[Your Name]
[Street Address]
[City, ST ZIP Code]
[Date]

[Recipient Name]
[Title]
[Company Name]
[Street Address]
[City, ST ZIP Code]

Dear [Mr./Ms. LAST NAME]:
I am writing to tell you about the Entrepreneur In Residence Study being conducted by the U.S. Food and Drug Administration in Silver Spring, Maryland. We received your name from the Center for Devices and Radiological Health (CDRH) MedSun program.

The purpose of this study is to compare the labeling for medical devices as it currently exists with labeling for the same medical device prepared using a format we are considering to standardize the labeling for medical devices. You may be eligible for this study if you have experience with at least one of the device types being tested in this study. Your participation will take approximately 90 minutes to complete. The study findings will help inform FDA's approach to standardizing content found in medical device labeling.

It is important to know that this letter is not to convince you to join this study. It is your decision. Your participation is voluntary and will be kept private to the fullest extent allowed by law by the research team. Whether or not you participate in this study, it will have no effect on your relationship with the U.S. FDA. Your response will be combined with the responses of others in a summary report that does not identify you as an individual. Although we expect there will be no risks from your participation, you will not directly benefit either. However, your input will help the FDA improve the clarity of future medical device labeling and you will be paid [FILL: INCENTIVE AMOUNT] via check in appreciation for your time.

If you have any questions about the study or questions about your rights as a research participant in this study you may telephone Mary Brady at 1-301-796-6089.

If we do not receive your reply within two weeks a study team member may send you another letter and/or contact you by phone.

Thank you for your time and consideration.

Sincerely,

[Your Name]
[Title]

FDA Device Labeling Study

Screening Script for Recruitment of Healthcare Practitioners

The Food and Drug Administration's Center for Devices and Radiological Health is recruiting healthcare practitioners from the MedSun program and from two area hospitals to participate in a 90 minute study to determine if medical device labeling is usable. Participants will be asked to react to scenarios for 3 types of devices. The results from this study will help FDA assess and improve medical device labeling.

MedSun practitioners will be asked to come to FDA's Silver Spring campus to participate in the study. Hospital employees will participate in the study on-site at their hospital. We may audiotape or videotape your responses. The recordings and your responses will not be linked to your name and will be destroyed once a summary report is written. Participants will receive an honorarium of [FILL: INCENTIVE AMOUNT] in appreciation for their time.

1. What is your practice area?
    a. Physician
    b. Physician assistant
    c. Nurse Practitioner
    d. Registered Nurse
    e. Therapist
    f. Technician
    g. Other _____
2. How many years have you been practicing in your present position?
3. How many years have you been practicing in your profession?
4. How familiar are you with each of the following devices' instructions for use (IFU)? (a-c is for Washington Adventist participants, d-f is for MedSun participants, and g-i is for Children's Hospital participants).
    a. GE Carestation
        i. Have you ever used a ventilator system? Yes/No If no, skip to "iv"
        ii. Have you ever used a GE Carestation? Yes/No if yes, go to "iii"

iii. Are you familiar with the manufacturer's instructions for use documentation for the GE Carestation? Yes/No

iv. Do you see yourself as someone who is a potential or future user of a ventilator system, given your current position? Yes/No

b. RAD-57 pulse oximeter

i. Have you ever used a pulse oximeter? Yes/No if no, skip to "iv"

ii. Have you ever used a RAD-57 pulse oximeter? Yes/No if yes, go to "iii"

iii. Are you familiar with the manufacturer's instructions for use documentation for the RAD-57 pulse oximeter? Yes/No

iv. Do you see yourself as someone who is a potential or future user of a pulse oximeter, given your current position? Yes/No

c. Accu-Check glucose meter

i. Have you ever used a glucose meter? Yes/No if no, skip to "iv"

ii. Have you ever used an Accu-Check glucose meter? Yes/No if yes, go to "iii"

iii. Are you familiar with the manufacturer's instructions for use documentation for the Accu-Check glucose meter? Yes/No

iv. Do you see yourself as someone who is a potential or future user of a glucose meter? Yes/No

d. KCI ActiVAC negative pressure wound therapy

i. Have you ever used a negative pressure wound therapy system? Yes/No if no, skip to "iv"

ii. Have you ever used a KCI ActiVAC negative pressure wound therapy system? Yes/No if yes, go to "iii"

iii. Are you familiar with the manufacturer's instructions for use documentation for the KCI ActiVAC negative pressure wound therapy system? Yes/No

iv. Do you see yourself as someone who is a potential or future user of a negative pressure wound therapy system? Yes/No

e. NxStage hemodialysis system

   i. Have you ever used a hemodialysis system? Yes/No if no, skip to "iv"

   ii. Have you ever used a NxStage hemodialysis system? Yes/No if yes, go to "iii"

   iii. Are you familiar with the manufacturer's instructions for use documentation for the NxStage hemodialysis system? Yes/No

   iv. Do you see yourself as someone who is a potential or future user of a hemodialysis system? Yes/No

f. Carefusion large volume infusion pump

   i. Have you ever used a large volume infusion pump? Yes/No if no, skip to "iv"

   ii. Have you ever used a Carefusion large volume infusion pump? Yes/No if yes, go to "iii"

   iii. Are you familiar with the manufacturer's instructions for use documentation for the Carefusion large volume infusion pump? Yes/No

   iv. Do you see yourself as someone who is a potential or future user of a large volume infusion pump? Yes/No

g. XXX fetal monitor?

   i. Have you ever used a fetal monitor? Yes/No if no, skip to "iv"

   ii. Have you ever used _XXX_fetal monitor? Yes/No if yes, go to "iii"

   iii. Are you familiar with the manufacturer's instructions for use documentation for the _XXX _fetal monitor? Yes/No

   iv. Do you see yourself as someone who is a potential or future user of a fetal monitor? Yes/No

h. XXX phototherapy unit

   i. Have you ever used a phototherapy unit? Yes/No if no, skip to "iv"

   ii. Have you ever used a _XXX_phototherapy unit? Yes/No if yes, go to "iii"

iii. Are you familiar with the manufacturer's instructions for use documentation for the __XXX __phototherapy unit? Yes/No

iv. Do you see yourself as someone who is a potential or future user of a phototherapy unit? Yes/No

i. XXX Left Ventricular Assist Device (LVAD)

i. Have you ever used an LVAD? Yes/No if no, skip to "iv"

ii. Have you ever used a _____XXX __LVAD? Yes/No if yes, go to "iii"

iii. Are you familiar with the manufacturer's instructions for use documentation for the __XXX _LVAD? Yes/No

iv. Do you see yourself as someone who is a potential or future user of a _____LVAD? Yes/No

We want each participant to respond to as many types of devices as possible in the area where they are doing the testing. Participants that respond they have experience with the highest number of devices in their facility, or at the FDA's site, will be selected first.

Public Reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:
Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act Staff
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