June 29, 2022 Webinar Q&A

Question: Is it possible to write a proposal that definitely meets one of those exemptions and still get in trouble with the human subjects test?
Answer: You can use Exemptions 1, 2 or 3 for the application process. Yes, it is possible because Exemption 1 and 3 can be clinical trials. You can use those exemptions, but just because it's Exemption 1 and 3 doesn't make it a clinical trial. It's what your study is doing that will be used to define it as a clinical trial or not a clinical trial. Also, please refer to NIH's Clinical Trial Definition: https://grants.nih.gov/policy/clinical-trials/definition.htm

Question: And it would still get disqualified because it's a clinical trial?
Answer: Yes. It would get disqualified if it's a clinical trial. It will not go to peer-review if it is designated as a clinical trial regardless of exemption. Right now, clinical trials are not allowed for this FOA, so try to focus on the product and whether it works to support the topics of the hazardous materials program. Don't over sell what your impact may be at the end. We want you to stay out of that gray zone.

Question: For getting the exemption and having the IRB review it, do we have to have the IRB stamp prior to application and a letter from the IRB, or is it sufficient to say we're pursuing IRB evaluation on award?
Answer: Though it is highly suggested you have an IRB review for your exemption prior to application, you do not have to have an approved IRB until at the time of award.

Question: The solicitation encourages participation with WTP awardees. What level of engagement is expected for Phase I proposals?
Answer: The level of engagement with WTP awardees is at your discretion. It's at whatever level of engagement you choose to connect with them.

Question: Are there any plans to update the Phase I budget?
Answer: The WTP is a small program, and we have a very limited budget. At this time, we're unable to increase any of the any of the award budgets. Phase I is allowed $100,000 total for one year. Phase II is allowed $200,000 total per year for two years.

Question: Does the SBIR allow for the usual 36% funding allocation to a university partner for research?
Answer: The Grants Policy Statement 18.5.2.3 and the RFA reflect the NIH standard for SBIR level of effort, which is 33% for Phase I and 50% for Phase II.
(Per the FOA: In Phase I, normally, two-thirds or 67% of the research or analytical effort is carried out by the small business concern. The total amount of all consultant and contractual arrangements to third parties for portions of the scientific and technical effort is generally not more than 33% of the total amount requested (direct, F&A/indirect, and fee). In Phase II, normally, one-half or 50% of the research or analytical effort is carried out by the small business concern. The total amount of consultant and contractual arrangements to third parties for portions of the scientific and technical effort is generally not more than 50% of the total Phase II amount requested (direct, F&A/indirect, and fee).)

Question: Does this include the component of $6,500?
Answer: Small Businesses may request up to $6,500 per year for a Phase I, and up to $50,000 across all years per Phase II project. Proposed TABA costs are only allowable if the proposed cost cannot be provided internally. Services provided by the small business applicant, affiliate of the small business applicant, an investor of the small business applicant, or a subcontractor or consultant of the requesting

firm otherwise required as part the paid portion of the research effort cannot be included as TABA costs. Therefore, TABA would not be included in the calculation of effort.

Question: What is the success rate for Phase I applications in the past?
Answer: 40%

Question: Is the Fast-Track awarded differently?
Answer: It is budgeted differently. The Fast-Track process allows you to submit both Phase I and Phase II in one application for review. The Fast-Track mechanism can minimize the funding gap between phases, but requires a fully developed Phase II application/plan at the time of submission. It would be limited by the available budget.

Question: What's the scope of work for Phase I?
Answer: Our FOA has the details on what we are looking for. We're looking for technology-enhanced training products to help train hazardous materials workers. The scope of the work would be your unique idea, product, and/or tool that supports this type of training.

Question: Can we contact certain departments before we submit the application?
Answer: It is suggested that you contact Kathy Ahlmark (ahlmark@niehs.nih.gov) or Jim Remington (remingtonj@niehs.nih.gov) to discuss your concept before applying.