



FOOD & WATERBORNE DISEASES INTEGRATED RESEARCH NETWORK
CLINICAL RESEARCH UNIT

Key Staff Members:

Principal Investigator	Title	FWD IRN Role
Carol O. Tacket, MD ctacket@medicine.umaryland.edu	<ul style="list-style-type: none"> • Professor of Medicine • Chief, Adult Clinical Studies Section 	<ul style="list-style-type: none"> • Research Unit PI • Emergency Response Plan Coordinator • Clinical Protocol Project Leader
Investigators		
Karen L. Kotloff, MD	<ul style="list-style-type: none"> • Professor of Pediatrics, Medicine • Chief, Domestic Epidemiology Section 	<ul style="list-style-type: none"> • Clinical Investigator
James D. Campbell, MD	<ul style="list-style-type: none"> • Assistant Professor, Pediatrics 	<ul style="list-style-type: none"> • Clinical Investigator
Robert Edelman	<ul style="list-style-type: none"> • Professor of Medicine, Pediatrics • Associate Director, CVD 	<ul style="list-style-type: none"> • Clinical Investigator
James P. Nataro, MD	<ul style="list-style-type: none"> • Professor of Pediatrics • Associate Director for Research Training • Chief, Molecular Diagnostic and Microbiology Section 	<ul style="list-style-type: none"> • Clinical Protocol Collaborating Investigator
Marcela F. Pasetti, MD	<ul style="list-style-type: none"> • Assistant Professor of Pediatrics • Chief, Applied Immunology Unit 	<ul style="list-style-type: none"> • Clinical Protocol Collaborating Investigator
Marcelo B. Sztein, MD	<ul style="list-style-type: none"> • Professor of Pediatrics, Microbiology & Immunology, and Medicine • Chief, Immunology Section 	<ul style="list-style-type: none"> • Clinical Protocol Collaborating Investigator • PI of the Food and Waterborne Diseases Integrated Research Network's Immunology Research Unit
Myron M. Levine, MD, DTPH	<ul style="list-style-type: none"> • Professor of Medicine, Pediatrics, Epidemiology & Preventive Medicine, Microbiology & Immunology • Director, Center for Vaccine Development 	<ul style="list-style-type: none"> • Clinical Protocol Collaborating Investigator
Research Unit Staff		
Lisa Chrisley, RN	<ul style="list-style-type: none"> • CVD Nurse Manager 	<ul style="list-style-type: none"> • Research Coordinator
Mary Lou Mullens, RN, MS	<ul style="list-style-type: none"> • Study Coordinator 	<ul style="list-style-type: none"> • Clinical Protocol Study Coordinator
Elisa Sindall, RN	<ul style="list-style-type: none"> • Regulatory Affairs 	<ul style="list-style-type: none"> • Regulatory Affairs Coordinator



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General information:

The Clinical Research Unit (CRU) is located at the Center of Vaccine Development (CVD), University of Maryland School of Medicine, on the main campus of the University of Maryland, Baltimore, Maryland.

Current FWD IRN Activities:

- Phase I clinical study entitled "Prime-Boost Study of the Immunogenicity of Vi Polysaccharide Typhoid Vaccine after Priming by Oral Vi + S. Typhi Strain CVD 909" (C. Tacket, project leader)

FWD IRN Mission and Expertise:

This Research Unit has capacity and expertise in Phase I and II clinical trials and enteric challenge studies. The CRU workscope includes several NIAID Category A and B Biosafety level 2 priority organisms, which are transmissible through food and/or water.

Specific expertise of the Clinical Research Unit includes:

- Phase I and II clinical trials to evaluate candidate prophylactic or therapeutic vaccines, biologics, new adjuvant, delivery vehicles and drugs with adherence to Good Clinical Practice standards
- Phase I and II trials of new doses, schedules, and routes of administration of licensed drugs
- Preparation of responses to FDA IND questions
- Participation in multi-site trials and Phase III clinical trials
- Challenge studies in vaccines and control volunteers for infections in which established models of experimental challenge exist, to assess protection; these include *Vibrio cholerae*, *Escherichia coli*, and *Shigella* infections
- Participation in mass vaccination program using licensed vaccines

Current Collaborators:

FWD IRN Immunology Research Unit
LigoCyte Pharmaceuticals, Inc.

Links:

Center for Vaccine Development (<http://medschool.umaryland.edu/CVD/>)
LigoCyte Pharmaceuticals, Inc. (<http://www.ligocyte.com>)