

Question and Answer Summary

Please also refer to HEI-Energy's website (<https://hei-energy.org/>) for forms, instructions, and FAQs

Date Posted	Question #	Question Relevant to Both RFAs	Answer
		Human Subjects Research	
25-Jan-2021	1	NIH has a policy known as sIRB for single-IRB, and involves the lead institution's IRB taking all responsibility for any human subjects approvals or exemptions regardless of the number of sub-awardees on the project. Does EPA have a similar policy, or would we need to ensure that all sub-award institutions also have IRB approvals (prior to beginning work)?	<p>EPA does not have a policy similar to NIH's single IRB policy. However, our boilerplate language for contracts with the Principal Investigator's institution addresses your question as follows:</p> <p>"The University and any assignee or subcontractor (at whatever tier) engaged in such research shall obtain an approval or exemption determination from an institutional review board (IRB) designated on its assurance with certification to the U.S. EPA and confirmation of the approval or exemption determination by the EPA Human Subjects Research Review Official...the University shall submit to the HEI:</p> <p>i. Copy of the Investigator's IRB application as approved or exempted by the IRB, including the protocol and informed consent form, if applicable. The Investigator's IRB application must cover and clearly delineate and document the full scope of work, whether it occurs at the PI's institution or at one of its subcontracting institutions.</p> <p>ii. Documentation of the IRB's final approval or exemption determination. This may be provided either by a copy of the IRB's approval or exemption determination letter or by submission of OMB Form 0990-0263, aka HHS Optional Form 310."</p>
25-Jan-2021	2	Do we need IRB approval at the time of submission?	<p>Investigators do not need to obtain or provide documentation of IRB approval at the time of application submission. In Form-13 of the application, please include the information about human participants listed on page 11 of "Instructions for Completing Applications" document.</p> <p>If HEI-Energy decides to fund your study, you will be asked to provide detailed IRB documentation. Approval of the study by the IRB is required before the study commences.</p>
		Budget	
25-Jan-2021	3	Is it acceptable to change the budget amount from the amount originally requested in the pre-proposal?	Please submit a budget that reflects what you expect will be needed to fulfill your research objectives. If you are funded and during the course of research require a substantial budget modification, you would need to first obtain HEI's approval of the change.
25-Jan-2021	4	Can we move money between budget categories during the course of research if unexpected events arise?	
25-Jan-2021	5	There is a question whether tuition for a Graduate student working on the project would be considered an allowable cost.	Tuition costs can be included in the base for indirect costs.
25-Jan-2021	6	The instructions indicate that HEI will cover travel and logistical costs for investigator workshops and stakeholder workshops hosted by HEI-Energy. The instructions also indicate that HEI intends to host a kick-off stakeholder workshop, but it is not clear whether HEI intends to host interim and final stakeholder workshops. Please clarify whether HEI intends to host interim and final stakeholder workshops.	Yes, HEI-Energy plans to host an initial workshop. At this stage, we cannot be certain what type and frequency of engagement will be needed thereafter. Please propose what you think will be needed and include it in your budget. We may be able to make funds available for additional workshops when we know more about specific needs for engagement.
		Contracting with HEI-Energy	

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25-Jan-2021	7	We have a question about how HEI would distributes funds for a multi-institution grant: (1) all funds to the lead institution, and subcontracts from there, or (2) funds going directly to each institution?	HEI-Energy enters into contracts only with the Principal Investigator's institution.
Research Timeline			
25-Jan-2021	8	Based on the anticipated award decision date of June 2021, we are assuming a start date of September 2021. Is this a reasonable/acceptable assumption?	Yes