RANDOMIZED CLINICAL TRIAL ON THE EFFICACY AND SAFETY OF INCREMENTAL HAEMODIALYSIS

(*acronym:* **REAL LIFE**)

INFORMED CONSENT

Hemodialysis modality:	
Incremental hemodialysis (once-weekly or twice-weekly)	
Standard hemodialysis (thrice-weekly)	

Hospital: _____

Service/Unit: _____

Doctor: _____

Patient: _____

ID: _____

Representative: _____

ID: _____

The document is intended to verify that you, or whoever represents you, have received verbal (and in writing) adequate and understandable information, including the purpose and nature of the above procedure, its risks and consequences. As with any action in the field of health, also the accomplishment of hemodialysis (incremental or standard) requires the free and voluntary consent of the patient, once all the information has been received and evaluation according to national and international regulations have been carried out.

I DECLARE: Doctor ..... has explained me that starting hemodialysis treatment is necessary in my situation. I have understood the information given and I am satisfied with the information I received. I have been able to formulate the questions that I thought to be necessary; the answers have clarified all the doubts I raised. I hereby consent, freely and voluntarily, to be administered the number of hemodialysis sessions prescribed per week. I have also been informed of the possibility that the results of the present study be used anonymously and disseminated to the scientific community through the usual means of scientific communication as part of a research project (REAL LIFE) and that in no case may it pose an additional risk to my health.

In *(place)*..... at *(date)*..... 202..

Signed
Miss/Mrs/Mr.....ID.....

ADDITIONAL INFORMATION ATTACHED TO THIS CONSENT

Your doctor has diagnosed a disease affecting your kidneys: it is called chronic kidney disease. Irreversibly, your kidneys do not clean your blood in an effective way; as a result, substances may remain in your body that are dangerous for your life. Therefore, your doctor thinks that you must start a treatment that is known as hemodialysis, which tries to supply, but only partially, some of the functions of your kidneys.

Dialysis consists of cleaning the blood, allowing the passage of water and toxic substances contained in the blood, through a specific filter, which we call dialyzer. This treatment allows to prolong your life. Hemodialysis is usually well tolerated although occasional side effects may occur. Some are common:

1) Nausea, vomiting, headache, arterial hypotension, cramps.
2) Hematomas or small blood loss from the puncture points or from a breakdown of the dialyzer.
3) Other uncommon but more serious events can occur such as cardiac arrhythmias, angina pectoris, strokes, severe allergic reactions, or rupture of red blood cells (hemolysis). The latter could endanger your life in very rare circumstances.
4) In some cases, infectious complications may occur. They are usually due to bacteria or viruses.
5) Other complications related to the vascular access can occur such as hemorrhages, thrombosis, infections, that can require interventional procedures.

As far as the number of hemodialysis sessions per week is concerned, several clinical guidelines recommend the dose and the frequency of sessions. The K/DOQI Guidelines recommend a minimum dose of Kt/V of 1.2 for a thrice-weekly schedule in the anuric patient, but open the door to adjusting the dose and/or the frequency of the sessions according to the residual kidney function of the patient. We rely on promising studies, which emphasize that starting hemodialysis once or twice a week preserves the residual kidney function, with no associated complications. These studies have also shown that the preservation of residual kidney function is associated with a decrease in morbidity and mortality.
The main aim of this study (REAL LIFE) is that of proving in a scientifically correct way that the incremental approach to hemodialysis is safe and effective. To get this scientific certainty, the patients must accept the priority rule that the enrolment into the study implies that the choice of the hemodialysis treatment for each of them (either standard thrice weekly or incremental, i.e., once or twice-weekly hemodialysis schedule) will be done through a validated statistical method called “randomization” (in common terms, by chance). During the follow-up, and especially in the group of incremental hemodialysis, special attention will be paid to volume overload, hyperkalemia, hyperphosphatemia and metabolic acidosis, as it is advised in the best clinical practice guidelines. The trial will be conducted according to the study protocol, international guidelines and the applicable national laws and requirements of the countries where the study is being carried out.
You have also been informed of your right to request additional information in case you need it, and that no additional procedures, other than those of which you have been informed and for which you have given your consent, will be prescribed to you, unless it is strictly necessary to save your life or to avoid some irreparable damage to your health.
Finally, in compliance with the laws on the protection of personal data (*check national regulations*), we inform you that the clinical informations related to your person will be collected into a database built-up for this study. We also inform you that the collection and the management of your data are intended to epidemiological, scientific and educational aims, respecting at all times your priorities of anonymity. If you wish, you can exercise the rights of access, rectification, cancellation and opposition, provided by the law.

CONSENT REVOCATION

I revoke the consent given on .....
I do not want to continue with the hemodialysis treatment that I consented to on this date.

In *(place)*..... at *(date)*..... 202..

Signed Miss/Mrs/Mr…….....ID.....