My international participant cannot fly to the NIH. Can I ship investigational product to her/him?

It depends. Import/Export laws govern the movement of drug out of the United States and into every foreign country. Every country has their own laws. Just like you would need an effective IND to ship an unapproved drug into the USA, other countries have the same or similar regulations. Therefore, there is a potential for three levels of approvals when you ship drug internationally: import/export approvals, Ministry of Health/in-country FDA-like regulatory body approval, and local ethics committee approval. The NIH is advising that drugs that can be shipped be sent to an identified local provider and not directly to the subject. (See the IRB's memo regarding the local provider.) It is ideal that this provider be at an FWA covered institution, however local laws that may differ from 45 CFR 46 still need to be followed. In addition, commercial import laws (rather than personal import laws) may apply.

Whose responsibility is it to determine if I can ship my drug internationally?

It is both the sponsor and principal investigator's responsibility to ensure the laws of the country are being met when shipping drugs. If the NIH Pharmacy is shipping the drug, they may require evidence of in-country approvals. Please refer to pharmacy guidance on Investigational Drug Shipment Request.

How can I find out the laws of the country I want to ship to?

Places to look for information include each country's Ministry of Health (MoH) website, customs websites, and embassy websites. Once you fill out the NIH shipping paperwork, you will be assigned to an experienced courier who will provide in-country agents. These agents provide the paperwork needed for each import, information on import/export approvals that are needed (which should also include MoH/FDA-like regulations in order to pass through customs), and can help with paperwork in the foreign country itself. Although these agents can help with the import/export laws, they cannot help with local ethics committee approvals. It is advisable to inquire with your identified local provider about the need for ethics approval at his/her local site.

What about the FDA?

The FDA prefers that all study participants are overseen by doctors that are Sub-investigators on the study in question. As this may not be possible in every situation during this uncertain time, it is important that a plan for the safety and oversight of your participant in a foreign country is put in place. The FDA is more likely to accept a plan if it is clear that there is a local provider educated on the study, there is regular oversight by the NIH principal investigator, and there is an established safety profile for the drug in question. Sponsor communication with the FDA is extremely important to ensure regulatory issues are addressed upfront and that the FDA is aware of when and where your participants are being treated.

Please note that this is our current thinking. As the situation evolves, we may have other information.