investigators are cancelling or postponing non-essential study visits or conducting phone visits instead of in-person visits to reduce COVID-19 transmission risks. In these situations, PIs may make such changes to the research to reduce risks without prior IRB approval, but they should report those changes to the IRB when possible.

18. How do grantees fulfill legally required COVID-19 tests results reporting?

When required by law to provide information related to an individual's COVID-19 test results to a public health authority, including individually identifiable information about individuals who are research subjects, the protection of human subjects regulations do not prevent PIs or institutions from fulfilling this requirement (even if doing so would be inconsistent with statements made in the study's consent form). The existence of a Certificate of Confidentiality does not alter an investigator's ability to disclose a research

subject's COVID-19 test results when required by Federal, State, or local laws. For example, if a research subject tests positive for COVID-19, a PI may provide this test result to a public health authority if required to do so under applicable State or Federal law. In such circumstances, investigators should inform the participant of the required reporting of results (see the (OHRP) guidance on COVID-19 at: OHRP Guidance on COVID-19).

In addition, certain grantees must also comply with the requirements of the Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR part 99) and the Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR part 98), as applicable. For example, in general, grantees that are subject to FERPA must obtain the written consent of a parent or an "eligible student" (i.e., a student who is 18 years of age or attends an institution of postsecondary education) prior to disclosing any personally identifiable information (PII) from student education records, unless an exception to FERPA's general consent requirement applies. 20 U.S.C. §§ 1232g(b)(1) and (b)(2); 34 CFR §§ 99.30 and 99.31. Pursuant to one such exception, which may under certain circumstances apply to State-mandated disclosures of COVID-19 test results, for instance, FERPA-covered grantees may non-consensually disclose PII from student education records to appropriate parties in connection with an emergency if these parties' knowledge of the information is necessary to protect the health or safety of the student or other individuals. 20 U.S.C. § 1232g(b)(1)(I); 34 CFR §§ 99.31(a)(10) and 99.36. Further, grantees that are local educational agencies subject to the PPRA must develop and adopt policies, in consultation with parents, regarding the administration of physical examinations or screenings to a student and, with the exception of any physical examination or screening that is permitted or required by applicable State law, grantees that are local educational agencies subject to the PPRA are responsible for notifying parents of students of any non-emergency, invasive physical examination (as defined in 20 U.S.C. § 1232h(c)(6)(B)) or screening that is required as a condition of attendance; administered by a school and scheduled by the school in advance; and, not necessary to protect the immediate health and safety of the student, or of other students. 20 U.S.C. §§ 1232h(c)(1)(D), (c)(2)(C)(iii), and (c)(4)(B)(ii).

19. Does a grantee need to report to the IRB if a participant or member of the study staff tests positive for COVID-19 and/or is hospitalized or dies as a result?

No. Unless the hospitalization or death is determined by the site investigator or PI to be unexpected, i.e., not identified as a risk to participants as described in the protocol and/or consent form, and possibly related to the research, e.g., the participant/study staff member was known to be exposed through their participation/involvement in the

study (see the (OHRP) guidance on COVID-19 at: OHRP Guidance on COVID-19). In addition, grantees that are subject to FERPA must ensure that any disclosure of PII from student education records complies with the requirements of FERPA, as applicable.

20. Must changes in the research related to the Covid-19 pandemic be reported to ED and the IRB?

Any changes in IRB-approved research procedures must be reported to the IRB and may not be implemented prior to review and approval by the IRB except when necessary to eliminate apparent immediate hazards to the subject. This is permitted by both the Common Rule (34 CFR §97.108(a)(3)(iii)) and FDA regulations (21 CFR §56.108(a)(4)) in order to prevent investigators from delaying the initiation of safety changes to eliminate apparent immediate hazards to subjects. Beyond the regulation, ED also has a responsibility to ensure the safety of its staff. As such, interim measures to eliminate immediate hazards to staff, which may involve deviating from approved study procedures prior to securing IRB approval, may be warranted.

Examples of modifications or safety changes include, but are not limited to, cancelling non-essential study visits, conducting phone visits in lieu of in-person visits, conducting safety screening (initiated by the PI) prior to in-person visits occurring, or other changes as deemed appropriate to eliminate immediate hazards to subjects because of the risk of exposure to this highly communicable disease.

In some cases, these protocol changes may involve the PI temporarily stopping subject recruitment or placing a temporary hold on all study procedures. PIs must consult with their ED program contact prior to initiating modifications to IRB-approved protocols without IRB approval.

21. Does a grantee need IRB approval if it decides to modify its study procedures or add study procedures?

If the PI decides to modify study procedures in order to protect participants and/or study staff, e.g., to replace in person visits with remote options for questionnaires, surveys, focus groups, check-ins, screening, consenting, etc., the PI should submit a modification prior to implementation. Please note: It may not be necessary to modify an IRB-approved protocol if it does not specify whether interaction will occur in person or remotely.

Any changes to a protocol or the conduct of research procedures still requires an amendment with the IRB. The IRB does not pre-approve deviations from protocol outside of the amendment process.

22. What does a grantee do if it needs to submit a change to its research, report new information, or start new research and the IRB office is not in operation?

The human subject protection regulations state that new human subjects research may not start without IRB review and approval. The regulations also state that no changes in already approved research may be initiated without prior approval by the IRB. The only exception is when a change is necessary to eliminate apparent immediate hazards to study subjects. But even in this situation, the grantee will still need to report the event to an IRB. Usual IRB operations are expected to continue, and IRB staff are generally working remotely for the foreseeable future. Additionally, monthly convened IRB meetings will be held remotely for the foreseeable future as well. If, however, the IRB is not in operation, typically resources will be pooled to ensure that IRB reviews will occur.

26. If a grantee is pausing recruitment and/or study procedures on a project reviewed by an external IRB of record (i.e., the IRB of Record is not the grantee's institution). Should the grantee notify that IRB?

It depends. The grantee should follow the requirements of the IRB that oversees its research regarding reporting changes and whether any review/approval will be needed prior to resumption of study procedures.

Electronic Research Technology:

27. What technologies may a grantee use to conduct its research remotely?

Researchers need to ensure that any technologies used to conduct research remotely are appropriately vetted within their organizations to avoid outside intrusions and to protect data confidentiality. For instance, grantees that are subject to FERPA must ensure that any such technologies which contain PII from student education records appropriately protect such PII from unauthorized access or disclosures under FERPA. Only vetted technology should be used. Additionally, when using an online meeting software, research should consider turning off meeting recordings, authenticating users, and setting meeting passwords. Note that any changes in technologies used for research may affect the study's data security level.

28. If a student or researcher needs to access and/or analyze a data set from home in order to keep working on a project, how does a grantee address privacy requirements, if the data set contains sensitive or private information?

As researchers, and the institutions they are associated with, prepare to support remote operations, ED anticipates that research teams may need to rethink how they access and analyze research data sets. Successful remote research operations during implementation of COVID-19 precautions require maintaining compliance with required controls. If a grantee's research data use is covered by a data use agreement (DUA) or other contractual obligations, or if an IRB has determined the data contain elements that are high risk, the grantee must submit a protocol and ensures the modification is approved by the IRB before moving data sets to a new technology platform.

29. How should electronic research data be stored?

Do not store electronic research data on unsecure devices to work remotely. Encourage the use of approved cloud services and Virtual Private Network access while working at home instead of storing data directly on personal devices. Do not take home physical research records or data (e.g., paper consent forms, case report forms, questionnaires/surveys, etc.). All physical records must continue to be stored in IRB-approved, secure locations.

Data Quality:

30. What are the implications of the COVID-19 pandemic for data quality in ED-funded research?

Transparency is crucial in ensuring quality data and analysis. The first questions that arise when a data user approaches a data set is "where did you get it from, and what did you do to it? What factors affected conduct of the intervention, reporting and study attrition?" This applies to understanding data collected during this COVID-19 pandemic. If people are taking out things that they consider outliers, ED should know that, because the raw data is very powerful. Similarly, information on attrition of study participants or sites, changes in mode of data collection, etc., should be documented and included with the data.

Without transparency related to data quality, users run the risk of assuming that a given piece of data is of higher quality than it really is. It is critical not only to safeguard data integrity, but more importantly ensure the mitigations adopted by the teams also address the reliability of the data to make scientific conclusions at the end of the study

and to enable replication of research findings. Research subjects' safety is always a priority, it is even more important during this COVID-19 pandemic.

Major risks and potential impacts to research data include:

- Study participants unable to travel to research sites resulting in:

    1. Missed visits– need to flag visits due to COVID-19 and associated Protocol Deviations.
    2. Missed procedures– need to flag assessments issued due to COVID-19 and associated Protocol Deviations.
    3. Unable to use the central lab or data processing resource.
    4. Compliance with site-based Covid-19 protection measures.
    5. Use of telecommunications to perform parts of the research visits.
    6. Needing to ship research materials to the study subject's home.
    7. Overall enrollment and screening impacts – option to screen-fail now and rescreen later in the year.
    8. Potential study attrition as a higher number of study subjects and/or sites discontinue participation.
    9. Other disruptions of research.

- Site staff unable to commute to work or need to go on leave, resulting in failure to implement an intervention or collect research data.

- Subcontractors or collaborating institutes unable to perform site visits resulting in failure to implement an intervention or collect research data.

- Vendors that face staff shortages or facilities shutdowns resulting in loss of critical support for research operations.

Risk-areas require thoughtful mitigations, and in cases where (unfortunately), there are no good options, the research may have to be extended out or additional study subjects may need to be recruited, or trial start-up delayed. In some cases, it may be required to put the clinical study on hold.

Who to Contact with Questions Regarding Human Subjects Research and this FAQ Document:

Request for additional information or questions regarding the Common Rule for the Protection of Human Subjects in Research may be directed to Jeffery Rodamar, ED's Protection of Human Subjects Coordinator at: HumanSubjectsResearch@ED.gov.