Informed consent and group vulnerability in the context of the pandemic

Fabio Macioce*

ABSTRACT: Group vulnerability is a standard issue in bioethics. Research ethics guidelines highlight the need for protection of vulnerable participants, and clinical trials are ruled by ethical and legal principles that concern possible health inequities experienced by vulnerable populations. In both the literature and the regulation, two conceptions of vulnerability are at work. On the one hand, the inherent vulnerability that is part of the human condition; on the other hand, the *situational* vulnerability that is associated with specific contextual factors, and that point out either a reduced autonomy or a greater risk of harms for individuals belonging to some groups. Both these two conceptions of vulnerability are exacerbated during a pandemic; on the one hand, specific populations are at heightened risk for medical complications from the virus (elderly, or immunodepressed); on the other hand, specific groups experience an increased vulnerability due to the social determinants of health, which influence individual resilience and exacerbate the impact of the virus. Among the many (income distribution, education and literacy, working condition, house and living conditions, disability, access to health services, etc.) the dramatic reduction of the space for free and informed consent, because of the mental and physical adverse effects coming from social isolation, age, culture, literacy, is relevant for both clinical research and practice. In this paper, I will discuss challenges for the informed consent in the context of the Covid-19 pandemic, with specific consideration of the condition of vulnerable groups.

KEYWORDS: Covid-19; informed consent; research ethics; vulnerability

SUMMARY: 1. Introduction – 2. Vulnerability as a bioethical concept – 3. Group vulnerability and the pandemic – 4. Trials and informed consent: the case of vulnerable groups – 5. Conclusions.

* *Full Professor of Philosophy of Law at Department of Law, Libera Università Maria Ss. Assunta (LUMSA) of Rome. E-mail: f.macioce@lumsa.it.* *This essay is developed within the European project "Improving the guidelines for Informed Consent, including vulnerable populations, under a gender perspective" (i-CONSENT), funded by the European Union framework program H2020 (Grant Agreement n. 741856). The article was subject to a double-blind peer review process. The Author thanks the Reviewers for their comments.*

Downloaded from www.biodiritto.org.
ISSN 2284-4503

1. Introduction

As witnessed during the 2009 H1N1 pandemic and the 2003 SARS epidemic, in the context of a pandemic a great amount of attention is paid - by health authorities, media, policy makers, etc. - to the protection of those members of the population who are exposed to a higher risk from a clinical point of view, or in relation to complications resulting from infections caused by viruses or bacteria. However, it is important to recognize that significant conditions of vulnerability can depend on social factors (referred to as social determinants of health), which influence people's resilience and can exacerbate the impacts of the pandemic[1]. For this reason, it is crucial to identify the factors that can produce, or aggravate, the vulnerability of certain groups of people in the context of a pandemic, because only in this way is it possible to prepare adequate forms of protection and guide the procedures and practices of research in order to guarantee the dignity and rights of people in conditions of vulnerability, also with reference to the processes of information and expression of consent.

In this article, I discuss the category of group vulnerability, and the consequences related to the processes of obtaining informed consent, with specific reference to the context of the pandemic. After a brief *explicatio terminorum* relating to the use, within the field of bioethics, of the category of group vulnerability and its usefulness, I discuss the repercussions of the pandemic on this category, and how the pandemic has consequently altered the traditional "map" of vulnerable groups. Finally, in the third part, I discuss the ways in which the processes of obtaining consent can represent an effective tool for mitigating the vulnerability - of people and groups - even in the context of a pandemic.

2. Vulnerability as a bioethical concept

Recourse to the notion of vulnerable groups, in literature and in regulation in the field of bioethics, is as old and widespread as it is characterized by its wide margins of vagueness; if on the one hand this vagueness is understandable, and linked to the multiplicity and unpredictability of the conditions which represent a particular exposure to risk and a reduced ability to cope with it, on the other hand it does not contribute to ensuring the objective of clarity and precision which, as stated, is particularly useful in the context of a pandemic. In fact, not only is the notion of vulnerable groups widely used in texts with normative value and in other types of documents (guidelines, opinions, recommendations) but it has entered the common lexicon of bioethics[2] especially in relation to the profile of consent, and with reference above all to the field of biomedical research. And yet, at the

[1] J.P. GAROON, P.S. DUGGAN, *Discourses of disease, discourses of disadvantage: A critical analysis of National Pandemic Influenza Preparedness Plans*, in *Social Science and Medicine*, 67(7), 2008, 1133-1142; INTERNATIONAL CENTRE FOR INFECTIOUS DISEASES, *Issues in Pandemic Influenza Responses for Marginalized Urban Populations: Key Findings and Recommendations from Consultation Meetings and Key Informant Interviews*, 2010 http://www.icid.com/files/Marg_Pop_Influenza/Issues_in_Pandemic_Influenza_Responses_for_Marginalized_Ubran_Populations_English_FINAL.pdf (last visited 02/06/2021)

[2] H. TEN HAVE, *Respect for Human Vulnerability: The Emergence of a New Principle in Bioethics*, in *Bioethical Inquiry*, 12, 2015, p. 396; M. THOMSON, *Bioethics & vulnerability: Recasting the objects of ethical concern*. In *Emory Law Journal*, 67(6), 2018, p. 1218.

Downloaded from www.biodiritto.org.

ISSN 2284-4503

same time, without a clear understanding of what exactly vulnerable groups are, and the factors which determine this vulnerability, can constitute a very serious obstacle for the provision of adequate forms of protection precisely in the context of clinical trials and the procedures for obtaining informed consent.

Now, the objective of protecting subjects and categories of subjects considered to be particularly fragile, or in need of specific forms of protection, has been perceived since the dawn of bioethics, that is, since the Nuremberg Code and the Declaration of Helsinki[3]. This initial imprint, will, in some way, also remain in subsequent documents: the need to grant special protection to vulnerable subjects, and to groups or categories of subjects considered to be particularly fragile, or exposed to particular risks, will be continually reaffirmed in all the documents related to research in the biomedical field, while, on the one hand, however, being based on a lack of definitional clarity, as a result of which, on the other hand, the identification of vulnerable subjects will continue to be inaccurate, and to some extent taken for granted[4]. In this sense, vulnerability in bioethics has tended to have the meaning of drawing attention to exposure to a *heightened* risk of harm, and/or to an ability to defend oneself or cope with this risk that is *lower* than standard; this is due to particularly complex circumstances, or to reduced subjective capacities, or to specific situations involving a reduced ability to protect oneself. So, certainly intuitively, and with a great deal of common sense, we can qualify minors, or people with psychiatric disorders, or patients in intensive care, as examples of vulnerable subjects/categories. Equally, however, an intuitive or common sense classification can not suffice, if the imposition of specific obligations for special protection, or additional guarantees[5] ensue.

A first explicit reference to vulnerability, and more specifically to group vulnerability, can be found in the Belmont Report[6], in which vulnerability is considered under three profiles: in relation to the issue of incentives, because "inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable"; with reference to the risk/benefit balance of research, since in the case of research including "vulnerable populations" this involvement must itself be demonstrated as necessary; finally, as a matter of justice, to prevent socio-economically weaker groups from being manipulated, exploited, and unduly involved in research. In the latter case, a first type of vulnerable group is also outlined: "Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or

[3] W. Rogers, C. Mackenzie, S. Dodds, *Why bioethics needs a concept of vulnerability*, in *International Journal of Feminist Approaches to Bioethics*, Vol. 5, No. 2, 2012, p. 14.

[4] W. Rogers, *Vulnerability and bioethics*, in C. Mackenzie, W. Rogers, S. Dodds (Eds.), *Vulnerability: new essays in ethics and feminist philosophy*, New York, 2014, p. 62.

[5] S.A. Hurst, *Vulnerability in research and health care; describing the elephant in the room?*, in *Bioethics*, 22(4), 2008, pp. 191-202.

[6] National Commission for the Protection of Human Subjects of Biomedical and Behavior Research, *The Belmont Report*, 1979 https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html (last visited 02/06/2021)

Downloaded from www.biodiritto.org.
ISSN 2284-4503

because they are easy to manipulate as a result of their illness or socioeconomic condition".[7] The Belmont Report approach, however, is indicative of a trend that seems to characterize all subsequent legislative and regulatory provisions, leaving unresolved the ambiguity between vulnerability as a general condition of subjects participating in biomedical research or of patients in clinical contexts, and vulnerability as a specific condition of some groups or categories of people, *particularly* exposed to risks of exploitation, manipulation, injustice and injury.

A few years later, in fact, in the 1982 International Guidelines for Biomedical Research Involving Human Subjects adopted by CIOMS, vulnerability is taken into consideration more explicitly as a relevant factor in biomedical research, but it is only in the 2002 version that a more precise definition of vulnerability is rendered, as the incapacity of some subjects to protect their own interests[8]: "Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength or other needed attributes to protect their own interests"[9]. What is important for this analysis, however, is that at the same time the CIOMS guidelines state that vulnerability is a general condition of a lack of power (incapacity to protect one's interests) owing to multiple factors, and refers to it as a *specific* condition of some groups or categories of people, in a supra-individual perspective. Thus, in addition to minors (Guideline 14) and persons not capable of giving valid consent due to mental or behavioural disorders (Guideline 15),the Commentary on Guideline 13 provides an actual list of vulnerable groups: persons in subordinate positions in highly hierarchical contexts ("Examples of such groups are medical and nursing students, subordinate hospital and laboratory personnel, employees of pharmaceutical companies, and members of the armed forces or police"),elderly persons with forms of senile dementia or who are institutionalised, people receiving welfare benefits or social assistance, poor people and the unemployed, people in emergency departments, ethnic and racial minorities, the homeless, nomads, refugees, prisoners, patients with incurable disease, subjects who are politically powerless ("politically powerless individuals") and members of communities that are unfamiliar with modern medical concepts ("communities unfamiliar with modern medical concepts")[10]. This list, clearly, lacks internal homogeneity, as it can, at most, be taken as an example of a list of cases in which, effectively, the lack of power and the limited capacity to protect one's own interests become particularly relevant.

Such a detailed list of conditions of vulnerability, or conditions in which the risk of vulnerability is higher and significant, is not found in other international documents. Indeed, it is probably the criticism directed at this "categorizing" approach over the years that has led to drastically limit mentioning vulnerable groups explicitly[11]. And so, if already in the UNESCO Declaration on bioethics

[7] National Commission for the Protection of Human Subjects of Biomedical and Behavior Research, *The Belmont Report*, cit., Part C. 3.

[8] On this point, see J.J. van Delden, R. van der Graaf, *Revised CIOMS international ethical guidelines for health-related research involving humans*, in *Jama*, 317(2), 2017, pp. 135-136.

[9] CIOMS-OMS, *International ethical guidelines for health-related research involving humans*, 2002, Commentary on Guideline 13.

[10] Ibidem.

[11] For these criticisms see K. Kipnis, *Seven vulnerabilities in the pediatric research subject*, In *Theoretical Medicine and Bioethics*, 24(2), 2003, pp. 107-120; F. Luna, *Elucidating the concept of vulnerability: Layers not labels*,

Downloaded from www.biodiritto.org.
ISSN 2284-4503

and human rights the reference to vulnerability is linked to the human condition (article 8), and group vulnerability is simply mentioned with reference to particularly vulnerable groups ("groups of special vulnerability") or to groups that are *rendered* vulnerable due to different factors ("groups ... rendered vulnerable by disease or disability or other personal, societal or environmental conditions")[12], in the 2013 Helsinki Declaration the reference to vulnerable groups is entirely generic ("Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm")[13].

However, the reference to group vulnerability has not disappeared from international texts and documents in the field of bioethics, bearing witness to its persistent descriptive capacity, or to its ability to linguistically represent certain contexts subject to protection. For instance, in the Barcelona Declaration on Policy Proposals to the European Commission on Basic Ethical Principles in Bioethics and Biolaw (adopted in November 1998 by Partners in the BIOMED II Project), vulnerability is indicated in itself as a fundamental bioethical principle, alongside autonomy, integrity and dignity[14]. However, in the Report concerning the Declaration, vulnerability is not simply indicated as an inherent characteristic of the human being ("the condition of all life as able to be hurt, wounded and killed"), but is understood as common to all forms of life ("concerns animals and all self-organising life in the world"), and grounds a social responsibility towards life as vulnerable, e.g. by imposing limits on experimentation, and the right to receive the assistance necessary to realise its potential[15].In EU law, for example, the field of biomedical research is one in which the reference to group vulnerability is most frequently used. With more specific regard to legal documents, the 2014 Clinical Trials Regulation[16] at art. 10 (titled "Specific considerations for vulnerable populations") states that for minors, incapacitated, pregnant and breastfeeding women, or other groups or subgroups, specific precautions and procedures are required to obtain authorization for enrolment in a clinical trial. Even if it is not specified what these specific considerations or cautions consist of, this vulnerability still seems to be linked, in an alternative and inevitably ambivalent way, on the one hand to a reduced decision-making capacity, in line with the provisions of the Oviedo Convention on human rights and biomedicine, and with the Additional Protocol on Biomedical Research[17], and on the other hand to an increased risk of suffering damage or injury.

---

in *The International Journal of Feminist Approaches to Bioethics*, 2(1), 2009, pp. 121-139; A.S. ILTIS, *Introduction: Vulnerability in biomedical research*, In *Journal of Law, Medicine & Ethics*, 37(1), 2009, pp. 6-11.

[12] https://unesdoc.unesco.org/ark:/48223/pf0000146180 (last visited 02/06/2021)

[13] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/ (last visited 02/06/2021)

[14] P. KEMP, J. DAHL RENDTORFF, *The Barcelona declaration. Towards an integrated approach to basic ethical principles*, in *Synthesis philosophica* 23(2), 2008, pp. 239-251.

[15] *Final Report to the Commission on the Project Basic Ethical Principles in Bioethics and Biolaw*, 1995-1998, http://cometc.unibuc.ro/reglementari/Basic-Ethical-Principles.pdf (last visited 02/06/2021)

[16] *Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC Text with EEA Relevance*

[17] COUNCIL OF EUROPE, *Convention for the protection of human rights and the dignity of human beings with regard to the application of biology and medicine*. Oviedo: 1997; ETS no. 164. COUNCIL OF EUROPE. *Additional Protocol to the Convention on Human Rights and Biomedicine, concerning biomedical research*. Strasbourg 2005. CETS no. 195.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

In this sense, the Regulation sets out in articles 31-33 particularly stringent guidelines for the acquisition of informed and free consent by minors, incapable subjects (these conditions of vulnerability stem from a reduced ability to safeguard their own interests), or pregnant or breastfeeding women (vulnerability is linked to a situation of increased risk), as well as, in art. 34, for other people who find themselves in contexts of hierarchical or institutional dependency likely to influence their ability to express consent (and therefore, once again, vulnerability is linked to a reduced ability to express *free* consent).With the same oscillation, Recital 15 refers to the condition of vulnerability of "frail or older people, people suffering from multiple chronic conditions, and people affected by mental health disorders" to encourage the inclusion of these categories in research precisely in order to *limit* their vulnerability[18], and Recital 31 refers to subjects belonging to an "economically or socially disadvantaged group", or to a context of possible manipulation and exploitation as a determinant of vulnerability.

Therefore, although vulnerability in bioethics is a notion as widespread and used as it is ambiguous, it is anything but a useless notion, or mere frill of rhetoric. Quite the opposite: as seen, vulnerability is always linked to specific obligations, duties of special protection and more burdensome procedures. In fact, vulnerability draws attention to the asymmetry of power which inevitably characterizes the clinical context and research in the biomedical field, given the inevitable situation in which patients or trial participants find themselves, with their being *dependent and exposed* towards the medical staff and research teams. In a certain sense, the whole development of the discipline of consent[19], at least within the liberal model, its primary objective was the guarantee of personal autonomy and the symmetrical limitation of vulnerability factors, at least within the perspective of reduced ability to decide for oneself; the growing centrality of consent, in fact, aims to rebalance this asymmetry between doctors or researchers, and patients or trial participants[20].

3. Group vulnerability and the pandemic

The "traditional" enumeration of vulnerable groups, as seen, is based on the idea that some physical, mental or existential conditions can adversely affect health in certain groups of people, either because these subjects are exposed to a *heightened* risk of harm, or because it involves for them a *lower* than standard ability to defend themselves or cope with this risk; Among the factors that can affect the condition of people and groups in this dual direction, there are certainly a number of factors attributable to the category of *situational* vulnerability, that is, to those conditions of vulnerability caused or exacerbated by environmental, political, social, economic factors, and so on. These are factors which can be interrelated with "existential" factors, for example because

[18] On this point see É. GENNET, R. ANDORNO, B. ELGER, *Does the new EU Regulation on clinical trials adequately protect vulnerable research participants?,* in *Health Policy*, 119(7), 2015, pp. 925-931.

[19]On which, in addition to R.R. FADEN, T.L. BEAUCHAMP, *A History and Theory of Informed Consent*, New York, 1986, see also N. EYAL, *Informed Consent, The Stanford Encyclopedia of Philosophy* (Spring 2019 Edition), E.N. ZALTA (ed.) https://plato.stanford.edu/archives/spr2019/entries/informed-consent/ (last visited 02/06/2021); H.T. ENGELHARDT, The Foundations of Bioethics, New York, 1996.

[20] R. ANDORNO, *Is vulnerability the foundation of human rights?* In *Human Dignity of the Vulnerable in the Age of Rights*, Cham, 2016, p. 259

Downloaded from www.biodiritto.org.

ISSN 2284-4503

economically disadvantaged conditions can, together with a not very protective institutional context, produce clinical conditions of fragility or proper pathological conditions; and vice versa, particular health conditions can lead, in certain contexts, to forms of social vulnerability, unemployment and loss of income, or more besides. However, in general, this is a vulnerability that depends on the context and the specific situation in which these subjects find themselves, even if the effects of this vulnerability can vary greatly in intensity depending on the subjective resources, and the degree of resilience of those in that given context[21].

Now, if in general the social determinants of health[22] are factors that influence the conditions of vulnerability of people and groups, it is important to note how, during a pandemic, some of these become particularly relevant and sources of increased vulnerability for specific groups. In other words, specific forms of situational vulnerability depend on the effects of the pandemic on certain groups, due to the pressure exerted on certain social determinants of health. For example, it is known that the act of washing hands frequently is one of the behaviours that more than any other reduces the risk of contagion, the fact that for almost two billion people in the world it is not *materially possible* to put this behaviour into practice represents a primary social determinant of exposure to contagion, and therefore of vulnerability[23]. Therefore, if on the one hand the conditions and social relationships in which people and groups are inserted constitute a known factor in the mortality and morbidity rates of the population, a pandemic acts on these factors by increasing the role these factors play on people's health, and producing outcomes that highlight the inequalities and vulnerable conditions of these groups[24], as well as exacerbating in turn the incidence of these socio-economic factors, in an almost circular way. A pandemic increases the importance of the factors that produce inequalities in relation to the right to health, both because it "aggravates" already unfavourable socio-economic conditions, and because it makes such conditions an obvious risk factor in the exposure to contagion and in the severity of the outcomes[25]. As the UNESCO

[21] On the distinction between intrinsic vulnerability and situational vulnerability, see first, W. ROGERS, C. MACKENZIE, S. DODDS, *Why bioethics needs a concept of vulnerability*, in *International Journal of Feminist Approaches to Bioethics*, Vol. 5, No. 2, 2012, pp. 11-38; and W. ROGERS, C. MACKENZIE, S. DODDS, *Introduction: What is Vulnerability*, cit., pp. 7-9.

[22] The social determinants of health identify the conditions "in which people are born, grow, live, work, and age and the systems put in place to deal with illness" (WORLD HEALTH ORGANIZATION, *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health. Geneva*, 2008). The literature on the subject highlights how among these determinants there are, for example, education, income, wealth, the type and conditions of work, availability and access to health services, housing, the environment. physical, social environment, and more besides: cf. M. MARMOT, *Medical Care, Social Determinants of Health, and Health Equity*, in *World Medical and Health Policy*, 10 (2), 2018, pp. 195-197.

[23] B. PATTERSON, *PBI Highlights the Importance of the Human Rights to Water and Sanitation During COVID-19 Pandemic. Peace Brigades International-Canada*, 2020 https://pbicanada.org/2020/03/25/pbi-highlights-the-importance-of-the-hrtws-during-covid19-pandemic/ (last visited 02/06/2021)

[24] C.L. MCNEELY, L.A. SCHINTLER, B. STABILE, B., *Social Determinants and COVID-19 Disparities: Differential Pandemic Effects and Dynamics* in *World Medical & Health Policy*, 12(3), 2020, p. 207.

[25] As the WHO points out, "(health equity) exists only when people have an equal opportunity to be healthy. Health inequity, therefore, is the unfair and avoidable difference in health status" (WORLD HEALTH ORGANIZATION, *Closing the Gap in a Generation: Health Equity Through Action on the Social Determinants of Health. Geneva*, cit.): the pandemic, in this sense, is an astonishing factor generating inequalities in guaranteeing the right to health.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

International Bioethics Committee correctly pointed out, "Vulnerable individuals become even more vulnerable in times of pandemic. It is particularly important to take note of vulnerability related to poverty, discrimination, gender, illness, loss of autonomy or functionality, elder age, disability, ethnicity, incarceration (prisoners), undocumented migration, and the status of refugees and stateless persons"[26].

Among these factors, the relevance of the economic factor is undoubtedly the most immediately perceptible. The levels of income and distribution of wealth in the population are indeed factors that more directly and evidently influence exposure to the risk of contagion than others, especially in the interaction with other elements[27]. The scarcity of economic resources can in fact affect exposure, access to healthcare, the possibility of receiving assistance, and the subject's own social behaviour (for example, in the effective possibility of limiting travel, or taking advantage of home working)[28] In this sense, for example, some authors have identified social housing residents, single-parent families and low-income populations as being at greatest risk during a pandemic. With limited financial resources and unstable income, such groups include people who may be forced to live in inadequate housing, i.e. with inadequate and crowded sanitation facilities[29], both factors that increase the risk of exposure during an epidemic. Similarly, many studies have shown that some income bracket may have no alternative to using public transport, which in turn is an important source of exposure to the contagion[30]. In a similar sense, the conditions and the type of work are factors that influence exposure to the contagion during a pandemic; for example, occupations that involve physical proximity (care jobs, domestic work, public transport), and which in turn are prevalent among the population groups with more limited economic resources, represent an element of strong exposure and an increased risk of contagion[31]not only that, but the risk of worse or fatal outcomes in the course of the disease is related to factors such as a worse state of general health, the presence of cardiovascular and liver diseases, diabetes and cancer, all conditions which have an inversely proportional relationship to the socioeconomic conditions of the population[32].

---

[26] UNESCO – IBC, *Statement on COVID-19. Ethical consideration from a global perspective*, 2020 https://unesdoc.unesco.org/ark:/48223/pf0000373115 (last visited 02/06/2021)

[27] In relation to the Covid19 pandemic see A. BANIK, T. NAG, S.R. CHOWDHURY, R. CHATTERJEE, *Why Do COVID-19 Fatality Rates Differ Across Countries? An Explorative Cross-country Study Based on Select Indicators*, In *Global Business Review*, 2020:0972150920929897-.

[28] E. VAUGHAN, T. TINKER, Effective health risk communication about pandemic influenza for vulnerable populations, in American Journal of Public Health, 99(S2), 2009, S324-S332; G. IACOBUCCI, Covid-19: Deprived areas have the highest death rates in England and Wales, in BMJ, 2020, 369; S. DREFAHL, M. WALLACE, E. MUSSINO, ET AL., *Sociodemographic risk factors of COVID-19 deaths in Sweden: A nationwide register study*, Stockholm Research Reports in Demography, 2020, 23.

[29] M. WALLACE, H.M., LIESL, G.C. KATHRYN, ET AL., *COVID-19 in Correctional and Detention Facilities — United States, February–April 2020*, in *MMWR Morb Mortal Wkly Rep*, 2020, 69 (early release).

[30] This element has been highlighted in relation to past flu epidemics; see for example P. BLUMENSHINE, A. REINGOLD, S. EGERTER, ET AL., *Pandemic influenza planning in the United States from a health disparities perspective*, in *Emerging Infectious Diseases*, 14(5), 2008, pp. 709-715.

[31] B. Burström, W. Tao, *Social determinants of health and inequalities in COVID-19*, in *European journal of public health*, 30(4), 2020, pp. 617-618.

[32] I. SOMMER, U. GRIEBLER, P. MAHLKNECHT, ET AL., *Socioeconomic inequalities in non-communicable diseases and their risk factors: an overview of systematic reviews*, in *BMC Public Health*, 15, 2015, p. 914.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

The economic factor, and in general unfavourable socio-economic conditions, are elements intertwined with other factors in determining conditions of vulnerability for particular social groups, such as for example ethnic minorities. The lower levels of education, socioeconomic status, worse housing conditions, and obviously less insurance coverage (especially in contexts where health care is not universal) and worse access to health services[33], in fact, they significantly contribute to determining higher rates of morbidity and mortality among these groups compared to the "general" reference population[34]. If this is generally true, the conditions linked to the pandemic exacerbate the incidence of these factors, and lead to greater vulnerability in terms of both exposure to risk and severity of outcomes for those belonging to these groups[35]; for similar reasons, a higher incidence of infections has been verified among people belonging to ethnic minorities and economically disadvantaged sections of the population, generally employed in sectors such as catering and healthcare in which the exposure to risk factors is greater, or personal care and service work that is incompatible with effective social distancing.

Other vulnerability factors emerging from the pandemic relate to health literacy, or barriers to accessing health services. Regarding the first factor it can be noted that the degree of competence and awareness with which people obtain, receive, and evaluate the information, in order to make competent decisions on health matters, is linked to the general level of education and ability to use information technologies; these skills are present in an inversely proportional measure to the socio-economic level of the subjects, and are often very lacking in groups such as ethnic minorities, irregular migrants, the elderly. These groups, therefore, and to the extent that health literacy is crucial in determining competent choices and behaviors in health matters, become vulnerable in the context of a pandemic precisely on account of the combined effect of multiple factors increasing the exposure to risks[36]. As for the second factor, it has unfortunately been known for some time that access and use of health services can be particularly burdensome for specific groups, due to language barriers, poor knowledge of bureaucratic procedures and mechanisms, fewer relational support networks, or directly xenophobic attitudes in the community of residence[37]; all these, and more, are factors that, by limiting or hindering access to health services, represent conditions of vulnerability for specific groups (for example, newly established migrant communities) in relation to the health emergency and the ability to face up to it.

[33] F. MACIOCE, *The Right to Accessible and Acceptable Healthcare Services. Negotiating Rules and Solutions With Members of Ethnocultural Minorities,* in *Journal of bioethical inquiry*, 16(2), 2019, pp. 227-236.

[34] B. THOMAS, *Health and Health Care Disparities: The Effect of Social and Environmental Factors on Individual and Population Health*, in *International Journal of Environmental Research and Public Health*, 11, 2014, pp. 7492–7507.

[35] S. YAYA, H. YEBOAH, C. H. CHARLES, A. OTU, R. LABONTE, *Ethnic and Racial Disparities in COVID-19-Related Deaths: Counting the Trees, Hiding the Forest*, in *BMJ Global Health*, 2020, 5:e002913. ; see also J.H. FARLEY, J. HINES, N.K. LEE, ET AL., *Promoting Health Equity in the Era of COVID-19*, in *Gynecologic Oncology*, 158(1), 2020, pp. 25-31.

[36] S. VAN DEN BROUCKE, *Why health promotion matters to the COVID-19 pandemic, and vice versa*, in *Health promotion international*, 35(2), 2020, pp. 181-186.

[37] B. RECHEL, P. MLADOVSKY, D. INGLEBY, J.P. MACKENBACH, M. MCKEE, *Migration and health in an increasingly diverse Europe*, in *Lancet*, 381(9873), 2013, pp. 1235-1245; L. MONTESI, M.T. CALETTI, G. MARCHESINI, *Diabetes in migrants and ethnic minorities in a changing World*, in *World Journal of Diabetes*, 7(3), 2016, pp. 34-44.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

In the opposite sense, it is interesting to note how the Sars Cov 2 virus has altered the horizon of group vulnerability, as it were. Groups traditionally considered as vulnerable seem to show particular resilience to the virus, in a way that is not entirely expected and predictable: very young children, for example, do not represent a particularly vulnerable group in the current context of the pandemic, as significant rates of morbidity and mortality have not been shown[38], compared to other far more vulnerable groups. Similarly, pregnant women, normally considered vulnerable to other viral infections (chickenpox, measles, other influenza viruses), being likely to have negative health consequences for the foetus (such as influenza H1N1 or Zika), do not appear to be exposed, in a significant way, to the risks associated with the Sars Cov 2 virus[39].

4. Trials and informed consent: the case of vulnerable groups

The issue of group vulnerability has assumed particular relevance in the context of the pandemic not only because, as mentioned, both the pandemic itself and the restrictions put in place to limit contagion have *generated* new forms of group vulnerability, or *aggravated* pre-existing conditions of vulnerability. Group vulnerability has also gained importance in relation to a more "traditional" context, so to speak, namely in relation to health treatments, and to participation in trials aimed at developing vaccines; what emerges - in a manner consistent with prominent bioethical principles in this area - is the need for the provision of additional precautions and reinforced safeguards in the context of research, in relation to the risks to which people belonging to groups identified as vulnerable are exposed.

As Van Delden[40] rightly notes, if the vulnerability is situational, similarly precaution and forms of protection should be shaped for the specific case, beyond pre-established paradigms and the risk of labelling. In this line, the prospective change adopted in the CIOMS Research Guidelines appears very reasonable, since the traditional approach based on the *preventive* identification of vulnerable groups is replaced by an approach based on case analysis: "The account of vulnerability in this Guideline seeks to avoid considering members of entire classes of individuals as vulnerable. However, it is useful to look at the specific characteristics that may render individuals vulnerable, as this can aid in identifying the special protections needed (…) Different characteristics may also co-exist, making some individuals more vulnerable than others. This is highly dependent on the context"[41].

On the one hand, group vulnerability is therefore context-dependent, and cannot be deduced prejudicially from the common characteristics of a group of people (minor age, economic status, etc.) participating in research. On the other hand, the fact that vulnerability must be detected by

[38] L. SOMINSKY, D.W. WALKER, S.J. SPENCER, *One size does not fit all - Patterns of vulnerability and resilience in the COVID-19 pandemic and why heterogeneity of disease matters*, in *Brain, behavior, and immunity*, 87, pp. 1-3.

[39] However, for some risks, see S.A. RASMUSSEN, ET AL., *Coronavirus disease 2019 (COVID-19) and pregnancy: what obstetricians need to know*, in *American Journal of Obstetrics and Gynecology*, 2020 doi: 10.1016/j.ajog.2020.02.017.

[40] J. VAN DELDEN, R. VAN DER GRAAF, *Revised CIOMS international ethical guidelines for health-related research involving humans*, in *Jama*, 317(2), 2017, p. 135.

[41] CIOMS-OMS, *International Ethical Guidelines*, cit., Guideline 15, p. 47.

Downloaded from www.biodiritto.org.

ISSN 2284-4503

induction from the analysis of actual cases does not mean that it is reduced to the *individual* dimension, or that it is not possible to speak of vulnerable groups or to postulate their existence; the group dimension of vulnerability remains, but it must be understood as a *presumptive* element, as a fact that must be verified in practice, and which can be denied in the context. However, this is, once again, a fact that - on this level of mere presumption - brings together groups and categories of people, placing them in a similar way in a condition of increased risk in relation to participation in a *specific* clinical research. And so, the condition of people living in old people's homes or psychiatric hospitals, or people in prison, is a condition which places these subjects up against a greater risk, if enrolled in clinical research, related to the possibility that their inclusion in an environment which is *intrinsically coercive* affects their freedom to express consent. Or again, women can be considered a vulnerable group if the specific circumstances in which they live (a cultural, family or social context in which manifestation of their will is bound to authorization by the spouse or father) and the specific characteristics of the research place them in a severely limiting condition regarding manifestation of consent and the possibility of exercising control over their own choices.

Returning to previously mentioned examples, people living in poverty or the homeless, or people receiving welfare benefits and social assistance can be considered vulnerable, if the specific conditions in which they live (for example, the limitations they encounter in accessing health care), and the modalities of the research, suggest the presence of constraints and a limited freedom in decision-making[42].

If this paradigm is applied to the current context, therefore, it is the specific task of those conducting research to foresee and model specific forms of guarantees for groups that *in the pandemic context* can be considered vulnerable, so that there are no more than minimal risks involved for procedures that offer no direct benefits for research participants; and it is always up to them to verify that research is conducted only when it refers to conditions specifically affecting these groups. The problem is that, in the context of the pandemic, the identification of vulnerable groups, and therefore of the subjects for whom precautions and additional forms of protection are required, not only cannot be solved by referring to pre-established classifications, but it presents unprecedented difficulties: in fact, in it not only are many conditions of vulnerability exacerbated, but new vulnerabilities emerge (with additional difficulties, precisely due to this novelty, in detecting them and understanding their dimensions and characteristics), and the factors that these vulnerabilities determine or aggravate intersect in unprecedented ways.

Consider, for example, the case of the elderly, who, as we have seen, can be identified as a particularly vulnerable group in the context of the Covid-19 pandemic, due to the high mortality and morbidity rates recorded in this segment of the population; and yet, considering this group as particularly vulnerable can lead to exclusion of the people belonging to it from enrolment in clinical trials[43]. If this is what has happened in some recent vaccine trials[44], the effect of this exclusion tends

[42] These are all examples included in the same CIOMS Guidelines in the commentary to Guideline 15.

[43] In fact, it is known that some groups traditionally considered as vulnerable (minors, the very elderly, people in detention, pregnant women, etc.) tend to be substantially excluded from research, or in any case their participation in research takes place in compliance with far more stringent and limiting conditions.

[44] B.K. HELFAND, ET AL., *The exclusion of older persons from vaccine and treatment trials for coronavirus disease 2019 —missing the target*, in *JAMA Internal Medicine*, 180(11), 2020, pp. 1546-1549.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

to increase the vulnerability of this group, rather than reduce it, because it produces an important lack of data and analyzes on efficacy, dosages and side effects on a group of patients which, paradoxically, is one of those most affected by the virus and suffers its effects most severely.

Similarly, the exclusion or severely limited participation in transnational trials of people residing in economically depressed areas or with very low per capita income stems from excellent reasons linked to doubts concerning the quality of the procedures for informed consent and effective freedom of individual choice, on the presence of a "double standard" regarding the use of placebo[45], on the availability of treatment and post-trial care, the absence or weakness of norms and local institutions that can protect the interests and dignity of individuals with regard to the commercial interests of those who fund research, and so on[46]. Such arguments, as mentioned, are more than reasonable[47], and moved by consideration of the specific condition of vulnerability of populations in developing countries: the idea that Africa, to put it plainly, should not be a kind of haven for under-regulated trials, within a para-colonialist paradigm , makes perfect sense[48]. And yet, the strong limitations and cautions linked to this vulnerability are likely to bring about, in the context of the pandemic, further, unintentional vulnerabilities for these very same populations: as different researches have pointed out, vaccine trials could as a result fail to take adequate account of important factors in the evaluation of immune response and disease course, for example to the extent that these are influenced by genetic variants[49]. The justified concern for the (economic, infrastructural) vulnerability of certain populations can in short generate, if absolute, new vulnerabilities, or, at least, may not lead to desired outcomes, but rather worsen the conditions of the populations involved; if, as already noted in other contexts, ethnicity can influence immune responses and the effectiveness of vaccines, the exclusion of African countries from the trials could expose these populations to greater risks, as unintended consequence[50].

In this context, in which the "traditional" conditions of vulnerability are modified or intertwined with other and new conditions determined by the pandemic, it is important that the tools for mitigating

[45] See for instance P. DE ZULUETA, *Randomised placebo-controlled trials and HIV-infected pregnant women in developing countries. Ethical imperialism or unethical exploitations?,* In *Bioethics*, 15, 2001, pp. 289-311.

[46] On these perplexities and risks, see M. ANGELI, *The ethics of clinical research in the third world*, in *N Engl J Med* 337, 1997, pp. 847-849; H. VARMUS, D. SATCHER, *Ethical complexities of conducting research in developing countries*, in *N Engl J Med* 337, 1997, pp. 1003-1005; see also F. LUNA, *Research in developing countries*, in B. STEINBOCK (ed.), *The Oxford Handbook of Bioethics*, New York, 2007, pp. 621-647.

[47] Even though, as clearly explained in the CIOMS International Ethical Guidelines for Health-Related Research Involving Humans, this paucity of resources and low level of income cannot be understood as a "local" factor, that is, linked exclusively to economically disadvantaged areas and countries: "Low-resource settings should not be interpreted narrowly as low-resource countries. These settings might also exist in middle- and high-income countries. Moreover, a setting can change over time and no longer be considered low-resource" (Guideline 2).

[48] The WHO Director General expressed this concern explicitly: *Coronavirus: Africa will not be testing ground for vaccine, says WHO*, in *BBC*, 6 April 2020 https://www.bbc.com/news/worldafrica-52192184. (last visited 02/06/2021)

[49] Much research is currently underway on the role of genetic variants in Covid19. See, for an overview, D.J. BURGESS, *Host genetics of coronavirus infection*, in *Nature Reviews Genetics*, 2021, 22(1) https://doi.org/10.1038/s41576-020-00310-y (last visited 02/06/2021)

[50] On this point, J.A. SINGH, *The Case for Why Africa Should Host COVID-19 Candidate Vaccine Trials, Perspective*, in *The Journal of Infectious Diseases*, 2020, 222 (3), pp. 351-355.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

the vulnerability itself are in turn modelled taking this context into account, and the specific conditions and forms of vulnerability of each group. From this point of view, the procedures for obtaining informed consent, that specifically represent one of the most typical tools of "empowerment" of the person undergoing health treatments, must be modelled in such a way as to make them not only effectively capable of vehicling the necessary information in a specific context, but also suitable, for each group of people, to make the care and protection *needs* linked to the specific condition of vulnerability emerge.

On the one hand, it is certainly true that the procedures for obtaining consent are in themselves tools for mitigating vulnerabilities, as they reduce the margins within which people are at risk, owing to their vulnerability, to be manipulated, exploited, deceived, or in any case exposed to the pressure of uncontrollable factors[51]. And above all, the fact that information must be provided in a *modality appropriate* to the conditions of the person whose consent is being sought[52] is an indication that the vulnerability factors should not be considered abstractly, but starting precisely from the concrete situation, from the specific conditions of vulnerability to which a person is exposed.

On the other hand, the fact that in the pandemic context the vulnerabilities are not only - as always - situational, but also largely unprecedented, makes it necessary to rethink consent in a relational direction, that is within communicative contexts, whose form, modality, and incidence are adequately taken into account[53]. The process of informed consent, in short, must be modulated taking into account, in addition to its information content, the context within which it is implemented, the power relations, the symbolic and discourse contexts that support and shape it[54], since all this gives shape to people's real possibilities to make choices, and their real possibilities to exercise personal freedom. In this direction, consideration of the conditions of vulnerability associated with certain groups - understood as an ensemble of people placed in a similar *position* in relation to determined risk factors - is crucial precisely because it allows the emergence and visibility of the specific needs of those people belonging to it, both in communicative and relational terms.

For example, in the context of the procedures for obtaining consent to participate in a trial, it is necessary - *in addition to* information on the risks and benefits, and any other information that the main national and international regulatory instruments rightly require[55]- that there should also be consideration of subjective perceptions in relation to the efficacy of the object of the trial, or

[51] For a comment on this model, see J. ANDERSON, A. HONNETH, *Autonomy, Vulnerability, Recognition, and Justice*, in J. ANDERSON, J. CHRISTMAN (eds.), *Autonomy and the Challenges to Liberalism, New Essays*, Cambridge, 2005, p. 130.

[52] Law 219/2017 art. 1 paragraph 4: "Informed consent (is) acquired in the ways and with the tools most suited to the patient's conditions".

[53] Contrary to what happens today, within models that place consent in an ethically neutral perspective: O. CORRIGAN, *Empty ethics: the problem with informed consent*, in *Sociology of Health & Illness*, 25(3), 2003, p. 770.

[54] O. CORRIGAN, *Empty ethics*, cit.: "this process is not situated outside the realm of power, but rather such decisions are made in contexts where prevailing discourses and norms shape the field of freedom and choice", p. 771.

[55] In the Oviedo Convention, for example, see arts. 5 et seq, but also 10 (on the right to information), 16 (on participation in experiments), 19 (on donation and transplants), 1997 https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164. (last visited 02/06/2021)

Downloaded from www.biodiritto.org.
ISSN 2284-4503

healthcare professionals' required knowledge[56], the role and involvement of family members, the expectations regarding the type of relationship between patient and researcher, role played by the institutions to which reference is made and which promote research, and many other factors[57]. But beyond that it is necessary to take into account those specific needs that vulnerable groups manifest, and which are not reduced to the many, and variable, individual interests: a vulnerable group does not simply manifest interests that are more or less reasonable, but needs that are unmet and determine specific conditions of vulnerability in a given context. For example, the vulnerability of "the very elderly" in the context of the pandemic cannot be reduced to the level of individual interests of patients, in relation to the information which may be needed due to the relational context in which they are placed, which the healthcare and research personnel must take responsibility for within the framework of the information process; the vulnerability of this group is also related to specific *common* conditions (on a clinical and epidemiological level, for example) which the subjects are not necessarily aware of, and which nevertheless determine specific information, relational, and care needs. In this sense, communication within informed consent processes cannot prescind from the consideration of the vulnerability of groups, as well as individuals, because only at this level is it possible to build *inclusive* information and communication processes, in which the need for protection and care stemming from the common positioning of subjects belonging to a group or category obtain an adequate response.

All of which, obviously, implies that the communication process cannot be conveyed by a form, or reduced to a series of information conveyed in a *top-down* direction, and least of all that such information can be standardized in models valid for everyone, because, as already stated, it depends on the context, on the relevant relationships in that particular case, on the subjects involved, and on the common needs of specific groups. These are elements that set aside, at least to a certain extent, the subject of the communication and its informational content, and highlight instead the point of view of the *methods* of communication, and the people involved in the communication process; but above all these are elements that can only be adequately assessed within a communicative context characterized by trust and entrustment.

The information underlying the consent must, therefore, be devised *in the context* of the relationship between doctor and patient, or researcher and trial participant; that is, they should not be thought of as something that is transferred from one subject to another - and which, therefore, pre-exists the relationship - but as something that is produced within the relationship itself, due to the characteristics and purposes of the participants in the interaction[58]. The information is therefore not

[56] For a review, see M. MURSHID, Z. MOHAIDIN, G. YEN NEE, *The influence patient's characteristics "requests and expectations" on physician prescribing behavior: A review*, in *International Journal of Pharmaceutical and Healthcare Marketing*, 10(4), 2016, pp. 390-411; K. WEINFURT, ET AL., *The correlation between patient characteristics and expectations of benefit from Phase I clinical trials*, in *Cancer*, 98(1), 2003, pp. 166-175.

[57] P. BIELBY, *Towards supported decision making in biomedical research with cognitively vulnerable adults*, in O. CORRIGAN ET AL. (Eds.), *The limits of consent: A socio-ethical approach to human subject research in medicine*, Oxford, 2009, p. 153.

[58] On this aspect, see N.C. MANSON, O. O'NEILL, O., *Rethinking Informed Consent in Bioethics*, Cambridge, 2007, p. 32; see also, for a broader analysis of the relationship between informed consent and vulnerability, F. MACIOCE, *Between Autonomy and Vulnerability. Rethinking Informed Consent in a Relational Perspective*, in *Notizie di POLITEIA*, XXXV, 134, 2019, pp. 111-128.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

adapted and relevant in abstract terms, or in relation solely to the patient's clinical condition, but it is adapted in terms of what the participants in the interaction do, think, expect, deem to be important, and in terms of the wider context within which they are placed. Consent is *informed* not only as regards the quantity and quality of the information that is exchanged, but also as to the modality and relational context within which this exchange takes place.

What makes the information truly adequate, in other words, is the relationship of trust that is established between speakers, and the consistency of their methods of interaction and dialogue with the affirmation and preservation of trust. Negatively, this also means that communication can fail not only on account of the quantity and type of information that is conveyed, but also on account of the way in which the participants in the communication interact; and consequently, regardless of the quantity, adequacy and relevance of the information, the outcome of the communication may strengthen the patient's vulnerability, despite having - as a merely theoretical possibility - guaranteed autonomy. In short, what guarantees the person, and reduces their vulnerability, is not the quantity or quality of information they receive (an important element in any case), but the dialogical relationship with the other, with the doctor or healthcare personnel, which constitutes the basis for a relationship of trust *within which* the person expresses his/her consent.

In the context of the pandemic, the role of trust is certainly very relevant[59], perhaps even more than it already normally is. On the one hand since, as is easily understandable, a pandemic affects the relationship of trust between rulers and ruled (with respect to the effectiveness of the contagion containment measures, the management and tracking of contacts, the information which is communicated through the media, and so on); on the other hand given that, in the face of a new virus, the investment of trust that is required of the whole community concerns the entire process of trials and mass vaccination and involves public institutions, research bodies, healthcare institutions, pharmaceutical companies, and others. In short, it involves systems and actors much broader and more complex than those normally involved in a clinical trial, in a context of urgency and with variables, therefore, being less controllable. Thus, as the Nuffield Council correctly pointed out in a recent statement on pandemic management health policies, "trust is essential in order to maintain support on the part of the general public for the measures proposed: without such trust, compliance with those measures is likely to be low"[60].

In this sense, clear, transparent and reliable communication of the "measures" adopted and the justifications that support them, as well as the risks and uncertainties of faster than usual trials, takes absolute priority not only for the health personnel directly involved, but above all for public institutions. Discussing on the media in a confused, non-transparent, and often contradictory manner - which unfortunately has happened in some European countries, is certainly a choice that does not contribute to building a relationship of trust between citizens and public institutions. It is equally important, however, that public institutions play a primary role in communicating with patients and people involved in the trials, or rather that the onus of providing information is not left entirely to

[59] A. DAWSON ET AL., *Key ethical concepts and their application to COVID-19 research*, in *Public Health Ethics*, 13(2), 2020, p. 127-132.

[60] NUFFIELD COUNCIL OF BIOETHICS, *Ethical considerations in responding to the COVID-19 pandemic*, 2020, p. 3

Downloaded from www.biodiritto.org.
ISSN 2284-4503

research teams: the specific conditions determined by the pandemic, and in particular the need for a mass vaccination campaign, entail that the communication and information needs of vulnerable groups are met in a perspective consistent with generally changed conditions. The measures adopted to deal with the pandemic, as well as the specific methods of managing the trials, represent a significant, and incredibly rapid, paradigm shift on a cultural level, because they have determined a shift of the cornerstone of clinical ethics from "the single individual -patient to the public interest". And it is necessary that public institutions - protagonists in taking decisions in the context of the pandemic –underline how this step involves no conflict between individual and collective interests; on the contrary, what stems from the adoption of a "relational perspective", on the basis of which a person's autonomy "always" manifests itself (not only during pandemics) within networks of social relations, and that individuals, insofar as they are internal to this system of relations, have interests that are not distinct from those of society as a whole[61].

5. Conclusions

As mentioned in these pages, if we want to prepare adequate forms of protection and orient research procedures and practices in order to guarantee the dignity and rights of people in vulnerable conditions, it is crucial to identify the factors that can produce or aggravate such conditions in the context of the pandemic. Indeed, it is important to consider, on the one hand, that a pandemic affects the conditions of vulnerability of individuals and groups, for example due to the pressure exerted on certain social determinants of health; on the other hand, it should be emphasized that the pandemic has somehow *altered* the horizon of group vulnerability, in such a way as to make *traditional* vulnerability categories not applicable, or at least not in an automatic way.

In the context of research, and especially in relation to participation in trials aimed at the development of vaccines, there is therefore a need for specific precautions to be put in place with regard to the risks to which people belonging to groups identified as vulnerable are exposed, and therefore those conducting the research are to provide such guarantee tools for those who, *in the context of the pandemic*, can be considered as particularly vulnerable; all this, as mentioned, even where identification of these vulnerable conditions proves to be particularly complex, given the new way in which the effects of the pandemic interact with more known and typical elements of vulnerability.

In this context, it is essential that in the procedures for obtaining consent to participate in a trial, not only is the relevant information to be provided, but consideration is also to be given to subjective

[61] On the relational perspective, with reference to autonomy and consent, see J. ANDERSON, *Autonomy and Vulnerability Entwined*, in C.A. MACKENZIE, W. ROGERS AND S.M. DODDS (eds.), *Vulnerability. New Essays in Ethics and Feminist Philosophy*, New York, 2014, pp. 134-161; M. FRIEDMAN, *Autonomy in Social Context*, in C. PEDEN AND J.P. STERBA (eds.), *Freedom, Equality, and Social Change*, Lewiston, New York, 1989, pp. 158-169; C.A. Mackenzie, N. Stoljar, *Autonomy Refigured*, in C.A. MACKENZIE, N. STOLJAR (eds.), *Relational Autonomy: Feminists Perspectives on Autonomy, Agency, and the Social Self*, New York, 2000; N.C. MANSON, O. O'NEILL, O., *Rethinking Informed Consent in Bioethics*, Cambridge, 2007; D.T. MEYERS, *Self, Society and Personal Choice*, New York, 1989.

Downloaded from www.biodiritto.org.
ISSN 2284-4503

perceptions and expectations, and the role of the institutions to which reference is made, and which promote research; above all, it is necessary to take account of the specific needs (of an informative type, but also of a social and relational type) that vulnerable groups manifest, and which are not to be reduced to the many, variable, individual interests.

To this end, the role of public institutions is crucial; only if, *alongside* the health personnel and research teams, public institutions carry out a task that is as informative as it is supportive, consent will be based not only on adequate information, but on interpersonal trust (towards health personnel) and systemic trust (towards institutions), so as to make it effectively expressive of the individual's autonomy. The investment of trust required of the community, and related both to the containment measures and to the timeframe and trail methods, as well as to the prioritization criteria for mass vaccination, in fact, involves public institutions, research bodies, health institutions, pharmaceutical companies, and all the actors involved in these processes; only if people perceive that their needs (as individuals and as groups) are adequately considered by them all, will the consent they manifest truly express their autonomy and willingness to participate in research.

Downloaded from www.biodiritto.org.
ISSN 2284-4503