Epidemiology and Infection Prevention

IRB Screening Form

**Human Research Involving Devices and Biologic or Infectious Agents Form**

This screening form serves to identify research protocols **involving humans** for review by Epidemiology and Infection Prevention (EIP) to provide guidance when conducting a trial of devices or biologic or infectious agents (e.g. live vaccine, probiotic) at UC Irvine Health facilities.

Please answer the following questions:

1. Will the research or portions of the research take place on UCI Medical Center campus or any UCI-affiliated clinical site (including clinical sites on campus or external affiliated sites)?

🗆Yes 🗆No

If yes, please list all affected locations

**If no 🡪 no need to complete form**

1. Which of the following does this research involve? (check all that apply)

🗆device 🗆infectious agent (e.g. vaccine, probiotics, viruses, bacteria, other)

**FOR RESEARCH INVOLVING DEVICES**

1. Will this device will be used on (check all that apply):

🗆intact skin 🗆mucous membranes 🗆body cavities 🗆other invasive sites

1. This device is FDA approved: 🗆Yes 🗆No
2. This device is single-patient use only 🗆Yes 🗆No
   1. If yes, is device sterile from the manufacturer? 🗆Yes 🗆No
   2. If yes, will this device be sterile at the time of use? 🗆Yes 🗆No
   3. If no, please describe device is used:

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1. This device will be used between patients and reprocessed (cleaned, then disinfected or sterilized) according to manufacturing guidelines: 🗆Yes 🗆No
   1. If yes, who performs the reprocessing? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   2. If no, explain why:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If 3a. is checked “yes,” then no further review by EIP is needed. Otherwise, proceed in completing this form and submit to EIP for review (Route 171, attention: Epidemiology & Infection Prevention; for inquiries, please call x5221).

**Requestor Contact Info**

Last Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Role in Study \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Device Description \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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If this device has been modified in any way, please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please provide description of why device does not pose an infection risk when used on patients:**

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**If not single patient use, attach detailed protocol describing 1) how the device will be cleaned, then disinfected or sterilized to assure prevention of infection when re-used between patients, 2) define who will perform the reprocessing, 3) define who is responsible for assuring protocol training and adherence. For guidance, please refer to the following national disinfection guidelines: http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection\_Nov\_2008.pdf**

**FOR RESEARCH INVOLVING BIOLOGICS or INFECTIOUS AGENTS**

1. Agent will be administered as approved by the research protocol🗆Yes 🗆No
2. Could the handling of the biologic or infectious agent cause any of the following? (include uncommon risks associated with attenuated agents)

Transmission by touching the agent/spilling on skin

🗆Yes 🗆No

Transmission if inhaled (aerosolization of droplets or airborne spread)

🗆Yes 🗆No

1. Will instruments or equipment used to administer the biologic or infectious agent be re-used between patients? (e.g. surgical instruments, tubing, containers)

🗆Yes 🗆No

1. If the biologic or infectious agent causes disease in a human subject, is that disease transmissible to others?

🗆Yes 🗆No

**Requestor Contact Info**

Last Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ First Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Email \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Role in Study\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Please attach a detailed protocol. Please ensure the following are addressed:**

1. Please describe the biologic or infectious agent
2. How will this biologic or infectious agent be administered to humans?
3. How will the biologic/infectious agent be stored and handled?
4. If the agent will not be administered as approved by the research protocol, please describe how agent administration differs from approved administration.
5. If it is possible for the agent to cause development of disease in the human subject that could be transmissible to others, please describe, including how this risk will be mitigated.
6. Describe how instruments or equipment that come in contact with the biologic/infectious agent be disposed?
7. Describe your decontamination protocol (Include products to be used, e.g., bleach, alcohol, etc.).
8. If agent is potentially transmitted by aerosol, describe your plan for airborne precautions.
9. If instruments or equipment are **re-used** between patients, how these items are cleaned, then disinfected or sterilized to assure prevention of infection (including defining and training those who will perform the reprocessing)?
10. Define who is responsible for assuring protocol training and adherence.

For guidance, please refer to the following national disinfection guidelines:[**http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection\_Nov\_2008.pdf**](http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf)

Submit requested information to EIP for review (Route 171, attention: Epidemiology & Infection Prevention). Once information is reviewed by the Epidemiology and Infection Prevention you will be contacted by e-mail.

This information will also be shared with UC Irvine Health Risk Management for review.

If you have questions, please call the UC Irvine Health Epidemiology and Infection Prevention Program at (714) 456-5221.

Version Date: July 2015