

On Tue, Oct 22, 2019 at 9:16 PM <edwardsm@vt.edu> wrote:

Dear Margot,

It has now been more than 1 month since we first asked questions about the ethical design of the IJID article (see attached).

It has also been 18 days since we submitted a list of questions about this study to the authors, under COPE guidelines, which IJID ascribes to.

May we please have a timeline, in which responses from the authors to our scientific and ethics questions, can be expected?

We do not understand why IRB approval and protocols for a human subjects experiment, which reported an astonishing result that 5/10 study patients died, has not yet been produced in response to our request. The only response we have received, was your 1 sentence assurance, that this study did receive HFHS IRB approval.

Best Regards,

Marc Edwards

From: edwardsm@vt.edu <edwardsm@vt.edu>

Sent: Friday, October 4, 2019 11:43 AM

To: 'LaPointe, Margot' <MLaPoin1@hfhs.org>; 'Susan Masten' <masten@egr.msu.edu>; 'Eskild Petersen' <eskild.petersen@gmail.com>

Cc: 'Clinical Trials Office "CTO" Research' <CTOResearch@hfhs.org>; 'HFAH Clinical Trials' <HFAHClinicalTrials@hfhs.org>; 'Judy Birk' <jbirk@umich.edu>; 'monica.malian@wayne.edu' <monica.malian@wayne.edu>; 'OswaldE1@michigan.gov' <OswaldE1@michigan.gov>; 'khalidunj@michigan.gov' <khalidunj@michigan.gov>; 'Amy Pruden' <apruden@vt.edu>; 'Siddhartha Roy' <sidroy@vt.edu>

Subject: RE: Questions regarding publication entitled Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

Hi Margot,

We have communicated with IJID editors and have agreed on the following manner of proceeding.

We herein, are formally submitting questions for the authors of the published IJID abstract, in the attached WORD document.

We do not know how to reach the corresponding author, and we trust you will provide these questions to them.

We hope the authors will provide us with answers to our questions about their study design, methods, data and conclusions.

If the authors and Henry Ford will not answer our questions, the editors will work under COPE guidelines, to seek answers to the questions we have posed.

I have cc'd the editor of the IJID journal, Eskild Petersen, to keep them in the loop.

Best Regards,

Marc

From: LaPointe, Margot <MLaPoin1@hfhs.org>
Sent: Monday, September 30, 2019 8:04 PM
To: edwardsm@vt.edu; 'Cynthia Shindledecker' <cshindle@umich.edu>; 'Susan Masten' <masten@egr.msu.edu>
Cc: Clinical Trials Office "CTO" Research <CTOResearch@hfhs.org>; HFAH Clinical Trials <HFAHClinicalTrials@hfhs.org>; 'Judy Birk' <jbirk@umich.edu>; monica.malian@wayne.edu; OswaldE1@michigan.gov; khaldunj@michigan.gov; 'Amy Pruden' <apruden@vt.edu>; 'Siddhartha Roy' <sidroy@vt.edu>
Subject: RE: Questions regarding publication entitled Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

Like all research conducted at Henry Ford Health System, this study by Dr. Marcus Zervos was thoroughly reviewed and approved by our Institutional Review Board. The IRB determined the study was appropriately designed and was in compliance with all required federal research guidelines as well as with all Henry Ford research policies and procedures.

From: edwardsm@vt.edu <edwardsm@vt.edu>
Sent: Friday, September 27, 2019 2:16 PM
To: 'Cynthia Shindledecker' <cshindle@umich.edu>; 'Susan Masten' <masten@egr.msu.edu>
Cc: LaPointe, Margot <MLaPoin1@hfhs.org>; Clinical Trials Office "CTO" Research <CTOResearch@hfhs.org>; HFAH Clinical Trials <HFAHClinicalTrials@hfhs.org>; 'Judy Birk' <jbirk@umich.edu>; monica.malian@wayne.edu; OswaldE1@michigan.gov; khaldunj@michigan.gov; 'Amy Pruden' <apruden@vt.edu>; 'Siddhartha Roy' <sidroy@vt.edu>
Subject: RE: Questions regarding publication entitled Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

***** External E-Mail – Use Caution *****

Dear IRB of Henry Ford, UM and Wayne State,

It has been 10 days since we first raised serious ethical issues associated with this IJID publication associated with authors from your institutions, and the associated FRONTLINE article.

If you will not provide us with reasonable answers to the questions posed, and documentation of IRB approving this study, which appears to be using HFHS patients POU filter samples and health data, as a basis for a generalized conclusion made in a research journal, we will be forced to make a complaint to the AMA via the appropriate MI state licensing boards and file a COPE query with the Journal.

If there is an innocent explanation (i.e., someone can publicly defend the study design and associated research ethics of this journal article), can someone please provide that to us at this time?

Thank you.

Marc

From: edwardsm@vt.edu <edwardsm@vt.edu>

Sent: Thursday, September 19, 2019 10:13 PM

To: 'Cynthia Shindledecker' <cshindle@umich.edu>; 'Susan Masten' <masten@egr.msu.edu>

Cc: 'mlapoin1@hfhs.org' <mlapoin1@hfhs.org>; 'CTOResearch@hfhs.org' <CTOResearch@hfhs.org>;

'HFAHClinicalTrials@hfhs.org' <HFAHClinicalTrials@hfhs.org>; 'Judy Birk' <jbirk@umich.edu>;

'monica.malian@wayne.edu' <monica.malian@wayne.edu>; 'OswaldE1@michigan.gov'

<OswaldE1@michigan.gov>; 'kaldunj@michigan.gov' <kaldunj@michigan.gov>; 'Amy Pruden'

<apruden@vt.edu>; 'Siddhartha Roy' <sidroy@vt.edu>

Subject: RE: Questions regarding publication entitled Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

Dear IRB of Henry Ford, UM and Wayne State.

Frontline has just written us, and on second thought, they now assert they did not collect the samples used in the cited publication.

Assuming that is true, we still have serious concerns about the ethics of this study design, and the ethics of how it is being reported.

There is only one control sample in Detroit with POU filters, there are alarmist study **RESULTS (100% infection rate amongst people using Flint POU filters, 5/10 deaths.)**, and there is a generalized conclusion that immunocompromised individuals in Flint and around the world should avoid POU filters. At a time when POU filter use is still being recommended in Flint by all responsible health authorities.

It is also perfectly obvious that the vast majority of deaths from Legionella and possibly pneumonia, occurred before September 2015, but the POU filters were not widely distributed in Flint until after that time. How on earth could the POU filters have caused the cited deaths and infections? The logic and timing presented in the paper, make no sense whatsoever.

We want to understand, how such a human health research study design, could be IRB approved.

Can we at least get a simple answer, as to whether this HFHS, UM and Wayne State study involving a reported 100% infection rate and 50% mortality and an alarmist generalized conclusion, was IRB approved or not?

Marc

From: Cynthia Shindledecker <cshindle@umich.edu>

Sent: Wednesday, September 18, 2019 11:26 AM

To: Susan Masten <masten@egr.msu.edu>

Cc: mlapoin1@hfhs.org; CTOResearch@hfhs.org; HFAHClinicalTrials@hfhs.org; Judy Birk <jbirk@umich.edu>;

monica.malian@wayne.edu; OswaldE1@michigan.gov; kaldunj@michigan.gov; Amy Pruden <apruden@vt.edu>;

Marc Edwards <edwardsm@vt.edu>; Siddhartha Roy <sidroy@vt.edu>

Subject: Re: Questions regarding publication entitled Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

Dear Dr. Masten,

Our usual process for requests such as this is to go through our FOIA office. Please refer to this website for more information: <https://foia.vpcomm.umich.edu/>.

Sincerely,

Cindy Shindledecker

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Cindy Shindledecker, CIP

Director

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)

University of Michigan

North Campus Research Complex

1600 Huron Parkway, Building 520, Room 1170

Ann Arbor, MI 48109-2800

734-615-9466

Website: <http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs>

On Tue, Sep 17, 2019 at 10:10 PM Susan Masten <masten@egr.msu.edu> wrote:

Dear Drs. LaPointe, Birk, Malian, and Shindledecker:

We are writing to request a copy of IRB protocols and approvals, for a research study conducted by Drs. Maki, Zervos, Misikir, and Perri of the Henry Ford System, Dr. McElmurry of Wayne State, and Dr. Love of University of Michigan on bacterial colonization of drinking water. These research results were published in ***the International Journal of Infectious Diseases***, Feb 2019, Vol 79, Supplement 1, pages 30-31 at the following location:

[https://www.ijidonline.com/article/S1201-9712\(18\)34667-8/fulltext](https://www.ijidonline.com/article/S1201-9712(18)34667-8/fulltext)

Details of our request and cause for concern are provided in the attached letter.

We thank you for your time and look forward to your response.

Sincerely,

Marc Edwards, Ph.D.
Siddhartha Roy, Ph.D.
Susan Masten, Ph.D.
Amy Pruden, Ph.D.

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Susan J. Masten, Ph.D., P.E.

Professor

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