Checklist 1.B

Determining When Human Subject Research Activities are FDA Regulated

1. The activity involves a FDA regulated test article because <u>one or more of the following are TRUE</u>:

   □ An article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them

   □ An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals

   □ An article (other than food) intended to affect the structure or any function of the body of humans or other animals

   □ An article intended for use as a component of any article specified in the above items

   □ Either of the following is true:

      □ The drug is not approved by the FDA for marketing

      □ The drug is not being used in the course of medical practices

   Check TRUE if any of the above items apply: ☐ True ☐ False

2. The activity involves a FDA regulated test article because it involves the use of a medical device, other than the use of a marketed medical device in the course of medical practice <u>because one of the following are TRUE</u>:

   □ Recognized in the Official National Formulary, or the United States Pharmacopoeia, or any supplement to them

   □ Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals

   □ Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

   □ Either of the following is true:

      □ The drug is not approved by the FDA for marketing

      □ The drug is not being used in the course of medical practices

   Check TRUE if any of the above items apply: ☐ True ☐ False

3. The activity is otherwise subject to FDA regulation because one or more of the following are true:

   ❑ Data from the activity will be submitted to, or held for inspection by, the FDA.

❑The activity involves an FDA-regulated article one or more of the following:

- ❑ Food or dietary supplement that bears a nutrient content or a health claim
- ❑ Food or color additive for human consumption
- ❑ Infant formula
- ❑ Biological product for human use
- ❑ Electronic product for human use
- ❑ Other article subject to the FD&C Act

Check TRUE if any of the above items apply: ☐ True ☐ False

4. The activity involves human participants because one or more of following is true:

- ❑ The test article will be used on one or more humans
- ❑ All of the following are true:
  - ❑ The test article is a medical device
  - ❑ The medical device will be used on human specimens
  - ❑ The activity is being done to determine the safety or effectiveness of the device
  - ❑ Data from the activity will be submitted to, or held for inspection by, the FDA.

Check TRUE if any of the above items apply: ☐ True ☐ False

If you marked any items listed above, the activities <u>are subject to FDA regulation</u> and must be submitted to the Health Sciences IRB to review. Please confirm your determination by selecting the appropriate item below.

Please confirm the determination below:

- □ The proposed activity involves a FDA regulated test article or is otherwise subject to FDA regulation and determined to be Human Subject Research because it meets the definition of human research subject regulated by the FDA that is subject to IRB review. All FDA regulated research will be transferred to the Health Sciences IRB for IRB review.
- □ The proposed activities are determined to **NOT** be Human Subject Research or FDA regulated activities because it fails to meet the DHHS or FDA definition of human research subject to IRB review.

Save Please SAVE.

<u>NOTE</u>

1. If it is determined the activities are NOT FDA regulated Human Subject Research, but it is subject to IRB review, the file will move to Checklist 1.C for further review. A <u>written confirmation</u> of the determination will be sent to the investigator after completion of the review process. *Automatic Recording: When the reviewer SAVES the document, the system will automatically create an "**Electronic Signature RECORD of Reviewer"** to confirm the determination. The system will also create an automatic **Electronic Date Stamp.***
2. If it is determined to be Human Subject Research involving FDA regulated activities the file will be transferred to the Health Sciences IRB and move to Stage IV. The reviewer will follow procedure for "Transfer File to the Health Sciences IRB" and document the justification for the

transfer in the record. A written confirmation of the determination will be sent to the investigator once the final review is complete. *Automatic Recording: When the reviewer SAVES the document, the system will automatically create an "**Electronic Signature RECORD of Reviewer"** to confirm the determination**.** The system will also create an automatic **Electronic Date Stamp.***