**

***Ministry of Foreign Affairs and International Cooperation***

***Inter-ministerial Committee for Human Rights***

***ITALY***

***Reply to the questionnaire on bioethics and disability***

***September 2019***

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Following to your query, Italian Authorities are in a position to provide the following information prepared with the collaboration of the Ministry of Health.

**Questionnaire on bioethics and disability**

According to WHO, “disability” is an umbrella term, covering impairments, activity limitations, and participation restrictions (<https://www.who.int/topics/disabilities/en/>)

The main categories of disability are physical, sensory, psychiatric, neurological, and cognitive. A physical disability generally relates to disorders of the musculoskeletal, circulatory, and nervous systems while sensory disability involves impairments in hearing and vision. Neurological and cognitive disability includes acquired disability such as multiple sclerosis or traumatic brain injury. Intellectual disability is related to intellectual and developmental disability associated with learning, communicating, remembering information and using it properly. Psychiatric disorders may include depression, and anxiety disorders.

Disabilities describe a congenital and continuing condition with or without chances of recovery as well as an acquired condition with or without chances of recovery.

The heterogeneous dimension of disability – in terms of categories and onset – emerges with dramatic implications within the scenario of scientific research and clinical practice, as it will be further discussed. Please consider that information provided is limited to the area of competence of the Division of Research and Innovation.

1. **Please provide information on the legislative and policy framework in place in your country in relation to:**
	1. **Prenatal diagnosis**

As regards the availability, accessibility and use of prenatal diagnosis in Italy, the fundamental regulatory framework is represented by the Decree of the President of the Council of Ministers 12 January 2017, containing *Definition and update of the essential levels of assistance*, referred to in article 1(7) of the legislative decree 30 December 1992, n. 502. (Official Journal, General Series, No. 65 of 18 March 2017), under which article 59 *Outpatient specialist assistance for pregnant women and for maternity protection* identifies the specialist outpatient services guaranteed from the National Health Service, provided by accredited public and private health facilities, including public counselling centre. **In particular, the following services are excluded from citizens’ participation to their cost**:

* Preconceptional care (PCC): specialist outpatient services necessary to ascertain any procreative risks related to a pathological condition, a genetic risk of one or both parents, evidenced by the couple's reproductive or family health history, prescribed by the specialist.
* During pregnancy: specialist outpatient services necessary and appropriate for pathological maternal and/or fetal risk conditions, prescribed by the specialist or by a medical doctor.
* In specific fetal risk conditions: specialist outpatient services necessary and appropriate for the a priori assessment of procreative risk, or for the risk detected during pregnancy.
	1. **Disability-related abortion**

With reference to the availability and access to **voluntary termination of pregnancy**, the law in force in Italy - Law 22 May 1978, no. 194 *Norms on the social protection of motherhood and the voluntary termination of pregnancy* (Published in the Official Journal of May 22, 1978, No. 140) - guarantees the right of every woman to resort to abortion, when her *situation is such that continuation of pregnancy, childbirth or motherhood would seriously endanger her physical or mental health, in view of her state of health, her economic, social or family circumstances, the circumstances in which conception occurred or the probability that the child would be borne with abnormalities or malformations* (Article 4 of Law 194/1978). The woman shall apply to a public counselling centre or to a fully authorised medical social agency in the region or to a physician of her choice. in addition to guaranteeing the necessary medical examinations, counselling centres and socio-medical agencies shall be required, especially when the request for termination of pregnancy is motivated by the impact of economic, social or family circumstances upon the pregnant woman’s health, to examine possible solutions to the problems in consultation with the woman and, where the woman consents, with the father of the conceptus, with due respect for the dignity and personal feelings of the woman and the person named as the father of the conceptus, to help her to overcome the factors which would lead her to have her pregnancy terminated, to enable her to take advantage of her rights as a working woman and a mother, and to encourage any suitable measures designed to support the woman by providing her with all necessary assistance both during her pregnancy and after the delivery (Article 5 of Law 194/1978). Furthermore, Article 6 of the Law provides that the voluntary termination of pregnancy may be performed after the first ninety days: where the pregnancy or childbirth entails a serious threat to the women’s life, and where the pathological processes constituting a serious threat to a women’s physical or mental health, such as those associated with serious abnormalities or malformations of the foetus, have been diagnosed. The physician performing the pregnancy termination shall be required to supply the woman with information and instructions on birth control and to acquaint her with the abortion procedures, which must, however, be carried out with all due respect for the woman's personal dignity. In the presence of pathological processes, such as those associated with abnormalities or malformations of the fetus, the physician carrying out the pregnancy termination shall supply the woman with the necessary details for the prevention of such processes. (Article 14 of Law 194/1978).

* 1. **Informed consent to medical treatment and scientific research**

In Italy informed consent is an ethical and legal requirement for medical treatment and for research involving human participants. The voluntary expression of consent by a competent subject and the adequate information disclosure about the research or the treatment to be performed are critical elements of the informed consent process. While competent subjects able to comprehend treatment- or research-related information should autonomously decide and provide consent or refusal, conditions posing challenges for informed consent may include situations of medical emergency or obtaining consent from “vulnerable” subjects and/or minors. A “vulnerable population” is defined as a disadvantaged community subgroup unable to make informed choices, protect themselves from inherent or intended risks, or keep their own interests safeguarded. In the health domain, “vulnerable populations” refers to physical vulnerability (*e.g.* pregnant women, fetuses, children, orphans, students, employees, prisoners, the military, and those who are chronically or terminally ill), psychological vulnerability (cognitively and intellectually impaired individuals) and social vulnerability (those who are homeless, from ethnic minorities, are immigrants or refugees).

Within this framework, the heterogeneousness of disability has a diverse impact. While a physical disability does generally not impair the informed consent process, a cognitive disability does. For this reason, both in research and in medical practice a standard form of informed consent for adults with capacity and a form dedicated to adults who permanently or temporarily lack capacity, and for which a legal representative is appointed, are always available. Due to a compromised ability to make conscious decisions, several ethical dilemmas (related to communications, privacy and treatment) often arise when research or medical care involves the heterogeneous category of vulnerable populations. Guaranteeing protection of rights, safety, data privacy and confidentiality of vulnerable subjects are prerogatives of good clinical practice, and law dispositions are regulated and strictly monitored by the applicable authorities. (Manti S, Licari A., How to obtain informed consent for research, Breathe 2018 14(2): 145–152.)

Concerning informed consent for medical treatment, a waiver to consent is recognized for emergency situations in which the patient temporarily or permanently lacks capacity for consent in the absence of a legal representative, and for situations in which the patient represents a recognized risk for third parties.

In research, the process of obtaining informed consent for clinical trials is tightly regulated; complications arise in circumstances when consent may be waived, or when needed from vulnerable populations. Research conducted on humans must be pre-emptively accepted by the subjects themselves through the procedure known as informed consent, which is a process by which “a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject’s decision to participate”, as stated in the International Council for Harmonisation Good Clinical Practice guidelines. Informed consent is documented by means of a written, signed and dated informed consent form. This form is required in the following cases: 1) when the research involves patients, minors, incompetent/incapacitated persons, healthy volunteers, immigrants or others (*e.g.* prisoners); 2) when the research uses/collects human genetic material, biological samples or personal data.

After institutional review board (IRB) or independent ethics committee approval is achieved, obtaining informed consent from each human subject prior to his/her participation in clinical trial is mandatory. However, when specific circumstances occur, the informed consent can be waived, and “research without consent” is possible under strict regulation (Manti S, Licari A, 2018 Jun).

General Regulation:

* Nuremberg Code
* Declaration of Helsinki
* Belmont Report
* Oviedo Convention https://www.coe.int/en/web/bioethics/oviedo-convention
* d.lgs. 29 maggio 1991, n. 178 (<https://www.gazzettaufficiale.it/eli/id/1991/06/15/091G0214/sg>) initially implemented in 1992 and then replaced by decreto del 15 luglio 1997 ([http://www.agenziafarmaco.gov.it//sites/default/files/Decreto\_Ministeriale\_15luglio1997.pdf](http://www.agenziafarmaco.gov.it/sites/default/files/Decreto_Ministeriale_15luglio1997.pdf))
* direttiva 2001/20/CE (<https://www.camera.it/parlam/leggi/deleghe/testi/03211dl.htm>) and direttiva 2005/28/CE (<http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2005&codLeg=23483&parte=1%20&serie=S2>)
* Regolamento n. 536/2014 del 16 aprile 2014 “sulla sperimentazione clinica di medicinali per uso umano e che abroga la direttiva 2001/20/CE” (<http://www.trovanorme.salute.gov.it/norme/renderNormsanPdf?anno=2014&codLeg=49603&parte=1%20&serie=S2>)
	1. **Protection of persons with disabilities undergoing research**

Please refer to answer provided to question No. 1(c) above.

* 1. **Euthanasia and assisted suicide**

Neither active euthanasia nor assisted suicide are explicitly regulated by legal frameworks in Italy, reason for which both practices have long been sanctioned pursuant to the penal code in force (articles 575, 579 and 580). However, the Constitutional Court with Ordinance 24 October 2018, No. 207, reiterated the importance of an intervention of the legislator to define ways and conditions of assisted suicide and to regulate the right to end-of-life care. In particular, the Court highlighted that “the current regulatory framework concerning the end of life leaves without adequate protection certain situations constitutionally worthy to be defended and to be balanced with other constitutionally relevant assets”.

While waiting for “an indispensable intervention of the legislator” with appropriate discipline, on the 25th of September 2019 the Court delivered its opinion on the question of constitutionality of article 580 of the Criminal Code as regards “the indictment of assisted suicide for those already determined to take their own life”. Accordingly, the Court considered “not punishable under Article 580 of the Criminal Code, under certain conditions, who facilitates the execution of the suicide intention, autonomously and freely formed, of a patient kept alive by life-support treatments and suffering from an irreversible pathology, source of physical or psychological suffering that he or she considers intolerable, but fully capable of making free and conscious decisions”. The ruling of the Constitutional Court demonstrates the attention paid to the issue of end of life and the right to assisted suicide in the current debate in Italy, as also shown e.g. from the issuing of Law 22 December 2017, No. 219, concerning “Norms on informed consent and advance directives”, and from the publication of the Opinion 18 July 2019 “Bioethical Reflections On Medically Assisted Suicide” by the National Bioethics Committee.

1. **Please provide any information and statistical data (including surveys, censuses, administrative data, literature, reports, and studies) in relation to:**
	1. **The availability, accessibility and use of prenatal diagnosis**

The prenatal non-invasive screenings are offered to all pregnant women. The ones currently available in Italy are:

* Nuchal translucency: ultrasound at week 11-13.
* Combined test: nuchal translucency and a blood test at week 11-13, plus successive blood tests at week 15-17. Additional information betters the precision of the results and allows evaluating also the risk of spina-bifida (malformation of the spinal column).
* Tri-test (triple test): blood test of mother’s blood which can be done until week 20.

Diagnostic (invasive) tests are only offered to those women who have increased risk as a result of the screening. Women over 35 years of age at the time of conception can choose whether to do a screening or directly request a diagnostic exam. The results clearly express if the baby is affected or not by Down syndrome or other rare chromosome diseases. The diagnostic tests currently available are:

* Chorionic villus sampling: placenta material is taken through the mother’s abdomen (in some rare instances it may be taken from the uterine cervix). The sample can be taken from week 10 of the pregnancy (the risk of miscarriage increases if done before).
* Amniocentesis: a sample of amniotic fluid is taken from the mother’s abdomen. The sample is usually taken between week 15 and 17 of the pregnancy. With the same sample the alphafetoprotein can be measured for the diagnosis of anomalies of the neural tube (spina bifida). The time needed to carry out the classic diagnostic tests (cariotype or chromosome map) take a minimum of 14 days.
	1. **The availability, accessibility and use of disability-related abortion**

In Italy the data on abortion is collected by the Epidemiological Surveillance System of Voluntary Pregnancy Interruptions (VIP), which has been active in Italy since 1980 and involves the National Institute of Health, the Ministry of Health, the National Institute of Statistics, the Regions and the two Autonomous Provinces. The monitoring takes place starting from the ISTAT D12 models that must be completed for each IVG in the structure where the intervention was carried out, then collected and transmitted by each Region to the Ministry of Health.

According to the 2018 Report by the Minister of Health on the implementation of the Law 22 May 1978, no. 194 *Norms on the social protection of motherhood and the voluntary termination of pregnancy,* 80,733 VIPs were notified in 2017, confirming the continuous downward trend of the phenomenon, to a slightly greater extent than that observed in 2016 (-4.9% compared to 2016 and -65.6% compared to 1982, year with the highest number of VIPs in Italy, i.e. 234,801 cases). All the indicators confirm the decreasing trend: the abortion rate (No. VIPs for 1000 women aged 15-49 living in Italy), which represents the most accurate indicator for a correct evaluation of the trend of the use of VIPs , was equal to 6.2 per 1000 in 2017, with a decrease of 3.3% compared to 2016 and with a reduction of 63.6% compared to 1982. The Italian figure remains among the lowest values ​​at international level. The abortion ratio (No. VIPs for 1000 live births) in 2017 was 177.1 per 1000 live births (or 17.7 per 100 live births), with a reduction of 2.9% from 2016 and 53.4% ​​with respect to 1982.

* 1. **The practice of informed consent to medical treatment and scientific research**

Guaranteeing protection of rights, safety, data privacy and confidentiality of vulnerable subjects are prerogatives of good clinical practice, and law dispositions are regulated and strictly monitored by the applicable authorities. National Ethics Committees are committed to safeguard and address the rights of persons, regardless of their degree of capacity. The laws and guidelines National Ethics Committee refer to are listed within section “General Regulation”.

With this regard, the National Bioethics Committee on September 28, 2012 expressed its position (http://bioetica.governo.it/en/opinions/opinions-responses/clinical-trials-in-adult-or-minor-patients-who-are-unable-to-give-informed-consent-in-emergency-situations/). In stressing the absolute need to safeguard the subject’s rights, safety and wellbeing, the Committee recognizes the lawfulness of clinical trials in emergency situations, should the patient be unable to give his/her valid informed consent and in the absence of a legal representative, in specific conditions: the approval of a protocol – based on strong experimental evidence – by a national ethics committee set up ad hoc, independent, made up of doctors and nurses working in the specific sector, jurists, forensic scientists, patient rights representatives and bioethicists; the ascertainment of any possible desire to the contrary previously expressed by the patient; the request for consent deferred by the patient or his/her legal representative; the publication of the results of the trials to avoid unnecessary duplications.

Please consider “General Regulation” as a framework.

* 1. **The existence of measurements of quality of life which affect both clinical decision-making and health policy**

As regards the measurements of quality of life which affect clinical decision-making processes and health policies, it should be noted that Eurostat recently released its survey on health and social inclusion for 2016. According to Eurostat, 25.3% of the population of the European Union over the age of 16 declared to have experienced in 2016 strong limitations in the possibility of carrying out usual daily activities for a period exceeding six months and for reasons strictly related to health. In Italy this percentage is slightly above the EU average, i.e. at 29%. Furthermore, 66.18% of people with disabilities in Italy (compared to 52.89% of the European average) encounter mobility barriers.

In addition, at the end of December 2017 ISTAT published data on municipal social services expenditure for 2014 and 2015. The survey represents the major source of information over the system of territorial social services and allows for the identification of some local welfare trends in different Italian regions. According to the survey, in 2015 the Italian municipalities, individually or associated, spent in social interventions and services over 6.9 billion euros, which means 0.42% of the Gross Domestic Product.

In 2015, 25.4% of social expenditures of the municipalities was allocated to disability (which does not include the spending for non-self-sufficient elderly people) for a value of 3,127 euros per inhabitant with disabilities (it was 2,736 euros back in 2013). In 2015, 51% of the public expenditure of the municipalities for disability was allocated to interventions and services, the 26% to cash transfers and the 23% to residential and semi-residential facilities. In 2015, at the national level, the main interventions and services provided for disability included socio-educational support in schools, which absorbed 19.6% of social expenditure for disability, day-care centres and other daytime facilities (20.3%), residential facilities (18.1%) and home-care services (15.2% overall, of which the most significant is social assistance, which represents 8.7% of total expenditure for disability).

With regard to health policies, it is to be noted that the aforementioned Decree of the President of the Council of Ministers (DPCM) of 12 January 2017 for the update of the essential assistance levels (EAL) pays particular attention to the protection of minors, women and families in different areas. In particular, article 24 is especially dedicated to "Healthcare for minors, women, couples and families" in home assistance and healthcare, i.e. the public counselling centres. The fundamental elements of the activity range from the protection of motherhood and responsible paternity, to the protection of women's and couples' health, to the protection of pregnancy, maternity and puerperium, etc. In particular: for gender-based violence, prevention, early detection and assistance in cases of gender and sexual violence; for sexual and reproductive health: in Italy access to services is ensured to all Italian and foreign women, including irregular women, including women with disabilities, especially through the establishment of Family Counselling Centres with Law 405 of 1975, referred to by the new EALs, in art. 24, specifically dedicated to "Healthcare for minors, women, couples and families". The Family Counselling Centres are basic social and health services with a low access threshold to protect the sexual and reproductive health of all women, including adolescents, including the prevention of voluntary termination of pregnancy (VTP) and support for couples and families. In the Family Counselling Centres the presence of gynaecologists, paediatricians, psychologists, social assistants is guaranteed and a strong integration with the social health area and with the child neuropsychiatry of the territorial areas of competence (Health districts) is assured. In particular, in terms of ​​district assistance, Chapter IV of the DPCM deals with "Social and Healthcare Assistance" (home and outpatient) and dedicates some specific articles to assistance to people with disabilities, of all ages, at different levels assistance, establishing that the national health service guarantees the provision of combined health and social care pathways for integrated access to services, the multidimensional assessment of functional and social clinical needs, the assistance to the person with disabilities and the definition of the individual rehabilitation project. More generally, the decree provides that the NHS guarantees all persons with disabilities the aids and prostheses necessary to enhance residual abilities and to promote autonomy; for people suffering from autism spectrum disorder (ASD): in Chapter VI “Specific assistance for particular categories” the EALs recall, for the services that the NHS guarantees to people with ASD, the law 134/2015 and therefore all performances thereby provided.

With regard to the system of detection and assessment of disability, as part of the adaptation of the Italian legal system to the principles enunciated by the UN Convention, the Legislative Decree 96/2019 concerning Additional and corrective provisions to the Legislative Decree 66/2017 "Norms for the promotion of school inclusion of students with disabilities" promises to be the first implementation of the concept of disability as articulated by Law 3 March 2009, No. 18 (Ratification and execution of the United Nations Convention on the Rights of Persons With Disabilities), which marked the definitive transition to a vision of the condition of disability, based on respect for human rights, understood as interaction between people with health problems or their consequences and barriers that can prevent their full and effective participation. At the Ministry of Health, an especially dedicated Working Group is in the process of defining the “Guidelines for ascertaining the condition of disability in the developmental age and for drawing up the Operating Profile”.

* 1. **The practice of experimental, controversial and/or irreversible treatments**

In Italy, the debate on the recognition of wrongful birth and wrongful life damages has been going for years. With judgement no. 25767 on 22 December 2015, the Italian Supreme Court provided a clear jurisprudence recognizing wrongful birth claims and rejecting wrongful life ones. The disabled child’s life cannot be considered a damage, assuming it has less value than the life of a healthy child. Therefore, the right to compensation for wrongful life claims has definitely been excluded (Frati et al. 2017).

* 1. **The practice of euthanasia and assisted suicide on persons with disabilities**

Please refer to answer provided to question No. 1(e) above.

1. **Please provide information on discrimination against persons with disabilities on research involving humans.**

People with intellectual disabilities (ID) are often excluded from research, in part because they may be perceived as lacking capacity to provide informed consent.

One reason for excluding people with ID from studies is that they may lack, or be perceived as lacking, ability to provide informed consent. In fact, it is not unusual for studies to list ability to provide informed consent as an inclusion criterion. What is less common in study descriptions is any explanation of how ability to consent was assessed. It is possible that people with ID may simply be assumed to be incapable and thus ineligible. However, many researchers in the ID field agree that a diagnosis of intellectual disability should not automatically lead to the presumption that an individual is incapable of decision making and providing informed consent to participate in research. Capacity to consent is typically conceptualized as encompassing four components, which include the ability to: 1) understand relevant information; 2) appreciate the consequences of the information for one’s own situations; 3) reason about the available options; and 4) communicate a choice.

1. **Please describe how national ethics committees address the rights of persons with disabilities. Please provide information on protocols, guidelines, decisions, investigations or publications in relation to persons with disabilities.**

Please refer to answer provided to question No. 2(c) above.

1. **Please describe to what extent and how persons with disabilities are involved in the work of national ethics committees.**

The composition of ethics committees in Italy requires the involvement of a lay member, from patient organizations, yet this member does not necessarily represent individuals with disability (Decreto 12 maggio 2006: Requisiti minimi per l'istituzione, l'organizzazione e il funzionamento dei Comitati etici per le sperimentazioni cliniche dei medicinali (<https://www.gazzettaufficiale.it/eli/id/2006/08/22/06A07882/sg> ; Decreto Ministero della Salute 8 febbraio 2013 "Criteri per la composizione e il funzionamento dei comitati etici" <https://www.gazzettaufficiale.it/eli/id/2013/04/24/13A03474/sg>)

1. **Please refer to any innovative initiatives that have been taken at the local, regional or national level to promote and ensure the rights of persons with disabilities in bioethical discussions.**

On 24 January 2019 the Italian government re-initiated the National Observatory on the Condition of Persons with Disabilities. Established by law n. 18 of 3 March 2009 of ratification and execution of the UN Convention on disability, the Observatory falls within the scope of the "coordination mechanism" that States Parties have the obligation to designate in order to promote and monitor the implementation of the CRPD pursuant to art. 33, par.1. In the last decade, the Observatory has provided as an independent institution a scientific-technical support and counselling to national policies on disability. Its main objectives are the promotion and implementation of the CRPD, the drafting of biannual action plans for the promotion of rights and social inclusion of persons with disabilities, data collection and reporting on disability policies. A representative of civil society, Gian Piero Griffo, member of Disability Peoples’ International (DPI) and president of the Italian Network of Disability and Development (RIDS) was appointed coordinator of the Observatory’s Scientific and Technical Committee. On the 15th of May 2019 the Observatory adopted its new rules of procedures, and on the 10th of July 2019 it issued both the operational rules for the new working groups and a new 3-year activity plan. The multi-year plan is divided into 9 thematic areas and 13 work groups. The approach envisages to address the issue of disability on the basis of the protection of human rights as sanctioned by the CRPD (non-discrimination, equality of opportunity) and to identify some particularly innovative areas (women, contrast to segregation, right to adult life, freedom , civil rights and participation, international cooperation) beyond traditional issues (accessibility, health, education, social policies, work) and continuous monitoring.