

# In response to "The negative impact of ad hoc committees for ethical evaluation: The case of COVID-19-related research in Ecuador"

We have read with great interest the Letter to the Editor entitled "The negative impact of ad hoc committees for ethical evaluation: The case of COVID-19-related research in Ecuador".<sup>1</sup> As Ecuadorian scientists, we are familiar with the topics covered in this letter and in general we agree with the main message, however we have some concerns.

To our knowledge, and after years of experience in several countries, Ecuador is the only country where authorization from a certified research bioethics commission is not sufficient for conducting research when this involves human subjects. In Ecuador, an additional screening process is required by a governmental office belonging to the Ministry of Health. This process often takes up to a year to complete. As Sisa et al. described in their letter, this requirement represents an obstacle for biomedical research in general and COVID-19 research in particular. Moreover, considering how difficult conducting scientific research is in a developing country like Ecuador, this overregulated environment discourages international collaborations and makes it difficult to apply for external funding.

For these reasons, we are concerned that Sisa et al. referred to a publication of our research group<sup>2</sup> on the following terms:

- "Across the analyzed period, we were able to identify only ten observational COVID-19-related publications that used either biological samples or confidential data".<sup>3</sup>
- "One of the published studies that used biological samples did not state whether they had obtained approval from an IRB or even consent from the study participants to use their laboratory results. Considering the standard requirements of scholarly journals, we find these results difficult to explain".<sup>4</sup>

Regarding these statements, we want to clarify:

1. The report that Sisa et al. are referring to was published in the prestigious journal "One Health", from Elsevier. Elsevier ethical policies for publication are available on-line<sup>5</sup> and were clearly not read by the Sisa et al. before affirming: "...considering the standard requirements of scholarly journals, we find these results difficult to explain". According to Elsevier, "studies on patients or volunteers require ethics committee approval and informed consent, which should be documented in the paper". Our publication did not fall under this category.
2. Our publication is a narrative description of the implementation of a SARS-CoV-2 laboratory in the Galapagos Islands in a collaboration between "Agencia de Regulación y Control de la Bioseguridad y Cuarentena para Galápagos" and the "Universidad de las Américas". It is not a research study, as we did not conduct any sample collection for research purposes. Sample collection was done by the Ministry of Health for SARS-CoV-2 surveillance according to criteria defined by the Ecuadorian Ministry of Health. Moreover, we simply described how the laboratory was set, the methods used for SARS-CoV-2 diagnosis, the number of samples processed, and the number of SARS-CoV-2 positive cases detected. We find it unconceivable that Sisa et al. considered this information confidential when the Ecuadorian Ministry of Health has made it available on-line for every province in the country.<sup>6</sup> Moreover, the "Comité de Operaciones de Emergencias" for Galápagos, the board responsible for SARS-CoV-2 surveillance on Galapagos Islands, also made this information available with permanent updates on their social networks.<sup>7</sup>
3. We want to draw attention to the fact that Dr. Iván Sisa, one of the authors of the referred letter, and President of the Bioethics Commission of the Universidad San Francisco de Quito, has previously submitted a complaint to the Ministry of Public Health of Ecuador accusing us of not adhering to the ethical requirements in Ecuador specifically referring to our publication mentioned

<sup>1</sup>Ivan Sisa, Belen Mena and Enrique Teran. (2021). The negative impact of ad hoc committees for ethical evaluation: The case of COVID-19-related research in Ecuador. *Developing World Bioeth.* 00:1-4. <https://doi.org/10.1111/dewb.12307>.

<sup>2</sup>Freire-Pasquel, B., Vega-Mariño, P., Velez, A., et al. (2020). "One health" inspired SARS-CoV-2 surveillance: The Galapagos islands experience. *One Health.* <https://doi.org/10.1016/j.onehlt.2020.100185>.

<sup>3</sup>O& Teran, op.cit.note 1.

<sup>4</sup>Ibid.

<sup>5</sup><https://www.elsevier.com/authors/policies-and-guidelines>

<sup>6</sup><https://www.salud.gob.ec/boletines-epidemiologicos-coronavirus-por-semanas/>

<sup>7</sup><https://www.facebook.com/cggalapagos/photos/4259282640771644>

above.<sup>8</sup> To date, the Ministry of Health has yet to make a decision in regard this matter.<sup>9</sup> Furthermore, the local hospitals involved in the sample collection have already informed the Ministry of Health that they did not collect any samples under our requirement. We believe it is unfair that Sisa et al. reproduce in their letter the same accusation against our article without waiting for a resolution from the Ministry of Health.

4. It is surprising that Sisa et al. claimed that: "one of the published studies that used biological samples did not state whether they had obtained approval from an IRB or even consent from the study participants to use their laboratory results. Considering the standard requirements of scholarly journals, we find these results difficult to explain"; when a publication by Dr. Enrique Teran (one of the co- authors of the letter), has been recently mentioned in the article: "Potential research ethics violations against an indigenous tribe in Ecuador: a mixed methods approach",<sup>10</sup> a publication describing potential ethical violations on research studies done with Waorani indigenous people in Ecuador. According to that study, Dr. Teran's report did not provide any information regarding neither informed consent nor ethical approval.<sup>11</sup> We have carefully read the original article, and we can confirm that no information regarding informed consent or ethical approval is

detailed, although we do not mean that this research was conducted without them and we do not aim to criticize the ethical policies for publication at such prestigious journal.<sup>12</sup> However, it is interesting that Sisa et al. are so critical in their letter towards our publication but overlook their own carelessness.

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<sup>8</sup>Freire-Pasquel, Vega-Mariño, Velez, et al., op. cit. note 2.

<sup>9</sup>Ibid.

<sup>10</sup>Esteban Ortiz-Prado, Katherine Simbaña-Rivera, Lenin Gómez-Barreno, Leonardo Tamariz, Alex Lister, Juan Carlos Baca, Alegria Norris and Lila Adana-Diaz. (2020). Potential research ethics violations against an indigenous tribe in Ecuador: a mixed methods approach. BMC Medical Ethics; volume 21, Article number: 100.

<sup>11</sup>Ibid.

<sup>12</sup>Edy Quizhpe, Gladys Ñauta, Juan Antonio Córdoba-Doña and Enrique Teran. (2016). Five-Year Eradication of Hepatitis B Infection After an Outreach Immunization Program in the Waorani Population in the Ecuadorian Amazon. Am. J. Trop. Med. Hyg., 95(3), pp. 670–673. <https://doi.org/10.4269/ajtmh.16-0248>