RFP-NIH-NIAID-DAIDS-04-42
Amendment #3 (Questions & Answers)

This Amendment provides questions submitted by potential applicants/offerors and the responses provided by the NIAID. The responses are offered for information only and do not modify or become part of this solicitation. This Amendment will be updated at least weekly to add any further questions and their related responses. All potential offerors are advised to refer back to this Amendment #3 for additional Q&A.

"HIV Vaccine Design and Development Teams"

Amendment to Solicitation No.:	RFP-NIH-NIAID-DAIDS-04-42
Amendment No.:	3 (1st Posting)
Amendment Date:	December 17, 2003 (Questions 1 – 32)
Proposal Due Date/Time:	February 19, 2004 at 4:00 P.M., EST
Issued By:	Jacqueline C. Holden Senior Contracting Officer NIH/NIAID Contract Management Program 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
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Applicants/Offerors must acknowledge receipt of this Amendment #3, for each posting, on each copy of the application/proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your application/proposal.

The hour and date specified for receipt of applications/proposals HAS NOT been extended.

Top | RFP-NIAID-DAIDS-04-42
NIAID Contracts Home | NIH RFP Directory | NIH Home

The following answers are provided to frequently asked questions and inquiries we have received.

QUESTION 1. Note 5 to Offerors says that we must submit agreement on collaboration IP and mechanism for resolving IP disputes signed by all parties. We will not have this agreement for the final receipt date as it needs to be negotiated by the commercial departments of 2 Universities. We expect to have this sorted by the end of the month. Will it be OK to have this signed agreement for then? If it would help, I can get signed letters from both the Collaborators saying that they are have seen the technical proposal and are willing to collaborate on the sections as detailed.

ANSWER With respect this agreement it says very clearly in the RFP (in bold letters) that "Proposals that do not include this agreement will be returned to the Offeror without further review and will not be considered for award." No extensions will be given to satisfy this requirement. Furthermore these agreements must be signed by someone with some administrative/business authority within the collaborating institution (e.g. the signature of an academic co-PI is not sufficient as such a person does not have the legal authority to assign a university's patent rights).

QUESTION 2. There is no technical proposal page limits. Is that correct?

ANSWER Yes, that is correct - no page limit.

QUESTION 3. We note that there has also been a program announcement (PA) under NIAID's Integrated Preclinical/Clinical AIDS Vaccine Development (IP/CAVD) funding mechanism, and are currently trying to determine what the principal differences are between this and the above RFP, and whether one is more appropriate. While we are currently analyzing that PA to determine whether it or the HIV Vaccine Design & Development Teams (HVDDT) RFP is more appropriate for our purposes, we wondered if you could shed any light on how the aims of this IP/CAVD PA differ from those of the HVDDT RFP?

ANSWER The IPCAVD PA is a mechanism for funding a multiproject "Grant." This is an older Program that is in evolution. These Grants usually combine 2 or 3 research projects linked to the central theme of later stage development of a particular vaccine, plus 1 or 2 core units that perform services for the research projects (one of these is usually an "administrative" unit and the other may be a "central lab" or "manufacturing" unit). As the name of this PA (Integrated Preclinical/Clinical AIDS Vaccine Development) indicates the effort must be linked to the purpose of getting a specific HIV/AIDS vaccine concept from the lab into clinical trials; however, some of the research projects have been very basic in nature. The HVDDT "Contracts" are more unified product development efforts. They can include additional basic research on developing further iterations of the vaccine, but they must present a clear development path for getting a vaccine product into clinical trials. The HVDDT Contract proposals are more carefully reviewed for an understanding of all the necessary technical parts of product development (e.g. GMP process development and manufacture, preclinical toxicology, regulatory compliance) as well as the science behind the basic concept. While both HVDDT Contractors and IP/CAVD Grantees are required to get a product into clinical trials in the time span of the Project neither are required to perform those trials under the Contract or Grant budget; in fact they are both encouraged to apply to the DAIDS HIV Vaccine Trials Network to perform the clinical trials (and this can decrease their costs considerably and allow them to focus their effort more).

Basically, these are two different funding mechanisms designed to do the same thing - that is to get more AIDS vaccines into clinical trials. The amount of money involved and the style of the projects/PIs may differ. The HVDDT Contracts have been funded so far at a little bit more money (about $3-5M/year compared to about $2M/year for IPCAVD grants) but there is no actual limit on the funds someone can request under either mechanism. The IPCAVDs have tended to include more basic research and, as grants, they have less frequent reporting requirements both of which the more academic type investigators like. But the IP/CAVDs have the disadvantage getting less attention (and helpful advice) from DAIDS Project Officers (there is actually a team of DAIDS project officers, with backgrounds in nonhuman primatology, manufacturing, regulatory compliance, and clinical trials, formed for each HVDDT Contract to track progress and help with problems). The HVDDT Contract mechanism was really designed to entice industry types (and those academic types who understand the difference between experiments and product development) into AIDS vaccine development; as such they use a milestone-driven contract mechanism (with yearly renegotiation of the milestone to both keep the goals reasonable and keep the projects going as more of collaborations between DAIDS and industry) which in our experience the more pragmatic industry types serious about vaccine product development feel more comfortable with.

QUESTION 4. Do we need preclinical efficacy data prior to this application?

ANSWER Demonstration of efficacy in a monkey model or demonstration of the ability to induce cross-reactive neutralizing antibodies is not required. However, the more your vaccine is based on a very novel concept or an idea that is definitely not mainstream (in the academic circles) the more helpful some evidence of efficacy from animal model studies will be in the review process. Also, it will be difficult for the Reviewers to think that your product will induce "broadly cross-reactive" neutralizing antibodies, if you do not present any preliminary data showing that it at least can induce some neutralizing antibodies.

QUESTION 5. Is a go/no-go decision point an acceptable milestone in principle? If the data support the no-go decision, does that preclude cost reimbursement for the work leading up to that decision point?

ANSWER A go/no-go decision point makes an excellent milestone. Even if the decision is "no-go" you will get reimbursed for your costs and fee. We are not going to penalize you for nature not being on your side. In good science good work does not always give you the results you are hoping for, but if we want our Contractors to deliver us something that works by doing good work and not glossing over problems then we have to reward them for telling us the truth and making decisions appropriately even when it is not the "truth" we had hoped for.

QUESTION 6. If significant budget commitments occur prior to reaching a milestone that triggers cost reimbursement, and these exceed a reasonable cash outflow for a small company Offeror to sustain, are there any mechanisms available to address cash flow constraints other than redistributing into a more frequent series of milestones?

ANSWER Invoicing has been monthly or quarterly, based on costs expended, rather than linked to milestone accomplishment. Fee payment will be linked to milestone accomplishment; otherwise milestones are a mechanism for Government technical oversight of the Contract as well as continuous assessment of progress in the Contract for yearly NIAID funding decisions.

QUESTION 7. The technology that will form the basis for our proposal is also the subject of an existing HIVRAD grant. It is our intention that our proposal will build on the output of that grant to develop improved vaccine candidates for clinical evaluation, and that the HIVRAD grant recipient will also be a collaborator/subcontractor for our proposal, although on work that is not included in their HIVRAD program. Are there other examples in which a single technology is a successful Offeror for multiple grants or contracts, and if not, is there any difficulty with such a scenario if the programs are complementary?

ANSWER It is very common for grant applicants and contract offerors to use a single technology as the platform for development of several different concepts or products or iterations of a single product. It is also common for applicants/Offerors to apply at different times for money to perform different aspects in the development of one product (e.g.. basic research, GMP production, regulatory compliance studies). This is acceptable as long as they do not request money to perform the same specific work twice. We will compare proposals that get funded with other grants/Contracts the Offeror may have for instances of "double-dipping" and we will alter the budget appropriately; reviewers will be informed of this so any possibly unfounded suspicions will not impact review.

QUESTION 8. The RFP refers to profit or fee as appropriate. Does this suggest that an Offeror is entitled to earn fees or profit over and above program costs, or does it allude to the necessity that commercial subcontractors will need to earn a profit on services or materials that they supply? If the former, are there guidelines for what is appropriate?

ANSWER The first interpretation is correct. Direct your attention to "Note 9 to Offeror" where fees are discussed.

QUESTION 9. Is it necessary that all required technical resources for the proposal be hired or in place in advance, or is it acceptable to identify roles/positions that would be filled contingent on the contract award?

ANSWER The second is acceptable. However, if subcontractors or key personnel or facilities are not yet in place then the Offeror should identify the criteria to be used in selecting them so that the reviewers can judge the Offeror's competence. And, obviously, if too many positions and subcontractors are "TBN" this will reflect poorly on the Proposal at review.

QUESTION 10. In the case of collaborators or subcontractors, how complete or formal a commitment is required in advance?

ANSWER What is required depends on how essential the collaborator or subcontractor is to the project. Commitment must be demonstrated for academic collaborators providing essential design input, companies with key Intellectual Property, or single-source manufacturers. However, in past competitions quotes from intended or competitive minor subcontractors were acceptable; contracts did not have to be in place. The same should be acceptable this time.

QUESTION 11. In the context of process and product development, many costs will be based on best estimates and will necessarily be based on assumptions. How flexible is program management in terms of handling ultimate required actual expenditure that exceeds original budget estimates? We would like to propose our most reasonable expected costs, but are anxious about having to absorb differences between estimates and actual costs in areas like clinical trial materials, where the cost of production is unavoidably uncertain at the time of submission.

ANSWER Most people are submitting estimates that take these considerations into account and then actually under spending. For unforeseen necessary costs that are within the scope of the contract additional funding may be provided through a supplement to the contract. However, as the availability of supplement funds changes yearly depending on NIH budget constraints, there is no guarantee that additional funds will be available when needed.

QUESTION 12. In certain instances we may prefer to designate certain external contributions to the project as suppliers and in others as subcontractors. Are there clear guidelines that specify these designations? Can either also function as either paid or unpaid consultants to the project outside their supplier or subcontractor capacity?

ANSWER There are not clear guidelines on whether to designate someone a supplier or a subcontractor. As to the second question there is no reason why you can't pay someone as a consultant for advice in addition to the actual work they perform as a subcontractor. (It is only “double-dipping” if they collect twice for the same piece of work.)

QUESTION 13. We understand our travel cost estimates are to include the costs of the scientific oversight committee and NIH staff periodic review visits. Can you provide any input on standard assumptions you wish offerors to use for this purpose?

ANSWER There are Government, university and business standards for travel; your organization may have already come to some agreement with the Government if you have a Grant for research. You should budget for the travel, lodging and meals of your external advisors; some past Teams have also paid modest consultancy fees to external advisors – this is permissible. The NIH budget pays for the travel of NIH staff on review visits so you shouldn't budget for that.

QUESTION 14. Regarding clinical studies (and in particular studies run in the NIAID’s HIV Vaccine Trials Network, the HVTN) do we need to indicate the clinical investigators in the proposal and do we need to list them as contractors or collaborators?

ANSWER You can say that you plan on performing clinical studies with the HVTN and submit a letter of understanding or support from Larry Corey (the PI of the HVTN) without listing HVTN investigators as collaborators or contractors.

QUESTION 15. Can we run clinical studies outside the HVTN (or ACTG)?

ANSWER You can run clinical studies outside the HVTN or ACTG but then you must either budget for them in your HVDDT budget or indicate that the money for those trials will come from specific other sources. And you should then pay very careful attention to how you will satisfy human research subject protection concerns, as expressed by the DHHS OHRP, in accordance with the norms and standards governing such studies performed using U.S. Government funds, and NIH minority, women and children inclusion concerns as discussed in the Evaluation Factors for Award section of the RFP.

QUESTION 16. If we plan to run SHIV monkey studies with the help of the NIH SVEU (Simian Vaccine Evaluation Units), do they need to be budgeted in the proposal?

ANSWER Monkey studies that the NIH SVEU has already approved should be indicated in the proposal, but not budgeted for because they are already being payed for by the NIH. It would probably be wise to request money in your HVDDT budget for future as yet unapproved studies because you can't be sure that all future requests to the NIH SVEU will be granted.

QUESTION 17. Is there a recommended length of the technical part?

ANSWER Long enough to describe all the assays and technical procedures, resources, etc. THOROUGHLY! It is not possible to be too long - it is possible to be too short. Several past proposals were considered non-responsive by the review panel because there was not sufficient detail about the technical procedures to be employed (including the key procedures of some key subcontractors).

QUESTION 18. Do we need to produce GMP (and later on commercial) clinical lots in the U.S.?

ANSWER You need to satisfy the FDA on this so that the product can be tested at trial sites in the U.S. if that is your plan. The FDA allows manufacture in inspected facilities outside the U.S. If you have any question at all about the acceptability of your manufacturing facility please consult the FDA.

QUESTION 19. Can we submit the proposal from our site outside the U.S. or do we need to apply from within the U.S.?

ANSWER This RFP is open to International Offerors. You will neither be penalized nor given any advantage at Review if you submit from a foreign site.

QUESTION 20. What specific expenses will this grant (sic; this is not a "grant" – it is a "Contract") fund to the company that can be used to pay for each of: corporate salaries, overhead, employee benefits, equipment for research/development/QC/QA, equipment for pilot plant manufacture of product for Phase I and Phase II trials and any other such corporate expenses?

ANSWER This program was actually specifically designed to get industry/companies involved in the manufacture of candidate HIV/AIDS vaccines. The Contract will pay for all of the things asked about (although there are some Government guidelines that cap salary reimbursement, and overhead/indirect rates must be negotiated with the Government). A website has been provided in the Instructions to Offerors indicating the Salary Rate Limitation. Your costs must be justified and the business proposal will be review and selection will be based on a "best buy for the Government." Cost, although not paramount, is a consideration in award.

QUESTION 21. With reference to note 6 to Offeror: Can we support manufacture of phase III product so that it would be ready for use in trials? Can we support renovation of facilities for GMP production of product?

ANSWER It says very clearly in the RFP that this is not meant to fund phase III trials. Of course when you are preparing your plasmid and viral seed and working seed banks at the start of GMP manufacture for Phase I you will put down enough to expand for phase III trials and that can be paid for in this Contract, but the actual preparation and vialing of the vaccine for the phase III trials should not be paid for with this Contract (the material is liable to expire before a phase III trial starts and that would be a waste). What we are seeking to do with this funding mechanism, at this time, is to increase the number and diversity of candidate HIV/AIDS vaccines in early-phase clinical trials; this mechanism is not intended to reward those most promising (at this time) candidates with the funds to jump to the head of the queue for entering into a phase III efficacy trial. We realize that everyone believes that their vaccine candidate is the best (this is how it should be); however the AIDS epidemic is so serious that the U.S. Government cannot afford to "put all of its eggs in one basket" and not advance as many truly different candidate vaccines as possible.

Contract money can be used to buy equipment, however, it is not normally used for building or major renovation.

QUESTION 22. Our team would like to know the importance the government review committee would actually place on the value of a close collaboration of a University research team with a vaccine manufacturing company in this project. Are we correct in understanding that this kind of "research university and company" collaboration is exactly what the government is truly looking for and would give much more approval consideration to that kind of partnership? That is, of course, assuming that the technology is cutting edge and the company capable.

ANSWER You are completely correct in thinking that this mechanism was designed to get university-industry partnerships working on HIV/AIDS vaccines (the academics have the bright, innovative ideas needed because the old ways of making vaccines haven't worked for AIDS, and industry has the crucial expertise in product development, GMP manufacture and regulatory compliance that is necessary to get a new vaccine into clinical trials where we can find out whether it works). However, your question seems to specifically ask whether "the review committee" is going to insist on seeing this (or give you extra credit). The Review panel will insist on a Proposal demonstrating a good idea that the Offeror can really turn into a clinically testable product; this may not require a university-industry partnership as long as all of the competencies are lined up. [Note: One of the successful Offerors in the first competition was a mostly university consortium that had an industry add-on to ensure that the industry portion was done right, while other Contracts went to Offerors where the industry partner was the lead PI.] Any university group that comes in alone, without any industry involvement (either as a co-PI or an integral subcontractor) will probably not be successful, while some large companies (with strong internal research programs) could be successful without a university partner.

QUESTION 23. I noticed that under Note 5 in the "Note To Offers", that the Offeror must provide draft agreements signed by all parties with their proposal. Traditionally, we have never had to provide signed agreements to the NIH. As we are not yet guaranteed an award it appears awkward to have agreements signed with potential collaborators if there is a likelihood that the grant will not be awarded. Can you elaborate a bit on the rationale for having these agreements in place?

ANSWER Note 5 states: "The Offeror shall provide a draft agreement signed by all parties involved outlining procedures to be used for: (1) obtaining patent coverage and licensing of the resulting HIV vaccine, and (2) procedures to be followed for the resolution of potential legal issues that may arise. If this agreement is not included in the Offeror's proposal, the proposal will be judged not acceptable. The Offeror should also plan to obtain patent coverage and/or licensing for all substances and technologies used in the vaccine product(s) made for research and clinical trials."

These are very large (for the NIH) and complex Contracts usually involving the collaboration of a group of individuals/companies. A signed agreement of the sort that we ask is an indication of the commitment, development, coherence, maturity, and management of the group. You can write an agreement to just cover this Contract "if it is awarded" and then you have no obligations or complications if you don't get the contract. If you cannot come to agreement on how to deal with intellectual property issues and resolve legal disputes among yourselves before you start to work then that does not bode well for the conduct of the Contract. In fact, in the first round of competition one of the Proposals almost fell apart after they made the competitive range cut and before the final selection because they couldn't come to terms on patent issues; that group is now functioning very well - but without one of the original co-PIs.

QUESTION 24. I have one question for you, since I am not familiar with the way DAIDS handles these particular RFPs. If a proposal does not meet the cut-off, is there an opportunity to re-submit it (after addressing the reviewers comments), as in the case of an R01?

ANSWER This is not a repeating RFP with regularly scheduled application deadlines like R01, HIVRAD, or IP/CAVD grants. But this is the fourth competition for HVDDT Contracts, so Offerors who did not make the cut in the past have the opportunity to reapply this time. We do not know at this time if another RFP like this will be issued (or if one is issued when that will be). All that can be said for sure about future HVDDT RFPs is that there will not be another one for at least another 12 months.

QUESTION 25. We are a biotech company with more than 500 employees. I noticed that several other large biotech companies, i.e. Chiron, have received contracts from NIAID. Am I correct that we are eligible to receive a contract under this RFP?

ANSWER This is not a small business set-aside (although small businesses are encouraged to apply – and have been successful Offerors in past competitions). Your company is eligible to receive one of these awards.

QUESTION 26. At our company we are currently calculating average costs per FTE for each specific R&D activity type (Bio-informatics, Molecular Biology, Purification, fermentation, clinical investigation...) that we could split between direct costs & indirect costs. We are also tracking and reporting the actuals the same way. Would it be acceptable to the NIH if we submit a budget where we: Provide an estimate of FTE for the project for each type of activity and valuate them with the average cost per person. We wouldn't then provide an actual estimation of materials consumption, or equipment used, or actual travel of persons directly involved in the project. That would be a direct function of the % FTE dedicated to the project. We are fully prepared though to list all major materials, equipment that would theoretically be used for the project and give you the cost/unit currently negotiated with our suppliers as INFORMATION.

An example: cost/person in Purification department = 150,000 USD
(: total costs of purif department/# of persons in purif department) we would split this between direct cost & indirect costs.
FTE estimated to work on HIV project for 2002 = 4.2
Then: Total costs for 2002 = 150,000 *4.2
+ List of price/unit of major materials, equipment used for purification
+ activities AS INFORMATION.

All identifiable external expenses such as lab analyses, investigators fees will be clearly allocated to HIV project and tracked as such

Would that approach be acceptable to the NIH?

ANSWER This is not like any of the budgets that came in for previous competitions. The initial Review panel will not look at the budget specifics (just a general breakdown, with which such a budget might be made to appear consistent). However, the Source Selection Group, which will evaluate the Proposals that made the competitive range after those Offerors have answered technical questions asked by the Review panel, will look at the budget in more detail and may not view such a budget favorably.

QUESTION 27. I have a few questions on what needs to be filled in for the section "qualification of Offeror"

1- General experience: the overall experience of the company with vaccine development? only HIV research?
2- Performance history & pertinent contracts: are we talking about any R&D collaboration for any vaccine development or specifically collaboration with NIH?
3- List of pertinent grants: only with NIH or other entities (EEC, Path,...)?

ANSWER This is an international competition; there are other excellent Offerors. You should try to overwhelm the Reviewers with how experienced and good you are, not just in HIV research, but also in other areas of vaccine research. Not just collaboration with the NIH but other collaborations on vaccine development. Of course you should highlight the HIV work.

QUESTION 28. Do you want us to send quotes/documentation on supplies/materials, consultants, etc. with the initial submission of the contract proposal? OR, IF it looks like we will get funded, then we produce the documentation? OR, just keep the documentation on file in case we get asked?

ANSWER You should send in as complete a budget as possible. Quotes from potential subcontractors are sufficient. You shouldn't sign contracts with subcontractors yet though because you don't know if you will get the money from this competition, but you should find out how much the work of the project will cost.

QUESTION 29. How many are on the External Advisory board, and would $1600 be an appropriate sum per board member?

ANSWER There should be about 5-6 people on your External Advisory Board. You should budget to fly them into wherever the annual review will take place, put them up at a hotel and feed them for 1-2 days for each yearly meeting. Some

Teams have also paid their external advisors a modest consultancy fee; this is permissible. The amount you should budget will depend on how far they have to come and the hotel you select but $1600 to $2,000 each is in the neighborhood of what the other Contracts are spending. Please remember to not propose specific advisors in your Proposal; advisors will be selected in conjunction with your NIAID Project Officer after the award is made.

QUESTION 30. I am wondering how to deal with the Human Subjects Evaluation section of the proposal. We plan to conduct clinical trials through NIAID's HVTN (or ACTG) in years 4-5 of the contract. Please let me know what information is required in the proposal at this time.

ANSWER If you plan on having the DAIDS HVTN or ACTG perform the clinical studies then you, yourselves, will not actually be performing Human Subject Research; and the DAIDS trial network and trial sites will meet all the requirements of OHRP. The HVTN or ACTG protocol development team will submit the clinical protocol to our DAIDS Prevention Science Review Committee (PSRC) or Clinical Science Review Committee (CSRC), our DAIDS Regulatory Affairs Branch would submit the IND (Investigational New Drug) application to the FDA, the VTN or ACTG trial investigators would get the necessary local IRB (Institutional Review Board) approvals from the local institutions where the clinical trials will be performed, and the HVDDT Contractor would simply be making the vaccine and submitting a Drug Master File to support the DAIDS IND. In this case the Contractor would be fulfilling their obligation to Human Research Subject Protection through their submission of information to the FDA and provision of information to the PSRC and the Clinical Investigators in the "Investigator's Brochure" which they will have to provide to the IND application. All of the training required for doing clinical trials and the regulations governing those trials will be satisfied by the HVTN or ACTG sites. In the proposal the Offeror should just make it very clear that clinical trials will not actually be performed with Contract money but will rather be performed by the DAIDS clinical trial network with product delivered to them that was produced under the Contract.

QUESTION 31. I have a question regarding the budgeting of clinical trials which we anticipate to be conducted by the HVTN (or ACTG). It is my understanding that we should not include patient and central lab costs in our budget. We also propose to use the AIDS Vaccine Evaluation Group (AVEG). Should we include the funding for immunological monitoring by this NIH supported service? We will include budget for Data Management, Clinical Supply Management and related FTE costs to manage our participation in the trial as well as travel to clinical sites. Can you clarify this issue of clinical trials run by the NIH supported networks?

ANSWER AVEG no longer exists. It was replaced by the HVTN. You should not budget for trials to be conducted by the HVTN (or ACTG) except: (1) insofar as you incur costs delivering product and documentation (e.g. that needed to support the IND application to the FDA) to the DAIDS network so that the trial can be conducted, (2) for your own Data Management, Clinical Supply Management and related FTE costs to manage participation in the trial as well as travel to clinical sites (e.g. for your company medical people), or (3) for your own analyses of samples if any are desired in addition to the HVTN's or ACTG's analyses.

QUESTION 32. We anticipate that it will be year 4 of the contract before we are ready for the clinical study. Do we need to identify the potential clinical investigator in the contract proposal? Also, how much scientific detail is required for the preclinical section of the proposal? Do the specific planned experiments need to be detailed - for example, if we will use PCR do we need to describe the PCR protocol?

ANSWER. If you plan on using the HVTN or ACTG to do your clinical trial then you only need to say so and submit a "letter of interest" from the appropriate clinical trials network head (you don't need to know who within the network will do the study; and we want to encourage you to use our clinical trials networks in order to both ensure human subject protection and the comparability of immunogenicity/activity data). But if you want the funds to do a clinical trial yourself or have a clinical collaborator or CRO do the trial for you then you must not only identify that individual (organization) but also you must address all the human subjects protection issues in detail in your proposal.

You do need to submit a lot of detail in the Proposal about the preclinical studies, but you don't need to submit laboratory protocols as long as you submit enough information to make it clear to the reviewers that you know what you are doing (in the absence of someone on your staff named as personnel in the Proposal who has a published article doing a procedure that you can reference you will need to submit more technical information about the procedure). Please supply the level of detail on procedures and clinical trial that you would supply in an R01 application, and then submit more information about facilities, GMP capability, and regulatory knowledge.