



Biomedical research involving patients with disorders of consciousness: ethical and legal dimensions

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Abstract

The directive 2001/20/UE and the research involving patients with docs. Research involving patients with disorders of consciousness (DOCs) deserves special ethical and legal attention because of its Janus-faced nature. On the one hand, it raises concerns about the risk to expose the involved subjects to disproportionate risks not respecting their individual dignity, particularly their right to be cared for; on the other hand, research is an essential tool in order to improve the clinical condition of patients with DOCs. The present paper concerns the ethical and legal dimensions of biomedical research involving patients with disorders of consciousness. In particular, it focuses on informed consent to experimental treatments, which is a challenging issue both from an ethical and legal point of view. The first part reads the Directive 2001/20/EU in the light of the experimentation of patients with DOCs, and suggests a revision in order to better assess the issue of informed consent.

The particular case of informed consent for observational studies of non-communicative patients. The second part presents an informed consent form for studies through video-recording of patients unable to communicate their own consent. This form has been elaborated by the bioethics unit of the project "Review of the nosography of vegetative states: application of methods of behavioral analysis to individuals in coma or vegetative state" developed at the Italian National Institute of Health.

Relevance of the suggested form. The paper describes the conceptual framework of the form for informed consent to studies through video-recording, which is a relevant example of what issues should be included in an informed consent for any type of studies through video-recording of patients unable to express their own consent. The article has been sent on November the 7th 2013, before the adoption of the Regulation (EU) no. 536/2014 (and consequent abrogation of the Directive 2001/20/EU) and the release of the new edition of the Italian Code of Medical Ethics.

Key words

- medicine
- ethics
- legislation
- coma
- informed consent

INTRODUCTION

Because of the invasive nature of the required procedures (e.g., intra-arterial or jugular lines required for quantification of PET data or modeling), or the use of neuromuscular paralytics, ethical concerns have been raised on the involvement of patients with disorders of consciousness (DOCs) in research trials, such as functional neuroimaging studies [1]. Other ethical and legal worries can be raised concerning the use of experimental pharmacological treatments on such patients. A provisional list of concerns that arise from the involvement of patients with DOCs in research trials includes:

- how to obtain knowledge which can be assumed as statistically significant and generalizable given the limited number of patients in such conditions;

- how to assess risks and benefits for such patients emerging from ordinary and research treatments;
- how to differentiate between risks and benefits emerging from ordinary therapeutic treatments, and risks and benefits emerging from research treatments;
- how to avoid the risk of misdiagnosis of minimally conscious (MCS) patients as vegetative state/unresponsive wakefulness syndrome (VS/UWS) patients (diagnostic error);
- how to track the evolution of the health condition of patients with DOCs (prognostic error): long-term residential facilities are often ill-equipped to track the evolution of the patient's condition;
- how to integrate the healthcare system of patients

with DOCs, particularly enhancing the collaboration between academic research centers and healthcare facilities, such as skilled nursing facilities, acute rehabilitation centers, hospitals, clinical units, long-term residential facilities;

- how to enhance the communication between the research and the healthcare system components;
- how to manage the movement of patients among the different system components.

The fundamental ethical and legal concern regarding the involvement of patients with DOCs in research trials is the impossibility of such patients to express their personal informed consent. A reasonable approach to this issue may be to find an adequate equilibrium between access to research and medical advances, and the protection of patients that are particularly vulnerable [1].

On the one hand, research on patients with DOCs is an essential task of contemporary medicine in collaboration with neuroscience. In fact, some studies have showed that there is insufficient evidence to recommend one treatment instead of another in the clinical care of patients with DOCs [2, 3].

On the other hand, patients with DOCs deserve special attention and procedural protections. For instance, the necessary precaution in the management of research on patients with DOCs must be informed with the risk that these “patients are also vulnerable to being denied potentially life-saving therapy if clinical research cannot be performed adequately” [1].

Some factors limiting the research on patients with DOCs have been described [4]:

- the centralization of scientific expertise in academic centers with the exclusion of short or long-term recovery facilities that host the largest number of patients of interest;
- the lack of or the difficulty to organize a method of surveillance in order to assess relevant variables of therapeutic and research protocols, such as incidence, prevalence, treatment efficacy, cost of care or long-term functional outcomes;
- the excessive dispersion of the patient population making it difficult to detect potential subjects for research;
- the limited financial resources;
- the difficulties of non-academic centers to participate in research.

However, the main ethical problem concerning research involving people with DOCs is the impossibility to obtain informed consent to participate in the research activity.

Another problematic condition is the direct benefit for the enrolled subjects. Actually this condition is problematic not only for research on patients with DOCs, but for clinical research involving people unable to express their informed consent in general. According to the n. 28 of the latest version of the Helsinki Declaration, such subjects can be involved in research only if three conditions are respected: there is likelihood of benefit for them or for the group represented; the research cannot be performed with subjects able to provide an informed consent; the research entails no more than minimal risk and burden [5].

Other particular problems arise from the implementation of a randomized controlled trial (RCT) involving patients with DOCs:

- phase I, aimed at assessing safety, identifying collateral effects, defining a safe dosage, understanding how the agent is absorbed and eliminated by the body (pharmacokinetics/dynamics), is not easy to implement. It can be difficult to obtain significant data from healthy volunteers or from patients with DOCs in an advanced stage of the disease: several aspects of DOCs are not comparable with healthy volunteers, and the condition is so critical that an advanced stage implies the death of the patients;
- phase II seems to not raise problems for patient with DOCs different than the problems arising from the involvement of other kinds of patients, particularly the assessment of risk;
- phases III and IV, involving hundreds to thousands or hundreds of thousands of patients, are challenging because of the relatively limited number of patients which risks to compromise the statistical relevance of the study;
- the confidentiality of the enrolled patients seems problematic because the limited number of patients hosted in each center risks making them easily identifiable;
- the management of control groups seems difficult, particularly for the use of placebo.

THE DIRECTIVE 2001/20/UE AND THE RESEARCH INVOLVING PATIENTS WITH DOCS

Article 3 of the Directive 2001/20/EU focuses on the “Protection of clinical trial subjects”.

In particular, regarding the specific case of patients unable to express their informed consent, article 3(1) delegates the member States to “adopt detailed rules to protect from abuse individuals who are incapable of giving their informed consent”.

Article 3(2) states the conditions a clinical trial must respect in order to be undertaken:

1. the foreseeable risks and inconveniences must be weighed against the anticipated benefit for the enrolled subject and other actual or potential subjects. A balance between individual risks and individual/public benefits is mandatory (art. 3(2)(a));
2. the trial subject or his legal representative must be informed and must have understood objectives, risks and inconveniences of the trial, the conditions for its conduction and his right to withdraw from the trial at any moment (art. 3(2)(b));
3. the right of the patient to physical and mental integrity, to privacy and to a confidential treatment of his data (art. 3(2)(c));
4. the trial subject or his legal representative must have given his written consent (or in exceptional cases his oral consent) after being informed of the nature, the significance, the implications and the risks of the trial (art. 3(2)(d));
5. the right of the subject to withdraw from the trial at any moment without any detriment;



6. the insurance or indemnity to cover investigator's and sponsor's liability has been made.

These conditions can be read with particular reference to the treatment of patients with DOCs.

Regarding condition 1, according to Liddell and colleagues [6], it is an expression of an aggregate risk analysis: it starts from an identification of research with therapy without distinguishing therapeutic and research components of clinical experimentation. For this reason, according to the authors, the article 3(2)(a) offers little protection to incapacitated adults because it allows the risk of research to be offset by anticipated benefits of clinical care, so that it allows the benefit to the public to outweigh any degree of risk to the individual. Clinical equipoise is not mentioned.

Furthermore, in the case of patients with DOCs, particularly with permanent vegetative state (PVS), it is not clear how to define individual risks and benefits or how to balance them.

Conditions 2, 4 and 5 seem to be appropriate even for patients with DOCs, or better for their legal representatives.

Condition 3 seems problematic for patients with DOCs. Besides the critical neurological condition affecting the patient, mental integrity could be compromised by the use of particular drugs (e.g., painkillers), which could decrease the level of awareness. Moreover, the relatively limited number of this type of patients and of the centers specialized in the research on them could affect the right to privacy of the trial patients.

Condition 6 applies to research on patients with DOCs as well.

Article 5 of the Directive 2001/20/EU specifically focuses on "Clinical trials on incapacitated adults no able to give informed legal consent".

As a general prerequisite, to be included in a clinical trial the patient must not have refused informed consent before the onset of his incapacity.

The following particular conditions must be respected:

1. the informed consent of the legal representative must have been obtained; this consent can be withdrawn at any time without any detriment to the patient (art. 5(a));
2. the person not able to express her consent must have been informed about the trial, its risks and benefits according to her capacity to understand (art. 5(b));
3. the explicit wish of a subject able to form an opinion and able to refuse to participate to the trial or able to withdraw from the trial at any time must be taken into account by the investigator (art. 5(c));
4. incentives or financial inducements, except compensation, are forbidden (art. 5(d));
5. the research must be essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods, such as animal research, and the research must relate directly to a life-threatening or debilitating clinical condition affecting the involved subject (art. 5(e));
6. the trial must be designed in order to minimize pain, discomfort, fear and any other risk (art. 5(f));
7. the Ethics Committee must have endorsed the protocol (art. 5(g));

8. the interest of the individual must prevail over those of science and society (art. 5(h));

9. it is expected that administering the tested medicinal product will produce a benefit to the patients outweighing the risks or no risks at all (art. 5(i)).

These conditions are revised as follows by the article 30 of the "Proposal for a regulation of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/20/EC":

"(a) the informed consent of the legal representative has been obtained, whereby consent shall represent the subject's presumed will;

(b) the incapacitated subject has received adequate information in relation to his or her capacity for understanding regarding the trial, the risks and the benefits;

(c) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator;

(d) no incentives or financial inducements are given except compensation for participation in the clinical trial;

(e) such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods;

(f) such research relates directly to a life-threatening or debilitating medical condition from which the subject suffers;

(g) the clinical trial has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed;

(h) there are grounds for expecting that participation in the clinical trial will produce a benefit to the incapacitated subject outweighing the risks or will produce no risk at all" [7].

Conditions 3 and 4, which correspond to the conditions c and d respectively, seem to be appropriate for patient with DOCs as well.

Condition 7, which, as appropriately outlined [8, 9], has no correspondence in the Proposal, seems to be appropriate for patient with DOCs as well.

Condition 1 corresponds to condition a, which adds that "consent shall represent the subject's presumed will". The cited Liddell *et al.* outline two problems arising from condition 1: no exceptions are recognized; no definition of legal representative are given. As a consequence, different definitions of legal representative are elaborated in the different Member States. We agree about the second worry, while it is not clear what exceptions could or should be allowed.

Condition 2, which corresponds to condition (b), seems problematic: even if some recent experiments show the possibility to implement a sort of communication with patients with DOCs [10], it seems not realistic to give them information about the trial: this is too complex to expect to be understood by the patient.

Condition 5, which corresponds to conditions (e)+(f), seems problematic, because given the com-

plexity and the severity of the condition no data for validation could be available. Rather, this case seems to be perfectly in line with the requirements of the art. 28 of the Helsinki Declaration: “For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden”.

Condition 6 corresponds to condition (g), which adds “in relation to the disease and developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed”. These conditions seem problematic, because in case of patients with DOCs it is not scientifically clear if there are pain and suffering and how to assess them [11, 12].

Condition 8, which has no correspondence in the Proposal, seems to be problematic if read in the light of a “component risk analysis” of research which distinguishes therapeutic and research components: while research is often (though not necessarily) combined with clinical care and other beneficial activities, it is the clinical elements that benefit the patient-participant [13, 14].

Condition 9, which corresponds to the condition (h), seems problematic. Liddell *et al.* outline that it is not clear how to apply the article 5(i) in case of clinical equipoise. In fact the literal reading means that the researchers must expect that the test-drug is better than standard available treatment or it is risk free, but both these conditions are problematic if researchers observe (as they should) clinical equipoise.

The conclusion (emerging from the articles 3(2)(a) and 5(i)) is that the Directive has overlooked the clinical equipoise, that is the genuine uncertainty by the medical community about the comparative therapeutic merits of each arm of a clinical trial. Yet for a researcher to not respect clinical equipoise means not to be in line with the Declaration of Helsinki and with the Additional Protocol to the Oviedo Convention [15], which is binding in many Member States.

Given the abovementioned problems, for instance Liddell *et al.* interpret the article 5(i) as follows:

“There should be ground for expecting that administering the medicinal product to be tested will produce a *therapeutic* benefit to the patient *equivalent to standard treatment* and outweighing the risks of *therapy and* produce no *serious research* risks at all” [6].

In other words, according to the authors an appropriate threshold is that research components entail no more than minimal risks. Such interpretation is in line with the Oviedo Convention [16], its Additional Protocol and the ICH-GCP guidance [17]. The National Bioethics Advisory Commission allowed more than minimal risk in some circumstances [18]. The Helsinki Declaration does not stipulate limits to the degree of risk, but that research must be justified by its potential value to future care.

POINTS DESERVING MORE ATTENTION IN RESEARCH INVOLVING PATIENTS WITH DOCs

Research involving patients with DOCs raises several ethical and legal concerns. Such concerns require the revision of the Directive 2001/20/UE, particularly of the article 3 and 5 concerning “Protection of clinical trial subjects” and “Clinical trials on incapacitated adults no able to give informed legal consent” respectively.

Such a revision should take into account the following priority points:

- definition and management of (proxy) informed consent;
- definition of legal representative;
- assessment of therapeutic and research components of experimentation involving patients with DOCs;
- enhancement of healthcare system for patients with DOCs;
- enhancement of research system for patients with DOCs;
- enhancement of the collaboration and integration between research and healthcare systems for patients with DOCs;
- enhancement of diagnostic and prognostic accuracy of healthcare and research involving patients with DOCs;
- definition and assessment of the statistical significance of a study involving patients with DOCs;
- differentiation and assessment of risks and benefits for patients with DOCs;
- differentiation and assessment of individual and societal interests;
- definition of the involvement procedures for patients with DOCs in experimental study;
- definition of the involvement procedure for institutions in research involving patients with DOCs;
- organization of a RCT involving patients with DOCs, particularly of phases I, III and IV, and the choice of control groups;
- assessment and respect of confidentiality of patients with DOCs involved in research procedures;
- definition and management of mental and physical integrity in case of patients with DOCs involved in research.

THE PARTICULAR CASE OF INFORMED CONSENT FOR OBSERVATIONAL STUDIES OF NON-COMMUNICATIVE PATIENTS

In contemporary bioethics informed consent plays a central “inter-cultural” role as expression of the principle of autonomy, which stands as the fundamental right of patients [19]. Obtaining the informed consent, and consequently respecting autonomy, are particularly problematic issues in case of patients unable to communicate, such as patients with DOCs. The issues are particularly striking in the case of experimentation with such patients [20].

The problem is relevant both for ordinary and for experimental treatments, such as pharmacological, instrumental or observational studies, which imply a certain degree of uncertainty about the outcome of a treatment.

We do not assume observational studies in their technical epidemiological and statistical meanings, but more basically as the study of patients in VS/UWS or of other non-communicative patients through video-recording.

Within the project "Review of the nosography of vegetative states: application of methods of behavioral analysis to individuals in coma or vegetative state" developed by the Italian Istituto Superiore di Sanità (Italian National Institute of Health), the observational phase consists in monitoring patients with VS/UWS at the bedside and in video-recording their behavior with the aim to contribute to elaborate a more detailed definition of DOCs.

The project complies with the Italian Code for the Protection of Personal Data [21], of professional secrecy and of the Code of Medical Ethics (Chapter Four - Information and Consent, Articles 30 to 35).

Regarding video-recordings, it is specified that they are made in accordance with the recommendations and regulations on video acquisitions in health facilities [21, 22].

Since informed consent forms for such monitoring and recording seem not available in the literature, the bioethicists involved in the project elaborated a specific informed consent form.

RELEVANCE OF THE SUGGESTED FORM

For all we know there is not a specific informed consent form for video-recording patients unable to communicate. Thus the proposed form could be internationally relevant for studies based on video-recording of patients in VS/UWS or with other patients unable to express their own consent. In fact, several practical issues arise from video-recording patients unable to communicate, particularly from video-recording patients in VS/UWS [23]. These issues, which must be assessed in the informed consent form, raise relevant ethical and legal implications.

Some national and international documents have assessed the general issue of video-recording patients. For instance, in 2002 the General Medical Council updated the guidance Making and using visual and audio recordings of patients [24]. In 2001 and 2003, the American Medical Association issued two opinions about filming patients in healthcare settings [25] and for educational purposes [26] respectively. In Italy, the Italian Data Protection Authority issued a provision on "Video surveillance" in 2010 [27].

From the abovementioned sources it is possible to infer the following practical issues that an informed consent form for video-recording of non-communicative patients, particularly of patients with VS/UWS, must clearly assess:

- Modality of video-recording: who does install the camera? Is an operator in the room for recording? If yes, how long will he be present?
- Time of video-recording: is the recording 24 hours? How long is the recording?
- Aim of video-recording: what type of research is the recording part of? What contribution could video-recording give to the quality of the record-

ed patients' treatment? Could video-recording have direct clinical impact?

- Use of video-recording: for what is video-recording used? For research only? Could it be used for dissemination, presentation, scientific communication, statistical analysis?
- Access to video-recording: who has access to the recorded videos? Only researchers who are part of the team or even other interested researchers? Are the family members allowed to watch the videos? How is the access to the videos managed in case the access to the ward is limited?
- Dissemination of video-recording: are the videos used in limited or public presentations? Can the collected data be used in scientific papers? If yes, are they previously anonymized?

The ethical and legal questions arising from the abovementioned practical issues are the following:

- confidentiality of patients' personal data: the sensible information collected through recording must be protected and the access to it limited in order to respect the privacy of the patients;
- free participation to the study: no coercion should be applied to the patient's family or legal representative to join the research;
- right to withdraw the consent: the legal representative should retain the right to interrupt the patient's participation to the study;
- quality of care: to participate or to not participate to the study cannot affect the quality of healthcare. No special rights will derive from the participation to the study, as well as no disadvantages will derive from no participation.

In case of experimental studies with non-communicative patients, especially with patients with VS/UWS, it is essential to assess the abovementioned issues. The proposed informed consent form is a relevant example of how to clearly present these issues to patients' families and/or to patients' legal representatives.

WHAT TO INCLUDE IN AN INFORMED CONSENT FORM FOR VIDEO-RECORDING PATIENTS UNABLE TO COMMUNICATE

We retain that in an informed consent form for video-recording patients with VS/UWS the following points must be included as essential:

- a description of the project that requires the video-recording, particularly of the project's aims and its potential clinical implications;
- a description of the specific interventions the informed consent regards, specifically modality and frequency of recording, number of copies that will be produced and their retention time, the use of recording for research and for scientific reporting, who have access to videos (e.g., researchers and not family if it is not allowed to visit the patient in the hospital department);
- laws regulating confidentiality;
- laws regulating video-recording;
- right of the person who signed the consent to require the videos at any time;



- right of the person who signed the consent to withdraw the consent at any time without any negative consequences on the clinical care of the patient;
- any other clinical parameter eventually measured during the registration;
- use of the data within the project and in the dissemination of its results;
- no use of the data in public projection.

In particular, studies through video-recording of patients with DOCs raise several critical and debated issues (e.g., autonomy, legal representation, surrogate informed consent, confidentiality, etc.). Besides the possible interpretation and assessment of these controversial legal and ethical problems, the information described in the paper should be included in the informed consent form for any study regarding this kind of patients in order to respect their rights.

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Conflict of interest statement

There are no potential conflicts of interest or any financial or personal relationships with other people or organizations that could inappropriately bias conduct and findings of this study.

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Appendix.

Informed consent to video recording of patients in vegetative state

In recent years, different definitions of coma and persistent vegetative state have been elaborated, with particular regard to patients' residual abilities. In general there is a broad consensus on the definition of severe disorders of consciousness, but the latest developments of scientific research and the new available technologies have allowed a more specific description of disorders of consciousness, allowing, for example, to distinguish between minimally conscious state, the so-called "permanent vegetative state" (that is reversible), the so-called "persistent vegetative state" (that is irreversible) and coma. For this reason, there is a need to elaborate a more detailed definition of such possible disorders. This is the aim of the research project of the Italian Institute of Health titled "Review of the nosography of vegetative states: application of methods of behavioral analysis to individuals in coma or vegetative state". This project starts from the conviction that a more detailed description of the disorders of consciousness may be useful not only for a more accurate scientific knowledge, but also for a more appropriate medical treatment. Anyway, any new treatment protocols do not fall directly in the project and will be eventually implemented only at a later stage, following the instructions of clinical practices, of professional ethics and, where relevant, of current legislation. A first step for achieving these aims is to monitor by video recording some patients in the so-called "vegetative" state in order to document all their spontaneous movements. Video recording will be done with a fixed camera, which does not require a full-time presence of an operator. After stabilization of post-trauma, patients will be recorded for a full day per week. After the first month, and for the next two months, patients will be recorded 24 hours a day on three alternating days per week. In particular, both eye movements and motor responses, i.e. movements of the head or limbs, can be recorded. During the same period of video monitoring, audio recordings of auditory stimulation may also be used, in order to check the patients' automatic reactions to short sentences of family members. In addition, the movements of the limbs will be measured by actigraphy, that is the use of automatic measuring of motion, which record the magnitude and duration of the movements. Several clinical parameters considered relevant to the study will be evaluated, particularly: heart rate, respiratory rate, electrocardiogram and some parameters obtainable from non-invasive neuroimaging techniques. The monitoring results are confidential and, therefore, like any other medical procedure in the strict sense, subject to the obligations and protections of existing law (Code for the Protection of Personal Data – so called Privacy Code, Legislative Decree no. 30/06 / 2003, No. 196), of professional secrecy and of the Code of Medical Ethics (Chapter Four - Information and Consent, Articles 30 to 35). In particular, the video recordings will be made in accordance with the recommendations and regulations on video acquisitions in health facilities (Article 4.2 of the Order dated April 29, 2004 by the Ombudsman for Privacy Rights; Articles. 22, paragraph 8, 83 and 167 of the so called Privacy Code, Legislative Decree no. 30/06/2003, n. 196). Moreover the recommendations from authoritative institutions (such as, for example, the American Medical Association and the British General Medical Council) regarding video recording in a clinical setting will be respected. Thus the recordings will be made in compliance with applicable law, we will produce ... copies that will be kept for a period of months ... during which the person who signed the consent may revoke its decision to participate in the study and collect recordings.

(continues)

(continued)

I, the undersigned, born in (Prov.)
 on .../.../... (dd/mm/yyyy) and resident in (Prov.)
 Postal Code
 Address.....n°..... tel.....
 Holder of legal representation o
 Relative not holding legal representation o
(tick as appropriate)
 of the patient..... admitted on at

understood the information given to me by the staff, particularly about the aim of recording, its usefulness, the purpose of the study for which they take place and the possible implications of the results, **DECLARE** to be aware of:

- The way and the time of the video recordings
- The aims of the research and the possible use of recordings for scientific reporting
- The possibility to stop the recording in any time I believed appropriate, particularly if they had a somewhat negative influence on the professional conduct of health personnel
- The fact that no registration can be made other than that described in this form
- The fact that there will be no modification to the procedures described in this form
- The fact that the recordings will be made in order to not compromise the privacy and dignity of the patient
- The fact that the records will not be used for purposes other than those described in this form without further explicit consent
- The fact that it will be realized only the number of copies specified in this form, and they will be kept for the period specified in this form
- The fact that I may request the delivery of records at any time
- The fact that withdrawing from the agreement to make recordings or requiring the delivery of the records do not affect the quality of care in any way
- The fact that the records will be watched even by personnel not part of the unit of care, but part of the research project entitled "Review of the nosography of vegetative states: application of methods of behavioral analysis to individuals in coma or vegetative state"
- The fact that not even family members will be allowed to watch recordings when the department in which the patient is admitted does not allow their visit
- The fact that at the same time of video recording some clinical parameters deemed relevant will be measured
- The fact that the data emerging from records and surveys, after being suitably anonymised, will be used for the project "Review of the nosography of vegetative states: application of methods of behavioral analysis to individuals in coma or vegetative state" and can therefore be included in publications, presentations, communications, scientific conferences, courses and any other method of dissemination will be considered appropriate
- The fact that the records will not be even partially projected in public spaces

I also declare to have had time and opportunity to ask questions and to have received satisfactory and understandable answers.

Therefore: **I consent** **I do not consent**

To recording and monitoring clinical
 parameters of the following patient

.....

The holder of handling personal data is the hospital.....,

located in

represented by the President,

Tel., e-mail

Place and date Signed:

The doctor

Signed