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Campinas, June 10, 2021.

████████████████████  
Policy Officer  
*GeneWatch International*

Re: BIPMed data sharing policies

Dear ██████████

Thank you very much for your letter inquiring about the Brazilian Initiative's data-sharing policies and confidentiality issues on Precision Medicine Genomic databases ([www.bipmed.org](http://www.bipmed.org)).

I will start by giving a background about BIPMed, the Brazilian health system, and ethical regulations about research with human subjects in Brazil.

BIPMed public genomic databases are not intended to share data of a single genomic project. Still, they were designed as a hub where any research group interested in accessing and/or sharing genomic information about the Brazilian population can go to. All funding supporting BIPMed is public, coming from Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP, [www.fapesp.br](http://www.fapesp.br)) and from the University of Campinas (UNICAMP, [www.unicamp.br](http://www.unicamp.br)) a public and tuition-free university supported entirely by the Government of the State of São Paulo, Brazil. At this moment, BIPMed aggregates nine databases.

The main objective of BIPMed is to share data for the purpose of research and medical care of the Brazilian population, which relies mainly upon the Brazilian Public Health System, called "Sistema Único de Saúde" (SUS). SUS was created by the Brazilian constitution of 1988 and offers free medical care to everyone who seeks medical attention in the country. Currently, SUS is responsible for all levels of medical care of 170 million Brazilians, which means it is the largest public health system in the world. Although the system supports a hierarchical organization, privileging preventive measures and primary care, complex medical procedures such as organ transplants are also offered free of charge to all Brazilians in need of medical care, including genetic testing. For molecular testing in the clinical setting, data is usually shared only in Tier 1.

Seven databases in BIPMed are comprised of single gene variants responsible for different genetic diseases. These have been used by clinicians interpreting genetic testing in the Brazilian population and scientists in Brazil aiming to improve genetic testing in the country. For these databases, there is also minimal phenotypic information (not individualized), which is also available. For these databases, data is shared predominantly in Tier 1.

Two other databases are of the general population, which refer to as reference population. One dataset contains genome-wide SNP-array information, and the other includes whole-exome sequence. We do not have whole-genome sequencing information as of today. There is no phenotypic information available for these genomic datasets in BIPMed. These databases are

shared data in Tier 2. Tier 2 data sharing occurred within Brazil most of the time, with one exception in which we shared Tier 2 data with a research group in Chile.

Based on the information above, it is evident that we do not use a single consent form since the database acts as a form of “publication” of the information, and it is not a single genome project *per se*. Thus, the consent form available on the website is just a suggestion for investigators interested in designing projects that will make genome data available in the future. However, because this arose the question posed by you, we decided to exclude the sample consent form from the website.

In Brazil, there is specific legislation, since 1996, which applies to research projects, and that will evaluate the consent form for each project individually, taking into consideration above all the protection of confidentiality and the rights of research participants. The Brazilian regulations regarding research ethics with human subjects are considered one of the most advanced, especially concerning the protection of research volunteers. All data available in BIPMed has been approved, together with the consent forms, by the institutional ethics committee of the different projects involved. All ethical approvals specifically address sharing the data in public genomic databases and the appropriateness of the consent forms used for each of the projects. According to our legislation on research ethics, Brazilian investigators are bound to use only the consent form that has been approved by the research ethics committee and cannot make changes without getting specific approval for that. Most research consent forms in Brazil already include clauses for withdrawing samples and data, as requested by our current data protection law, and BIPMed follows these regulations.

BIPMed has a steering committee that evaluates all requests for Tier 2 data-sharing. Currently, we only share data with research groups with public funding and, for specific purposes, research objectives stated in the agreement. We also only share data with research groups belonging to institutions with similar computational infrastructure and safety measures as our own, University of Campinas, SP, Brazil. I personally read all the proposals, and I give the final approvals to all requests for Tier 2 data sharing within BIPMed.

We do not sell data, and we have no *a priori* legal obligation under Brazilian law to disclose information to law enforcement or any other entity. Research records are protected, as are medical records in this country. On the contrary, we must protect the confidentiality of the research participants under the Brazilian law regulating personal information, which is very similar in scope to the European Data Protection Act. To make this clear, we are changing the website to include the information above.

Our data is currently stored in high-performance computing systems at the University of Campinas, under the same high protection as other sensitive information such as my personal information (ID number, social security number, address, medical record, bank account, and others) as for all staff at UNICAMP. These systems are only accessible through VPN, and only a small set of authorized personnel can access the full databases. The data center at our university follows the same rules and regulations for personal data protection as the State of São Paulo Government. We have been sharing data only with research groups in other public Brazilian universities with the same high standards for data protection under Brazilian law.

It is important to note that we analyze all requests for Tier 2 data-sharing in BIPMed carefully and only approve requests that fulfill the data protection requirements under Brazilian law. Thus, we have the discretionary power to refuse to share Tier 2 data.

Since the inception of BIPMed in 2015, we have been following the technical and ethical recommendations of the Global Alliance for Genomics and Health ([www.ga4gh.org](http://www.ga4gh.org)) for the ethical and responsible sharing of genomic data.

Finally, I would like to thank you again for reaching out with such important questions, which made us revise the information on our website for accuracy and transparency.

I hope I have answered all your questions. Please let me know if there is anything else you would like to know about BIPMed. Rest assured that one of our major goals is to be transparent with the way we share data so that our model may be followed in other Latin American countries and other mid-income countries worldwide.

Sincerely,

[Redacted signature]

University of Campinas (UNICAMP)  
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Member, Steering Committee  
The Brazilian Initiative on Precision Medicine

[Redacted contact information]