

Question and Answer Summary

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Date Posted	Question #	Question Relevant to Both RFAs	Answer
		Eligibility for Funding	
27-Aug	General-1	Are government agencies (that have research programs and qualified scientists) eligible to apply?	Scientists from <u>non-regulatory governmental agencies</u> are eligible to participate in, but not lead, HEI-funded research. Thus, such agencies need to seek collaborations with established research institutions. Also, HEI-
27-Aug	General-2	Can investigators from government agencies participate in a proposal or lead a proposal? Can they get salary?	Energy prohibits individuals from <u>governmental sponsor agencies</u> from being formal members of research teams to maintain independence between HEI-Energy sponsors and the research that HEI-Energy funds. Of course, sponsor agency staff can provide data and information to investigators just as they would any other member of the public.
27-Aug	General-3	Are Federal Agency Scientists eligible?	
9-Sep	General-4	Can investigators from the oil and natural gas industry participate in a proposal or lead a proposal? Can they get a salary?	HEI-Energy encourages its sponsors from the oil and natural gas industry and other oil and natural gas companies and related trade associations more broadly to provide access to data and study sites as appropriate to facilitate research. However, HEI-Energy prohibits individuals from industry sponsor companies and other oil and natural gas companies and related trade associations from being formal members of research teams to maintain the independence of HEI-Energy's research. Of course, industry sponsors and other oil and natural gas companies can provide data and information to investigators just as they would any other member of the public.
28-Aug	General-5	If for-profit consulting companies are members of a proposed research team, should they be included as subcontractors or as consultants?	They should be included as consultants.
27-Aug	General-6	Are you accepting applications or co-PI s from Europe?	PIs can originate from outside the United States, but the proposal must be responsive to the RFA objective to better understand UOGD exposures in the United States.
27-Aug	General-7	Are there any restrictions on investigators being part of more than one submission to a specific RFA?	HEI-Energy does not recommend sending more than one application, as the PI or co-PI, per RFA by the same scientist. However, being part of another application as a collaborator is acceptable, as is applying to more than one RFA at the same time.
27-Aug	General-8	Please define what an "established research organization" means for the PI qualification	HEI-Energy considers "established research institutions" to be academic or independent, non-profit, free standing research institutions. Academic research institutions are most likely to have the expertise and resources available to achieve the research criteria specified in the RFA. At the same time, we fully recognize the value of multi-sector research teams, with the goal being that each team has the wide breadth of necessary multi-disciplinary expertise.
		Proposal Format	
27-Aug	General-9	What is the page limit for the preliminary application?	The Preliminary Application form includes this information.
27-Aug	General-10	I just want to clarify that for the preliminary application no actual HEI forms are needed to include in the proposal and we should use the guidelines in the web site to generate the proposal document.	Please see the RFAs and the HEI-Energy website for this information.
22-Sep	General-11	What time are proposals due on September 24, 2020?	Proposals are due no later than 11:59 pm EDT on September 24, 2020
22-Sep	General-12	Must biographical sketches include date-of-birth?	No; please feel free to leave that entry blank.
		Budget	
27-Aug	General-13	I understand the maximum budget is \$2.5M, but do you have a maximum for the indirect costs?	Yes, 30%. Please see "Instructions for Completing Preliminary and Full Applications" and budget instructions in the Full Application forms.
27-Aug	General-14	The limit of 30% on indirect costs is less than the overhead limits set for university by the US Govt. Are overhead costs considered a direct cost for University research?	No. HEI-Energy is following the longstanding practice of the Health Effects Institute of limiting indirect costs, and overhead costs will not be allowed in the direct costs for the proposal.
27-Aug	General-15	Should the proposals include effort and costs to prepare manuscripts for publications?	Yes, in the Full Application budget forms you can specify a modest amount for the purpose of covering journal publication fees. Your budgets also should include the effort required to make your data accessible in accordance with HEI-Energy's <i>Policy on Data Management, Preservation, and Access</i> .
27-Aug	General-16	Is it fine to budget for a graduate student or a post-doc?	Yes; be sure to include them in the Full Application budget forms.
27-Aug	General-17	Can the indirect rate cap be waived?	No.
9-Sep	General-18	Would both an "existing data" and "new empirical research" proposal be required to allocate 5% of their budget to stakeholder engagement activities, as described in the application instructions?	Yes. However, if an applicant is invited to submit a Full Application, HEI might recommend another arrangement if it is more suitable to the specific proposed research.

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Investigator Conflict-of-Interest			
27-Aug	General-19	We need clarification on the HEI-Energy disclosure requirements. "Investigators should report financial relationships with entities in the exposure science or environmental health areas that could influence, or be perceived to influence, the proposed research." Would paid projects with oil and gas companies be perceived as to influence our research? If so, how does this affect the need to establish stakeholders who can assist with access to O&G sites? Additionally, does the requirement to "Please report all sources of revenue paid (or promised to be paid) directly to you or your institution on your behalf over the past 36 months greater than \$3,000" apply to only projects that might be perceived to influence or ALL sources of revenue, and if ALL, what level of detail is required with respect to listing of the sources?	<p>While financial support from HEI sponsors for other projects does not in and of itself preclude an investigator from applying, the HEI-Energy Research Committee will need to know whether research teams have financial relationships with our sponsors, which include oil and natural gas companies, including service companies, and the U.S. Environmental Protection Agency.</p> <p>Having said that, HEI-Energy recognizes the value of industry and other sponsor cooperation to access data and research sites. This cooperation needs to be defined clearly and completely in your proposal and would not represent a conflict of interest.</p> <p>You need not report all sources of revenue; only those that might represent potential conflicts of interest for this research program.</p>
Industry and Government Partnerships			
27-Aug	General-20	Will HEI, via their industry contacts, help with getting access to UOGD sites?	At the Preliminary Application stage, HEI-Energy is interested to know of collaborations that you have already established or plan to establish. At the Full Application stage, there might be opportunities for HEI-Energy to connect PIs with industry to help with gaining access to study sites or data about operational conditions during sampling periods and to share expertise about UOGD operational practices and trends. We are actively looking at opportunities to make that happen. Also, some research proposals might be successfully implemented without industry cooperation.
27-Aug	General-21	Is it important to have industry partner commitment to participate for the preliminary proposal if we plan to involve them in the final proposal?	At the Preliminary Application stage, it would be ideal to have industry partner commitment letters if industry partnerships are needed to successfully implement the proposed research, but they are not essential. If such partnerships are needed, commitment letters must be provided at the Full Application stage.
27-Aug	General-22	Must every proposal have evidence of industry participation and public participation?	Yes, letters of commitment.
27-Aug	General-23	How would one demonstrate real participation by industry or regulatory partner in the preliminary proposal? Letters of commitment?	Yes, with the caveats noted above in response to questions about eligibility for funding.
27-Aug	General-24	Can a government agency provide a partner letter?	
UOGD Definition			
27-Aug	General-25	Is the definition of UOGD in this RFA focused on a geological definition (source rock) or engineering definition (well stimulation/hydraulic fracturing)?	The definition of UOGD is on the first page of the RFAs. It includes both geologic and engineering components. HEI-Energy uses the term "unconventional" as USGS and others would in reference to shale and other unconventional resources. In addition, the UOGD definition refers to the extraction of oil and natural gas from unconventional resources using horizontal wells combined with multistage hydraulic fracturing.
27-Aug	General-26	Would you also be interested in potential exposures from acidizing (as opposed to hydraulic fracturing)?	It is the Committee's understanding that acidizing requires much lower volumes of water than hydraulic fracturing, resulting in a lower intensity of development than what has given rise to recent questions about potential human exposures and health effects. For the reason, it does not meet the definition of UOGD.
27-Aug	General-27	I assume that coal bed methane is not UOGD. But I am a little confused as to whether CBD might be UOGD.	It is the Committee's understanding that coal bed methane development, specifically the type and intensity of completions, does not meet the definition of UOGD.
Study Design			
	General-28	Is exposure modeling an acceptable/desired component of the proposal or should the focus be on measurements?	Yes, in fact, the RFAs refer to the value of combining measurements with modeling toward the purpose of maximizing the generalizability of research findings and establishing a link between a specific UOGD process and an exposed population, should such a link exist.
	General-29	Should one proposal focus on a single UOGD Zone? or do a cross-regional comparison.	You can submit an application for research in a single region or multiple regions. Research in a single region is welcome. Please be aware of the need to work with HEI to coordinate research programs across regions to ensure comparability where possible and useful. A cross-regional study would also be welcome.
	General-30	Is biomonitoring of exposure acceptable?	Yes, however, the Committee is not aware of biomonitoring protocols specific to UOGD that would allow investigators to make a direct connection between UOGD and human exposure. However, the Committee is open to novel ideas about biomonitoring that is specific to UOGD.

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Study Design (continued)			
27-Aug	General-31	I am still confused as to whether we need to actually study a population ...i.e. collect health data. What does "complete exposure pathway mean"...that we have to show a process puts a chemical into environment, that the environment allows mobility of that chemical, and then we would have to show the chemical went into the human population ? or just that it could have gone into the human population..?	<p>Please see the RFAs, which solicit exposure research, not health research. We are not requesting that you "collect health data." After obtaining results from the exposure studies, we might fund health studies under a separate RFA in the future.</p> <p>Please see Figure 1 in the RFAs, which illustrates a complete exposure pathway. A complete exposure pathway defines a connection, should one exist, between a UOGD process and an exposed population. However, you need not measure agents that "could have gone into the human population." For example, a study design might allow one to define a link between a specific UOGD process and a change in air quality in a residential neighborhood. It will be sufficient to measure the change in air quality in the residential neighborhood; you do not need to confirm that the agent you measured in air entered the bodies of residents.</p>
27-Aug	General-32	Does exposure include people behavior including behavior trying to avoid exposure?	This variable is one of many that you might need to take into account to ensure that your proposed study design meets the RFA objectives.
27-Aug	General-33	Are you interested in long term impacts of hydraulic fracturing or only short term impacts that happen during the treatment?	The Committee is interested in potential human exposures that might be the result of brief or long-term UOGD operations.
Date Posted Question # Question Relevant to Both RFAs Answer			
27-Aug	General-34	Wondering about studies that span both air and water monitoring. How would these be addressed to the respective RFAs? When trying to understand complete exposure, it seems hard to only look at one side of this exposure puzzle, as these people are likely exposed via both routes. Would a successful application need to focus on either air OR water, or how would an application assessing both be targeted?	One could accomplish this goal by applying for funding under both RFAs.
27-Aug	General-35	Are there priority areas/regions for either study (e.g., Permian vs. Marcellus) ?	The Committee has not defined priority regions; however, they have defined a list of factors to consider in choosing a study location. Please see the relevant discussion in the RFAs.
27-Aug	General-36	Are preliminary data important for these proposals?	Preliminary data would be a positive attribute of any Preliminary Application but are not required. Please keep in mind that you must take earlier work into account in designing your studies.
27-Aug	General-37	The RFA states that methane is not really a focus. But methane movement in the subsurface causes mobilization of arsenic and other metals. Could that be a focus? Also, methane can explode in a house and that is a health impact. Could that be a focus?	Studies about the mobilization of chemicals would be of interest if the mobilization might result in exposures that could be harmful to health. Methane explosions are not likely to be of interest because they represent a well-understood safety hazard that is already the subject of guidance and regulation. And if you are aware of such safety hazards, they should be reported immediately to emergency response officials.
27-Aug	General-38	What exactly is a "causal link"?	Please see discussion in the RFAs; "causal link" in the context of this RFA refers to an empirical demonstration of human exposures that result from specific UOGD processes.
27-Aug	General-39	Can you explain a bit more what you mean by your interest in routine production rather than accidents? you emphasize routine production but you are interested in accidents too...that is the part I am confused about. Tons and tons of shale cuttings are being deposited in landfills. Almost no work has been done on the effects of this. Would this possibly be of interest?	Please see the discussion of this topic in the RFAs. Investigators can design a priori research about routine operations, but not accidents. At the same time, exposures that result from accidents are of interest, so study designs should allow for their investigation should they arise during the course of your research. Reviews of existing data could potentially focus on accidental conditions given that they reflect events that have already occurred.
27-Aug	General-40	With the industry winding down so many operations, are you concerned about getting accurate (and worst case) emissions data?	The industry is subject to fluctuations in the level of activity; investigators must take this variable into account in their study designs, keeping in mind the RFA objectives. One of the objectives is to better understand variability in the frequency, duration, and magnitude of potential exposures, not just "worst case" or "best case" exposure conditions.
28-Aug	General-41	Are you concerned that industry operators choosing to participate in research will be on their best behavior?	This variable is one of many that you might need to take into account to ensure that your proposed study design meets the RFA objectives.
HEI-Energy Research Oversight			
27-Aug	General-42	Talk more about HEIs process of accountability once performance of grant gets underway. It does seem that it is somewhat different in terms of requirements and progress compared to NIH for example.	See HEI-Energy FAQs: "For investigators currently funded by HEI-Energy."
27-Aug	General-43	How much time is available to conduct the research? Also, have you considered how long it might take to obtain active collaboration with an operator?	Please see the RFAs for anticipated study periods under each RFA.
Webinar-specific Requests			
27-Aug	General-44	Would you be able to share a recording of this presentation?	No. The webinar was recorded for internal purposes only to ensure that we accurately captured all questions and responses. The recorded webinar will not be distributed or broadcasted.
27-Aug	General-45	Will these slides be shared?	Yes, they have been posted to the HEI-Energy website along with this Q&A summary.

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		Research Teams	
28-Aug	General-46	Can proposals include more than one Principal Investigator?	For various reasons, HEI-Energy prefers having one Principal Investigator (PI) per project. We can make an exception if the applicant can justify that it is essential for the project to have two co-PIs with equal responsibility. If the co-PIs are at different institutions, the contract will be between HEI-Energy and one of the institutions; the other institution will be a subcontract. The PI of the main institution will ultimately be responsible for all deliverables.
28-Aug	General-47	How should the proposal explain the coordination plan between PIs?	See the relevant discussion in the "Research Teams" section of the RFAs.
Date Posted	Question #	Question Relevant to RFA E20-1	Answer
27-Aug	E20-1-1	To make sure I understand correctly, would measurements of exposure to various chemicals in the air, specifically CH4 and VOCs, potentially be responsive to the call, without necessarily having team members to connect the levels of exposure to health effects at this point?	Correct, we seek exposure research, not health research. However, we do seek to identify exposure measures that could be used in a future health study.
27-Aug	E20-1-2	The Air RFA is focused on UOGD emissions. To what extent is Ozone a priority for study compared to HAPS and criteria pollutants?	Please see the section of the RFA about chemical agents that you might propose to study. You will see some examples but no all-encompassing list. It is for the applicant to define the chemicals to include in your study, and ozone could be one of them.
27-Aug	E20-1-3	Noise pollution is mentioned but it's unclear if this is a key component of the first RFA. Would a proposal that does not consider noise pollution be totally responsive?	It would not be totally responsive under this RFA. The Committee seeks primarily exposure research related to chemicals in air, but the RFA also calls for a supplemental line of investigation about noise.
27-Aug	E20-1-4	Is the committee interested in relating emission of chemical agents that affect health to greenhouse gas emissions?	We are not entirely sure about the meaning of this question. We can confirm that the Committee is interested in chemical emissions that might result in human exposures, but it does not seek health studies under either RFA.
27-Aug	E20-1-5	Does the RFA cover both the direct UOGD emissions (e.g., VOCs) and indirect (pollutants originating with traffic to and from the site)?	The RFA specifically includes traffic emissions that are related to UOGD operations, and they would be of interest.
27-Aug	E20-1-6	Just to be clear, air studies on the midstream or downstream that are agnostic to how hydrocarbon were produced would be exempt?	We seek proposals for research to assess exposure associated with upstream operations (i.e., in the production zone where resources are being extracted), not midstream (e.g., refineries), or downstream operations.
28-Aug	E20-1-7	Are assessments of indoor air quality of interest? Or measurements of stress?	While these may be worthy areas of research, the Committee had to set priorities given available funding. Please see the priorities specified in this RFA, specifically assessment of chemical concentrations in outdoor air and noise.
Date Posted	Question #	Question Relevant to RFA E20-2	Answer
27-Aug	E20-2-1	Are you interested in experimental work on produced water treatment/reuse/management?	See the RFA for discussion specific to this question. We are primarily interested in understanding exposure pathways that link specific UOGD processes with exposed populations. Understanding the composition of produced water could be useful for assessing exposure and might comprise a subcomponent of research, but the primary purpose of research needs to be the assessment of one or more exposure pathways.
27-Aug	E20-2-2	Are you interested in mapping contaminants (quality and quantity) due to produced water?	Studies about the mobilization of chemicals would be of interest if the mobilization might result in exposures that could be harmful to health.
27-Aug	E20-2-3	Are you only interested in compounds that are introduced into the environment during UOGD and how they affect people, or are you also interested in elements/compounds that are mobilized through the process from natural sources, e.g. arsenic, or organics in shale that might be mobilized into water?	Yes, this would be of interest. Keep in mind that under both RFAs, the Committee expects proposals that make maximal use of existing, relevant data. HEI-Energy prefers not to fund collection of data that are already available and of sufficient quality to address your study question.
27-Aug	E20-2-4	It seems you are interested in either in meta analysis of already-collected data OR collection of new data. What about a proposed project that does both? Would that be acceptable or possibly of interest?	Ideally, yes, assuming that doing so is needed to be able to make a connection between a UOGD process and community exposure.
27-Aug	E20-2-5	Would the study ideally have associated produced water characterization (from that site) to go along with the environmental samples taken from the surrounding area and community?	With the mention of "water collection...", this question seems to pertain to RFA E20-2. "For RFA E20-2, HEI-Energy seeks innovative analyses of existing data and empirical research that involves collecting original data" (Page 17 of the RFAs). Given this context, "new empirical data" are observations collected during the course of scientific research that have not already been collected by other investigators. Such data would certainly include those resulting from investigators collecting and analyzing water samples. In contrast, the first of the two provided examples represents a re-analysis of "existing data" that were collected by other investigators and seems to fit squarely in the category of "innovative analyses of existing data" rather than in the category of "empirical research." The second example is more difficult to classify as the samples have already been collected (fits in the "existing" category) but the geochemical analyses have not been done (fits in the "collecting original data" category). In their Preliminary Applications, investigators can make their case for why additional analyses or re-analyses of previously collected water samples, or even compiling water quality data that are not publicly available, represents empirical research that requires the larger budget that HEI-Energy has estimated for this purpose.
9-Sep	E20-2-6	How does HEI define "new empirical data"? Must this involve water collection and measurements? For example, could you inform me whether the following would qualify: - Generating a new dataset based on existing data that is not publicly available and would require acquisition and processing - Analysis of stored samples for new analytes (i.e., previously collected and archived)	