A GUIDE TO DOING BUSINESS WITH FOREIGN INSTITUTIONS

Prepared by Paul D. McFarlane for October 24, 2006 Presentation – 2006 NIH Acquisition Symposium

This guide is arranged to correspond with the most common acquisition process phases, from acquisition planning to contract closeout. It is not intended to be a complete guide, only a reference tool.

"Today's advances in transportation and communications technologies make the job of contracts professionals more complex. It's important to be open-minded when planning any acquisition. Develop a mindset for the process of acquiring goods and services from foreign institutions. Expect to encounter obstacles and anticipate having to develop unique strategies to overcome them or to work through them. Language differences between people of different countries are only part of a process for learning that there's more to successful contracting than the exchange of paperwork. These countries and their diverse cultures make living in a global economy all the more exciting." [P. McFarlane]

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Acquisition Plan/Request for Contract Phase -

This phase includes all pre-solicitation activities.

Consider the context of the buy.

What are you buying and where will the item(s) ultimately be delivered, utilized, disposed of, etc.?

If the buy is for services, where and how will these be performed e.g. will the prime contractor be a foreign or US entity?

Will the prime employ consultants that will perform work in a foreign country?

Will the prime hire subcontractors in foreign sites to perform some of the statement of work?

Example: A research and development (R&D) contract to set up and run an HIV-AIDS clinic in an African village has greater issues than a request by your US-based prime contractor to purchase several motorcycles for use in the same village to allow clinic staff to get to and from patients who can not travel to the clinic.

There is no difference between the US Government's right to consent to subcontracts under a prime contract regardless of whether the prime contractor is a US or a foreign institution. However, a foreign clearance must be obtained from the US Department of State prior to the Government awarding a prime contract or consenting to any subcontract with foreign institutions.

Also, the requirement for a prime contractor to flow down any of its contract provisions, including those under Section I, is no different when the subcontractor is a foreign institution. However, questions remain about whether a subcontractor (regardless of their tier) is also required to flow down contract provision from their agreements with a government prime contractor. It is the responsibility of the government Contracting Officer to follow the provisions at FAR Part 44 Subcontracting Polices and Procedures, when planning to consent to any subcontracted work.

If your requirement entails clinical trials work in counties other than the US, it's important to know that any contractor(s) or their subcontractors will have to adhere to some special regulations for the conduct of that work depending on whether or not their country is a member of the European Union (EU). Currently, there are 15 member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom.

The European Union Clinical Trials Directive (EU CTD) has been in place since May 2004 and it governs the conduct of clinical trials in the European Community. This Directive is fairly new and the ramifications from this are still unfolding. The regulatory requirements of the EU CTD include the following:

> Legal Representation - Sponsors (NIH) of clinical trials must be either established in the EU or appoint a legal representative who is established in the EU. Although the sponsor is ultimately responsible for a clinical trial, the EU legal representative is responsible for civil and criminal liability in the EU. The EU representative therefore needs to have in place insurance or other financial arrangements with the sponsor that are sufficient to provide coverage in the event of civil or criminal liability.
>
> Insurance – Each member of the EU community requires insurance to cover protocol-related patient injury.

Any research involving human subjects or human materials, even if performed outside of the US and its territories shall be governed by Human Subjects regulations. Contact the NIH Office for Human Research Protections (OHRP) regarding these matters. Research involving human subjects that is not covered by an Offeror's Federal Wide Assurance shall not be conducted under a resultant contract until a written notice of approval has been provided by the Contracting Officer, following the Offeror's provision of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," Form OMB No. 0990-0263 (formerly Optional Form 310), agreeing to comply with the requirements of 45 CFR 46 to protect human research subjects. Note that foreign countries may have their own regulations governing the conduct of human subject research and it's best to familiarize yourself with what these are early in the acquisition planning process.

If possible, discuss with your IC's scientific review unit whom they will assign as the scientific review administrator (SRA) for your acquisition. Obtaining their input on development of the technical evaluation criteria and the acquisition milestone schedule is important.

As the work of the NIH relates to biomedical sciences and healthcare, it's important to be aware of the existence of the World Health Organization (WHO). The WHO is a global organization comprised of 193 member states. The constitution of the WHO requires its member states to be vigilant and proactive in the health needs of its people. This is the official WHO web site; check it to see if the country to which your award will be made is a member of the WHO. http://www.who.int/en/
In April 2005, the WHO governance board set forth changes to its International Health Regulations known as IHR (2005). It's worthwhile checking these regulations to get a sense of the types of scientific research on which the WHO may have published guidelines or regulations that could impact your contract's requirements. http://www.who.int/csr/ihr/revisionchange/en/index.html

Once you have a dollar figure for the government's estimate, determine how that sum equates to the currency of the foreign country(ies) in which the work will be performed. Is it sufficient? Is it too much? [Quite often, the cost of doing business overseas can be less expensive than the same work with a domestic firm.]

Here are three foreign currency conversion web sites that are worth investigating.

This site has some foreign countries' currencies that the one below does not.

http://www.gocurrency.com

This site allows you to plug in past, current, and future dates to identify a currency's value.

http://www.xe.com/ict/#top

This site is arranged with an easy to use, less cluttered page than the first two.

http://www.xe.com/ucc/

Will the planned contract involve the use of priced options for additional quantities of items or time? [Considering this in the acquisition planning stage will ensure it is part of the government's cost estimate.]

The statement of work may require special considerations in how the work will be conducted based on the local customs e.g. traditions of the location where the work will be performed or the materials purchased or sent once purchased.

Are any special data rights or patent rights issues to consider? [For assistance consult your ICs office of technology development or the NIH Office of Technology Transfer.]

Are any proposals expected from any other Institutes and Centers (ICs) of the NIH, from DHHS, or from other Federal agencies? [This is important to how the requirement is constructed. Check in advance about whether or not a particular component of the DHHS or any other agency has authority to compete for Federal dollars.]

If the requirement involves the transfer/shipment of drugs, human materials, or animal materials between countries, the institutional review boards (IRB) of the awarded contractors will need to be consulted to gain advance approval. It’s best to build this into the acquisition plan so that it is identified in the solicitation and not left as a last minute consideration.

Solicitation Phase –

Will the solicitation allow proposals from foreign institutions? [If the solicitation will limit competition to only US businesses individual ICs may require advance approval from with the IC or beyond to allow this. Note that it's a common understanding among NIH COACs that, unless a solicitation states otherwise, offers from foreign institutions are welcome.]

Does your Office of Acquisitions have specific guidelines for handling requirements that will be performed outside the United States and its Territories? [The nature of the requirements of some ICs dictates that a greater percentage of their requirements will be performed outside the US.]

Will the solicitation require special content e.g. clauses, articles, attachments, etc.?

Most ICs provide sample contract clauses in their solicitations. If it is anticipated that a foreign institution will be awarded a contract what types of Advance Understandings might need to be considered for placement in the sample contract?

Note that FAR Part 19 Small Business Programs does provide definitions of foreign businesses. However, small business subcontracting provisions (i.e. small business plan requirements) do not apply to awards with foreign institutions.

Will the solicitation allow for a pre-proposal conference if necessary?

Will the solicitation require pre-proposal or pre-award site visits to allow Government program officials to become familiar with the facilities to be utilized, the flow of the work, the geographic vicinity where the work is to be conducted?

Thinking ahead - If your solicitation contains a proposal intent response mechanism where Offerors provide advance notice (often 30 days prior to proposal receipt) to the contracting office of their intent to submit a proposal, be on the lookout for these. Get copies of these to both the assigned Project Officer and the assigned scientific review administrator (SRA). This will keep them apprised of the type and number of proposals that are likely to be received.

Proposal Evaluation Phase –

Certainly, there are different considerations regarding an Offeror's technical proposal versus their business proposal.

Note that the determination of Responsibility as defined in FAR Part 9 Contractor Qualifications does not apply to proposed contracts with foreign, state or local governments.

At the NIH, much of the proposal evaluation phase is handled by the scientific review branch/program of each Institute or COAC. However, it's important to remember that communicating early and often with the assigned scientific review administrator (SRA) is key to building good working relationships.

Discuss all aspects of the peer review with the SRA in advance of the meeting. Learn if they know of any regional customs or traditions to be considered related to the countries from which proposals were received and that will be evaluated.

Be certain to familiarize yourself with the technical proposals at least to the point where you can navigate their table of contents and can easily locate document content. Ensure that the Technical Proposal Instructions as well as the Business Proposal Instructions of the solicitation have been followed regarding the document's content.

It is equally, if not of greater importance to familiarize yourself with the content of each business proposal to ensure that each Offeror complied with the solicitation in preparing this document and its attachments. Ensure that the solicitation's requirements are enforced when practicable. Understand that the solicitation may have requirements that do not apply or cannot be applied to foreign Offerors.

Did any Offerors misinterpret any of the US Federal regulations or forms?

How, if at all, will these issues be address prior to the peer review?

Negotiation Phase -

This phase includes cost analysis and cost realism analysis.

Here again, considering the context or scope of the requirement is important.

Of equal importance is the nature of the customs or traditions of the people in the country and specific region where the work will be performed or the goods purchased (there or elsewhere and shipped) and delivered and used.

Once you have the Offerors' cost estimates, figure out how that sum equates to the currency of the foreign countries in which the work will be performed.

See Acquisition Plan/Request for Contract phase above for the currency converter(s).

Does the foreign institution have an indirect rate agreement with a US auditing entity?

One or more of the Offerors may already be doing or have done business with a US Federal agency. Check to see if they have a negotiated rate agreement with the DHHS or the Department of Defense e.g. Department of Defense Contract Audit Agency (DCAA). How do these rates compare with the type of work related to your acquisition?

Some COACs, like the NIAID, have employed consultants to assist overseas institutions with the process of preparing for indirect rate negotiations. These consultants are themselves businesses and may have offices in several countries.

If the Offeror proposes the purchase equipment follow the standard practices of completing a Determination and Findings to justify these purchases and of having the NIH Property Office check the NIH inventory for the items. It's most important to understand where the equipment will be purchased (i.e. in the US or abroad) and the logistics of how the items will be gotten to the worksite(s). The shipment of equipment to an overseas location can adds time to the purchase as well as special insurance and inspection requirements depending upon the nature of the items. Carefully coordinate the provision of any Government Furnished Property to a foreign institution with your Institute's Property Administrator.

On September 11, 2006, the Associate Director for International Research, NIH Director, Fogarty International Center announced the rollout of the NIH Foreign Tracking System (FTS) that NIH has been piloting for several months to US embassies worldwide. This Web-based FTS is intended to replace the paper form-1820 clearance system. See award phase below for more details on this system.

The earlier the better, contact the Fogarty International Center to begin the process of obtaining US Department of State clearance also know as a *foreign clearance* for any planned prime or subcontract awards to institutions outside the US and its Territories. This clearance process can take between 2 weeks and 10 months depending on the foreign country. This is so because of the individual business customs within the various countries.

FIC makes the determination of whether or not a clearance is required. There is no dollar threshold for determining when this clearance is required, as it's required for no-cost actions as well. A form 1820 is required for every foreign country where work will be performed.

Award Phase –

NIH Extramural Grant/Contract Foreign Tracking System (FTS) - On September 13, 2006, Mr. Bruce Butrum, FIC Grants Manager, and Mr. Kevin Bialy, Program Specialist in FIC/DIR, provided a presentation on the newly established NIH electronic extramural Grants/Contract "Foreign Tracking System" (FTS) to the membership of the NIH International Representatives Meeting. They outlined the genesis of the development of this new novel system that was originally developed to expedite approval of NIH extramural grants/contracts made in foreign countries, which are subject top review, by the Department of State for foreign policy implications. The FTS has the dual purpose of providing a tool for the NIH to effectively and efficiently track all foreign extramural collaborative activities and provide a simple web-based system to seek clearance/approval of NIH projects through U.S. Embassies abroad. The FTS offers a number of benefits, including the ability of ICs to submit projects directly to FIC; easy accessibility to a web-based system; track and report all NIH extramural collaborations by country (including funding levels by country) and research criteria and to easily identify foreign investigators and foreign research institutes. FIC is currently seeking to expand Embassy access to the system beyond the approximately 50 Embassies using or intending to use the FTS system. ICs will use the system through https://fts.nhlbi.nih.gov/nihfts/login using staff IMPAC II initials and password. ICs are requested to contact FIC (Mr. Bialy and/or Butrum) if they have additional questions. FIC intends to organize further briefing sessions for IC users this fall. A set of written instructions for the use of the FTS is attached to this handout. Note that this system was first developed in 2004 and the NHLBI was chosen to pilot it, hence the NHLBI acronym is embedded in the web site above.

Once you have obtained the appropriate State Department clearances for the country(ies) in which your prime contract(s) and [if applicable] their subcontract(s) will perform work, you're free to send a contract for signature. Note here that the customs of a foreign country will determine the ease with which the contract is reviewed, accepted, and finally signed and returned. Plan to build some time into this award phase, as it can often take longer than you think to accomplish this task.

Just as US contractors, foreign contractors are required to obtain a Dunn and Bradstreet (DUNs) number. This is done via the institution registering on the Central Contractor Registration (CCR) web site at www.CCR.gov [Contractors may also telephone the CCR at 1-800-333-0505. The NIH office that interacts with the CCR is Accounts Payable, OFM on 301-435-3505.]

Also, in order to be paid via electronic means, foreign contractors must obtain an EIN number, which they obtain via their registration in the CCR.

Contract Administration Phase –

As Contract Specialists, we don't always handle acquisitions from cradle to grave. The fact is we often inherit contracts to administer and there's a learning curve associated with transitioning a contract from one Specialist to another. That said, it's important to leave a clear, clean paper-trail in the file(s) so that whoever inherits our contract can get up to speed on the uniqueness of the project with ease.

During contract administration, it could happen that your prime contractor, that never envisioned subcontracting with an institution in a foreign country, decides to do so. This is where many Contract Specialists first encounter the process of obtaining a foreign clearance.

See foreign clearance process outlined under the Award Phase above.

Make the time to keep abreast of changes in regulations that may impact your acquisitions with foreign institution. Some ways to do this are:

- Keep an eye on the Federal Acquisition Circulars (FACs) that amend the content of the FAR.

- Subscribe to the online publication **Today's Acquisition News published by the Acquisition Solutions Research Institute™** (This is published each business weekday and you can receive it via e-mail from ResearchInstitute@acqsolinc.com)

Planning for the successful completion of a contract is important. Many NIH contracts contain statements of work that require a transition plan be engaged within 6-8 months of the contract's completion date. It's incumbent on the Contract Specialist to know if such a requirement exists and to act on it timely. Many times a contract will be renewed and if so, the transition plan requirement in the existing contract should be investigated to see that it is sufficient for the renewal. Some contracts' allow the Contracting Officer to call for a draft transition plan earlier than planned so that the planning for a contract's renewal, which often begins 18 months earlier, may be accomplished successfully. This is so whether or not a contract is with a foreign institution.

Check the statement of work on any existing contracts with a foreign institution to see that all activities related to obtaining final deliverables e.g. database content, files and papers as well as bringing contract activities to a smooth end are considered.

Note that past performance evaluations do apply to contracts with foreign institutions.

Closeout Phase -

One conundrum encountered at contract closeout is the reconciling of final payments to the foreign contractor. This issue is compounded by the fact that the contractor performs work at a time when one currency rate is effective, bills for that work when another currency rate may be effective, is paid for that billing when yet another billing rate is effective and against all this – may be encountering over and/or under-recovery of indirect rates. Not to worry, the same policies for making final payments to a contractor and for closing out their cost records apply to domestic as well as foreign contract institutions. This is not to say that this makes the job of the closeout Specialist any easier, however.

A common question that arises when a contract with a foreign institution nears its expiration is whether or not any government furnished property or contractor-acquired property is required to be returned to the US government agency. The answer depends on the final condition/usability of the equipment, the shipment costs relative the value of the items, and whether or not the foreign institution is a for-profit entity. Note that equipment shipping costs are most often borne by the contractor that is giving up the equipment. Once again, it's important to coordinate these activities with the NIH Property Office.

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ATTACHMENT (1)

STEP-BY-STEP INSTRUCTIONS FOR USING THE NIH FOREIGN COMPONENTS TRACKING SYSTEM (1820 SYSTEM) CONTRACTS
Version Date: 1/7/2005

Technical Assistance

IMPAC II User ID and Password: Carol Simmons, simmonsc@nhlbi.nih.gov, phone 435-0135

User Assistance: Select the "contact us" button on the main page of the Foreign Components Tracking Systems Web site or Contact Patrice McCaulley, mccaullp@nhlbi.nih.gov, in NHLBI's IRTP.

Logging-In

Access the 1820 System via the Internet at: https://fts.nhlbi.nih.gov/nihfts. On the homepage, enter your IMPAC II username and password, and then click on the "**Login**" button. This will take you to the page where you can begin creating a new 1820, or updating an existing 1820. **If you do not have an IMPAC II username and password, you will need to contact IT staff at your IC to obtain one.**

Click on the "**Create/Update 1820**" button to begin the process. This will take you to the **Search Criteria** page.

In the **Contracts** search window, enter the portion of the grant number beginning with the IC letters. There should be 6 digits following the IC letters, using "zeros" if the number is less than 6 digits long (e.g., HL000345). Be sure you are entering the correct number, or a message will appear saying there were no grants found based on your criteria. You may search with or without the year suffix (e.g., HL000345-**03**). If you do not use the suffix, IMPAC will return all paid grants from the current competitive segment.

If there is no record found and one has not been created, then you will have to create a base record. You will see the following statement:

There were no Contracts found based on your criteria. Click here to create a new contract record.

Click the "here" link and it will take you to a data entry screen to create a record for the contract. You will have to fill in all the appropriate information. Since contacts are not in IMPAC II yet, ***please put in your IC's initials in the PCC entry box****.*

Once all the information is entered and saved, click the "close" button and the base record will have been created.

If there is a record in the system, then select the appropriate year and click the "**Create New**" button. For instance, if foreign component involvement does not begin until the –03 year for FY05, you will create an 1820 for the –03 year.

Main 1820 Screen

On the following Main 1820 screen, IMPAC auto-populates the form with the contract number, P.I. name, institutional address, etc. Beginning with the **Foreign Clearance** section of the screen, select **New**, or if this contract has had a State Department Clearance in any previous year, select **Renewal**. Select either **Direct to Foreign** or **Domestic Award**. If the contract is a Direct to Foreign Award, you must also select whether a **Foreign or Domestic subcontract** (or both) is applicable. You will also have to select which country is involved. You will have to do a separate 1820 for each country.

In the **Submitting IC s**ection, IMPAC should have auto-populated the IC (e.g., NHLBI). If incorrect, enter the appropriate IC. Enter the Contact (usually a GMS or PO assigned to the contract) name, e-mail address, telephone and fax numbers.

In the **IMPAC Project Information** section, assure that information on human subjects, animals, AIDS, etc. has auto-populated and is correct. If it is not correct, you will have to use one of the IMPAC modules like ICO to correct the imported data. Make yes/no changes as appropriate – **Stem Cells** and **Bio Defense** do not currently auto-populate. You cannot advance to another screen unless these items are completed.

Archive Record – This feature is not active so you do not need to fill in this information.

In the **Awarded Project Dollars** section, note that in the column labeled **Estimated Cost** IMPAC will auto-populate with direct costs only if the contract has not yet been funded. You will not be able to enter total costs into this column. If an award has already been made, this section will auto-populate with total costs as reflected in the Notice of Award. The **Estimated Foreign Subcontracts** column is a calculated field and will contain the total of all subcontracts created later in this process. You cannot enter information into these fields.

If the contract will be a **Direct to Foreign Award**, complete the column labeled **Parent Foreign Dollars**. Fill in the total costs of the award that are only for the foreign site. If you have more than one 1820 for a Direct to Foreign Award, please only enter the foreign dollars on the first site created. This will avoid the duplication of $ in the system.

If the grant will be a **Domestic Award with a Foreign Subcontract**, you must create a subcontract by clicking on the "**Add Subcontract**" button, near the top left of the screen. You can add many subcontracts for a country by clicking the "**Add Subcontract**" button as many times as needed.

Foreign Site Screen

In the **Principal Investigator** section, complete the information for the foreign P.I. The information can often be obtained by reviewing the parent application (letters of collaboration, etc., often found near the last pages of the application).

Assurances and other information requested on the upper right side of the screen should usually match information on the Main 1820 page. Complete accordingly.

In the **Awarded Project Dollars** section, enter the estimated total costs for the foreign subcontract. These amounts should be available in the parent application, or contact the applicant organization.

Research Objectives Screen

The Research Objectives should be a summary of the aims of the proposed contract, and are often written by the assigned Program Officer in simple language. Avoid copying the application abstract into this section.

If you have additional comments that would be helpful for clarification, click on the "Add a Comment**" button and enter your comments in the window that will open. You may choose whether you want your comments to be viewable by Fogarty and/or State Department or by your IC only. The comments will appear in the "**Snapshot**" (available via the button on the red task bar), but will not appear on the printed 1820.**

Releasing the 1820

Release the 1820, only after reviewing it for completeness and accuracy, by clicking on the "**Release to FIC**" button on the red task bar. You cannot delete a submitted 1820. If there is a problem you can contact DIR staff at FIC, and they can change the status and return the record to the IC for modification or deletion.