From: OC GCP Questions
To: [redacted]
Subject: Question pertaining to enrolling a Subject into a clinical trial:
Date: Tuesday, September 22, 2015 6:17:01 AM

Good afternoon --

FDA does not have specific regulations that pertain to research involving illegal immigrants, nor prohibitions against their participation in research. However, it is well accepted that some subjects (generally referred to as "vulnerable subjects") may need additional safeguards to adequately assure and protect their rights, safety, and welfare. The sponsor and the IRB would need to be informed. Special consideration should be taken into account as to how the subject will be able to make scheduled follow-up visits per protocol. Additionally the subject should not be influenced or coerced in to participating in the study. You would also need to follow state and local laws related to illegal immigrants.

For IRB review the full text of the regulation can be found at (21 CFR 56.107(a)) -- "If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experience in working with those subjects."

Additionally if this special population does not speak English special consideration would need to made for translation of the informed consent. FDA has a general guidance on informed consent, "A Guide to Informed Consent - Information Sheet Guidance for Institutional Review Boards and Clinical Investigators" (available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm), that includes some information on translating consent forms:

Non-English Speaking Subjects
To meet the requirements of 21 CFR 50.20, the informed consent document should be in language understandable to the subject (or authorized representative). When the consent interview is conducted in English, the consent document should be in English. When the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in a language other than English, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. As required by 21 CFR 50.27, a copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

If a non-English speaking subject is unexpectedly encountered, investigators will not have a written translation of the consent document and must rely on oral translation. Investigators should carefully consider the ethical/legal ramifications of enrolling subjects when a language barrier exists. If the subject does not clearly understand the information presented, the subject's consent will not truly be informed and may not be legally effective. If investigators enroll subjects without an IRB approved written translation, a "short form" written consent document, in a language the subject understands, should be used to document that the elements of informed consent required by 21 CFR 50.25 were presented orally. The required signatures on a short form are stated in 21 CFR 50.27(b)(2).

Additionally we just issued a draft guidance on informed consent. Please see the link below. http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf Enrolling non-English speaking subjects is addressed starting on page 30.

I hope this information is helpful. Please contact us again at gcp.question@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, September 21, 2015 9:34 AM
To: OC GCP Questions
Subject: Question pertaining to enrolling a Subject into a clinical trial:

Dear Sir/Madam,

I have a question that was posed to me that I am wondering if you could help clarify. Can an **illegal immigrant** be enrolled into a clinical trial? I am not sure if this would be considered to be a vulnerable Subject, and if so, is there a certain type of approval that needs to be given? If not, I don't want to deny a patient from any potential medical care that is available (whether it be Standard of Care or investigational drug use), but I certainly do not want to break any regulations either. Can you please advise? Please let me know if you have any questions, and thank you very much in advance.

Sincerely,

[redacted]