CNPq – The National Council for Scientific and Technological Development
Research Project: Bioethics, Distributive Justice and Pandemics
Coordinator: Darlei Dall'Agnol (UFSC/CNPq)
Adjunct Coordinators: Alcino Bonella (UFU/CNPq); Marcelo de Araujo (UERJ/CNPq); Marco Oliveira de Azevedo (UNISINOS/CNPq) and Roger Crisp (UEHIRO/Oxford)
Partners: several researchers listed below in each line of investigation.

1. Research Problem: which are, in the health care sector, the best public policies to distribute resources (e.g., for allocation of intensive care units and other scarce technologies, vaccine and drug production, incorporation of scientific knowledge in medicine, health-related problems caused by climate crises), to foster human and social development both in pandemic and in non-pandemic times?

2. Aim: The main goal is to provide bioethical justification for the application of a principle of justice grounding public health policies, with a focus on producing empirical evidence to improve decision-making processes in the areas of public health and clinical care during pandemic and non-pandemic times.

3. Objectives:

a) to evaluate adopted guidelines for the fair selection of patients to intensive care units during the Covid-19 recommending, if needed, new ones;

b) to formulate guidelines for non-discriminatory use of new diagnostic and treatment technologies in precision medicine based on artificial intelligence;

c) to propose bioethical guidelines for research related to HCS (Human Challenge Studies) and the production of new vaccines;

d) to construct environmental guidelines to increase public health during pandemic and non-pandemic times.

4. Lines of research:

4.1 – Allocating Scarce Resources such as Ventilators and ICUs

Responsible Researcher: Darlei Dall'Agnol
Partners: Benjamin Thomas Davies (PhD, Oxford); Evandro Barbosa; Igor Tavares da Silva Chaves (UFSC); Janyne Sattler (UFSC); Lara Patrícia Kretzer (AMIB); Lisa Forsberg; Maria Braulia de Souza Pôrto Fares (UFSC/SES-SC); Mario Machado Filho (UFSC/UNIFEBE); Marta Inez Machado Verdi (UFSC); Roger Crisp (Oxford).

Abstract: What should be the guidelines for fair allocation of scarce Intensive Care Units (ICU) in the Covid-19 pandemic be? In our previous works, we presented a proposal that adopts the directive of the highest probability of patient recovery. Some institutional preconditions were supported. First, that the competent authorities establish the protocol and declare the period of calamity during which the protocol is to be observed. Second, that medical triage teams, separate from the intensive care teams, be established in each institution with ICUs for the admission of critically ill patients. The guidelines would then be as follows: the triage team, consisting of specialized and experienced professionals, would classify patients into three priority groups, according to the degree of greatest chance of recovery, as measured by the SOFA (Sequential Organ Failure Assessment) score, except for two situations, [a] front-line health professionals, in high priority, and [b] patients whose condition did not recommend intensive care at all, in low priority. With the SOFA total scores, a classification of patients in order of priority care would be obtained, from the lowest score to the highest. A low SOFA's score reveals a high probability of recovery. To break ties, within the priority groups, it is proposed to adopt, first, the use of the life- cycle, and, if the tie persists, a draw. We present the main ethical reasons for the proposal, to save the greatest number of people. Then, we discussed some opposing reasons, compared the proposal with four others released in Brazil in 2020, and criticized the use of performance status present in one of them. A further investigation is now needed: what were the results of using these protocols? In Brazil, particularly in the State of Santa Catarina, the government recommended (March 2021) the adoption of the Brazilian Association of Intensive Medicine (AMIB)'s protocol based on the SOFA plus a points system first using age and afterwards performance (ECOG). We would like now to know whether it was fairly implemented and whether it effectively saved more lives in the hospitals where it was used and, if not, to propose new guidelines.

4.2 – Human Challenge Studies for New Vaccines

Responsible Researcher: Alcino Bonella
Partners: Alberto Giubilini; Brunello Souza Stancioli (UFMG); Carlos Henrique Martins da Silva (UFU); Denilson Luís Werle (UFSC); Flávio Guimarães da Fonseca; Helena Borges Martins da Silva Paro (UFU); Julian Savulescu (Oxford); Maria de Lourdes Alves Borges (UFSC); Maximilian Kiener; Yara Cristina de Paiva Maia (UFU).

Abstract: A Human Challenge Study (HCS) for Covid-19 is a way of evaluating and developing vaccines that involve, in a controlled environment, intentionally infecting (with a version of the SARS-COC-2 virus, a "challenge"), around one hundred fully informed volunteers who freely consent to participate. The experiment would last around one to three months. These kinds of studies are considered more risky than the usual way of testing the safety and efficacy of vaccines. The purpose of pandemic challenge testing is to ethically accelerate knowledge of the disease and potential remedies and vaccines. They would provide faster and more accurate data about vaccine candidates as well as information about the special course of the disease. Thus, we would like to investigate whether, even in the post-Covid-19 case (or new pandemics), we could develop more vaccines, improve first generation ones, retrofit them to new variants of the virus and to discover vaccines using platforms better suited for large-scale vaccinations. In some countries such as Brazil, there are multiple systems that, when coordinated by solid public policies, would provide greater security to participants and society, so we hypothesize

that HCS should really be used. The country has three systems: SUS (the Unified Health System) a public, universal and free health system; CONEP (the National Research Ethics Commission), an ethical evaluation and surveillance system; and ANVISA (the National Health Surveillance Agency). It also has a system of excellence in scientific and technological research. With these systems and researchers acting in coordination, perhaps in a national task force, adequate conditions will be in place to ensure ethical and methodological integrity for successful challenge testing. This line of inquiry, then, will focus on researching bioethical problems related to pandemics and post-pandemic contexts, and we would like to investigate whether there are conditions and limits in which challenge tests are ethical and should be carried out. The topic deserves responsible dissemination to the community, especially to research ethics committees, health researchers, teachers and other groups. In order to secure that some good practices of HCS take place, it is also necessary to think carefully about the sanitary surveillance and health policy makers in the country. These aspects are closely connected with the themes of evidence-based medicine, public population and clinical health assessment.

4.3 – Big Data and Precision Medicine: Epistemic and Bioethical Issues

Responsible Researcher: Marco Antonio de Oliveira
Partners: Bianca Lima da Silva Andrade (Unisinos); Delamar José Volpato Dutra (UFSC); Dominic Wilkinson (Oxford); Flavio Pereira Kapczinski (UFRGS); Ivan França Junior (USP); Marcelle Coelho do Rosario (Unisinos); Maria Leticia Rodrigues Ikeda (Unisinos); Maximiliano das Chagas Marques (AESC); Muriel Leuenberger; Ricardo Seara Rabenschlag; Viktor Savchenko.

Abstract: One of the characteristics of the digital era we live in is the huge volume of information that is disseminated between individuals, groups and institutions. New digital technologies make possible the creation of networks expanding and reconfiguring traditional social arrangements. 'Big data' is a broad expression to denote such information, which is available to individuals and institutions through technological devices such as smartphones and personal computers. Big data is subject to analyses based on artificial intelligence designed to extract new data using a process called "machine learning." One of the areas in which such analytic systems can and are currently applied is the health sector. In human health, traditional technologies dealt with information operated experts or by simple algorithms, are capable of being understood and used by clinicians. Machine learning models differ by building rules from data that are much more varied and presented in a more dynamic way. For instance, they start with patient-level observations, scouring variables, looking for combinations that can predict outcomes and so on. What changes can we predict that medicine will have with the expansion of the usage of big data analysis and machine-learning techniques to clinical care? It is believed that this new reality will change medicine as we know it today making it more precise and more individualized. This fits well with a Patient Centered Medicine, which is not incompatible with an Evidence Based Medicine. We would like to investigate what epistemic (collective sharing knowledge) and, especially, bioethical impacts these new information technologies may have on health practices in our present and future way of life. To answer these questions related to the impact of the new digital era and big data analysis is crucial to two areas in the

healthcare system: in public health and in the clinic. There are several other bioethical issues, for instance about the risks of applying these techniques. If they are effectively accurate, it is possible that knowledge about individuals can be used to amplify stigmas and prejudices. Take, for example, the case of forensic psychiatry. Machine learning approaches have been developed with the aim of predicting crimes committed by people with mental disorders. Such tools, if used without discretion, could worsen the condition of people already stigmatized by possible psychiatric illnesses or by their status as convicts or accused of some crime, which is clearly unfair. One hypothesis is that this new reality imposed on us an approach in bioethics, particularly on the principle of justice, which takes into account not only general retributive aspects, but also non-comparative ones, something that we could associate with the idea of a bioethics of precision.

4.4 – Health and the Environment

Responsible Researcher: Marcelo de Araújo
Partners: Alessandro Pinzani (UFSC); Ana Paula Lemes de Souza (UFRJ); Annelise Aurea Araújo de Moura (FIOCRUZ, ENSP); Daniel de Vasconcelos Costa (UERJ/FAPERJ); Diego Kosbiau Trevisan (UFSC); Jonathan David Pugh (Oxford); Lukas Meyer (University of Graz); Milene Consenso Tonetto (UFSC); Pedro Fior Mota de Andrade (UFAC/UFRJ); Romina Rekers; Santiago Truccone-Borgogno; Vilmar Debona (UFSC).

Abstract: The COVID pandemic has raised a plethora of moral questions relative, for instance, to the behavior of citizens during a health crisis or the behavior of richer states toward poorer ones in the distribution of vaccines, to mention just a few issues. But little effort has been made so far to conceptualize all these ethically relevant questions within the conceptual framework of a distinctive field of inquiry, to which we would like to refer as pandemic bioethics. Our intention is then to further develop this idea. Just in the same way that climate ethics and neuroethics emerged as broad fields of inquiry in their own right, it seems to us that pandemic bioethics is, broadly conceived to include environmental issues and our relations to non-human animals, likely to emerge as a field of inquiry within applied ethics. We have examined some key concepts in the climate ethics debate, particularly mitigation and adaptation, and will now try to develop a conceptual framework for pandemic bioethics by drawing public policies exploring the relations between health and the environment. For instance, 'mitigation' can refer to measures to mitigate the impact of an actual pandemic (in this case, the pandemic has already become a fact). For this reason, we can draw a distinction between ante-factum mitigation and post-factum mitigation. Different moral issues arise depending on whether we have the former or the latter in mind. There has been some intense discussion on attribution of responsibilities for actions (and omissions) in the course of the 2020 and 2021, when a pandemic had already become a fact and post-factum mitigation was in full swing. But there has been hardly any discussion on attribution of responsibilities for actions (and omissions) regarding the period that preceded the onset of the COVID pandemic, which required what I call ante-factum mitigation. Consider, for instance, the findings of the "Exercise Cygnus Report", which had shown as early as 2016 that Britain was not prepared to address a pandemic. During our research, we intend to examine this point further. Adaptation is another key concept in the climate ethics debate. Climate adaptation policies aim at reshaping the infrastructure of cities in order to make them more robust against the consequences of heat

waves, extreme weather, sea level rise etc on human health. When it comes to pandemic adaptation, though, it is the other way round: we protect people from pandemics by changing them –their immune system– so that they become fit to live in their new surrounding environment. If one has been vaccinated and decides to leave one's environment, one takes the adaptation with them. Now, unlike anthropogenic climate change, which is an unprecedented event in human history, pandemics are not one-off events: they are cyclical. Humanity, then, at all levels of agency, has the moral responsibility to break the cycle of pandemics. This means that many of the societal changes and technological breakthroughs that emerge during a pandemic can become instrumental for the development of capabilities that may enable us to avert future pandemics; and if another pandemic does strike again, we have a duty to employ lessons from past pandemics in order to better address the current one. Thus, different bioethical issues emerge in each of these three temporal timeframes – issues related to actions (and omissions) that occur before, during, and in the aftermath of a pandemic. The implication for pandemic bioethics is that the normative theories we deploy to address issues that arise in one timeframe should not be taken as unrelated to the moral reasons we articulate in another in order to construct solid public policies for the health care sector.