**Tip #1: What is a FDA Form 3674?**
This form is submitted to the FDA to confirm that the sponsor (or sponsor-investigator) will comply with the registration of the clinical trial as required under FDAAA.

[http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketssubmissions/humanitariandeviceexemption/default.htm](http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketssubmissions/humanitariandeviceexemption/default.htm)

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**Tip #2: When do I need to submit form 3674 to the FDA?**
The most common submissions of the form 3674 to the FDA are as follows:
- As part of an IND application (including IND exemption request)
- As part of a new protocol submission to the FDA, under existing IND
- Other unique and unusual situations may apply, please check with CRSC


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**Tip #3: When is form 3674 not required to be submitted to the FDA?**

**Specifically, for drugs, Form 3674 is NOT required for:**
1. Single patient INDs
2. Single patient or Individual patient protocol
3. Emergency IND
4. Emergency protocol (an amendment to an existing IND)
5. Intermediate-size patient population IND
6. Intermediate-size patient population protocol (an amendment to an existing IND)
7. Treatment IND
8. Treatment protocol (an amendment to an existing IND)


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**Tip #4: Where can I find the template for FDA Form 3674?**
[http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsNumerically/default.htm](http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsNumerically/default.htm)

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**Tip #5: How do I complete a FDA Form 3674?**
Instructions can be found at:
[http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsNumerically/default.htm](http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsNumerically/default.htm)

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**Tip #6: When do I check A, B, or C in section 9?**
Box A should be checked if the submission to the FDA does not include, relies upon, or otherwise references a clinical trial, or a submission that does not include any information that needs to be posted. This option is primarily for pharma or device companies that submit all sorts of non-trial documentation to the FDA.

Box B should be checked if the submission to the FDA is for a study that either
(1) was determined to NOT be an Applicable Clinical Trial under FDAAA, hence does not need to be registered under FDAA requirements, or
(2) was determined to be an Applicable Clinical Trial under FDAAA but the study did not yet need to be posted per FDAAA because the submission to the FDA is prior to the 21 days after the first subject was enrolled.

Box C should be checked if the study is an Applicable Clinical Trial under FDAAA, hence is required to be registered at Clinicaltrials.gov, and all applicable clinical trial information has been posted within 21 days of the first subject being enrolled. This also means that you should have an NCT #, and that number needs to be provided in the next section of the form. Note that Option C also needs to be checked for an HDE.

http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsNumerically/default.htm

http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/humanitariandeviceexemption/default.htm

Tip #7: For more information, go to:
http://www.fda.gov/regulatoryinformation/guidances/ucm125335.htm
or call the Clinical Research Support Center at (303) 724-1111