From: OC GCP Questions
To: [redacted]
[redacted]
Subject: FW: Informed Consent Questions
Date: Wednesday, April 24, 2019 11:27:26 AM
Attachments: [redacted]

Good morning –

I can give you a link to FDA's guidance on emergency use. Please see below.
https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf

FDA regulations on emergency use.
CFR - Code of Federal Regulations Title 21

Also, since you mention that you are planning an IDE study, you should speak to someone in the Center for Devices (CDRH). Please see their contact information below.

Phone: 1-800-638-2041
Phone: 301-796-7100
Fax: 301-847-8149

DICE@fda.hhs.gov

CDRH can specifically answer your questions related to the informed consent process for your potential IDE study.

Please also see FDA webpage that outlines how to submit and IDE application.
Investigational Device Exemption (IDE) > IDE Application

Please see additional information below.

While specific devices may have special requirements, the route to market has much in common across device types. Marketing requires either a premarket notification [510(k)] or a premarket approval (PMA), depending upon the device and the technology involved. If a PMA is required, the results of clinical studies will be expected to support the marketing application. Such studies may also be required for a 510(k).

It is not clear from your message at just what stage in development you are presently in - i.e, whether you are on the drawing board or in mechanical or animal testing and still require an Investigational Device Exemption (IDE) to conduct clinical studies or have already advanced into clinical studies. Therefore, I suggest you start by looking at the device advice site at (Experience has shown that more specific information on many of the subjects this site links to is best available through the search mechanism from the CDRH home page - Medical Devices If clinical studies will be needed and are not yet underway, you may benefit from a pre-IDE meeting. Such meetings are also structured and require a preset agenda listing the issues to be discussed.

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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From: [redacted]
Sent: Tuesday, April 23, 2019 4:30 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Cc: [redacted]
Subject: Informed Consent Questions

Hello,

We are currently planning an IDE study and are hoping your group can help us with two questions related to informed consent. A brief background and the questions are below.

The investigational device is intended to manage perforations during percutaneous coronary interventions (PCI). During PCI procedures, a perforation is a rare (< 1%) but life-threatening complication that occurs when an interventional device engages a vessel wall, penetrates the arterial tissue, and exits into the surrounding anatomy. A coronary perforation is an unforeseen complication and does not allow time for a legally authorized representative to provide consent prior to use.

The options for informed consent that we've identified are (1) consenting all patients undergoing PCI prior to the procedure and only considering them enrolled if the investigational device is used or (2) following the emergency research regulations.

We have two questions for the GCP Office:

1. Are you aware of any other potential pathways for informed consent for emergency use type devices?
2. Do you have any resources (guidance documents, templates, etc.) related to informed consent under the emergency use regulations?

If there's additional information I can provide, please let me know.

Thanks in advance for your help!

[redacted]