

Recommendations

# French Clinical Practice Guidelines for Living Kidney Donation

SYNTHESIS

# PUBLICATION DESCRIPTION

<b>Title</b>	<b>Clinical Practice Guidelines for Living Kidney Donation.</b>
<b>Methodology</b>	Clinical Practice Guidelines. A working group and a review group were involved
<b>Objectives</b>	Develop the practice of living kidney donation. Improve the quality and safety of care. Assist healthcare professionals and patients in seeking the most appropriate care. Harmonise practices at the national level.
<b>Target Audience</b>	<b>Individuals concerned by the topic:</b> <ul style="list-style-type: none"> <li>Any patient referred to a kidney transplant program, particularly if a relative is a candidate for living kidney donation.</li> <li>Any person with a relative eligible for kidney transplantation, especially if they wish to become a candidate for living kidney donation.</li> <li>Any patient partner in nephrology.</li> </ul> <b>Professionals concerned by the topic:</b> <ul style="list-style-type: none"> <li>Nephrologists, urologic and vascular surgeons, anaesthesiologists-intensivists, general practitioners, nephrology nurses, dialysis or transplant nurses, coordination or care pathway nurses, advanced practice nurses, psychologists/psychiatrists, social workers, medical validators from the French Biomedicine Agency, hospital administrative and financial services.</li> </ul>
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## Grading of Recommendations (Regulatory and Ethical Aspects Are Not Graded)

A	B	C	EC
Established Scientific Evidence	Scientific Presumption	Low Level of Evidence	Expert Consensus

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# LEGAL, REGULATORY AND SOCIETAL ASPECTS

## Legal Framework for the Procurement of Organs from Living Donors

The legislative framework has evolved since the first bioethics laws of 1994. The circle of authorised living donors includes:

- The father, mother, siblings, sons or daughters, grandparents, uncles or aunts, and first cousins;
- The spouse of the recipient's father or mother;
- A person providing proof of cohabitation with the recipient for at least 2 years;
- Any person providing proof of a close and stable emotional bond with the recipient for at least 2 years.

Article L.1231-1 of the Public Health Code permits a paired kidney exchange program involving multiple incompatible donor–recipient pairs. The relationships between the donor and recipient within a pair engaged in a paired exchange are the same as those in a compatible living donation.

In cases with multiple possible pairings, a scoring system determines the best option for the exchange. Anonymity between the donor and recipient must be maintained.

The maximum number of donor–recipient pairs involved in a paired exchange is limited to six. All procurement procedures must be completed within a maximum of 24 hours. Transplantations are carried out consecutively after each procurement.

The 2021 law allows for the use of a deceased donor to increase the chances of matching between donors and recipients engaged in a paired exchange and as a substitute for the procurement from one of the living donors.

Altruistic (non-directed) donation is not permitted in France.

Living donation is not allowed for minors or adults under legal protection with representation concerning their person.

## The Expert Committee for Living Donors

An expert committee, known as the “Living Donor Committee” ensures that the donor has received and understood information about the procedure, its potential risks, and possible consequences. The committee must ensure that the consent is voluntary and informed and that the donation complies with the conditions stipulated by law.

The donor petitions the judicial court in the jurisdiction where the health facility in which the procurement is planned is located, the health facility in which the recipient is hospitalised, or, if the donor resides in France, their place of residence. The donor is assisted in their procedures by the procurement and transplantation team according to their needs.

The expert committee grants or denies authorisation for the procurement following the donor's expression of consent before the president of the judicial court or the magistrate designated by them. The decision of the Living Donor Committee is not explained.

In cases of a parent–child relationship, the donor must be received by the Living Donor Committee, but the committee cannot oppose the donation.

## Financial Neutrality

The principle of donation free of charge implies the principle of financial neutrality for the donor: all expenses incurred during the donation process must be reimbursed to the donor, and the donor should not suffer any loss of income due to their donation.

In practice, the donor benefits from two types of financial coverage:

- **Medical expenses related to the donation:** these are covered by health insurance with exemption from the co-payment and daily hospital fees in case of hospitalisation. Medical expenses include those for examinations and care before or after the procurement.
- **Non-medical expenses:** transportation costs, accommodation expenses, loss of income, etc. These costs must be covered by the health facility performing the procurement upon presentation of receipts. These expenses may also apply to a companion if the donor's condition requires it.

**The procuring facility compensates the donor's loss of income** according to the following rules:

- When a sick leave is prescribed, this compensation for income loss is additional to any benefits received by the donor, such as daily allowances paid by health insurance and supplements from mutual insurance or private insurance companies.
- When sick leave is not justified, compensation must be provided for absences (for pre-donation assessments, completing formalities with the judicial court, meetings with the Living Donor Committee, or any examinations and care apart from the procurement).
- The amount is based on actual expenses:
  - No waiting period;
  - When daily allowances are paid, the amount cannot exceed four times the daily allowances;
  - Upon presentation of receipts.

**Supporting documents** are as follows:

- For employees: the last three pay slips or an employer's certificate of net salary loss per day of absence.
- For self-employed workers: the professional income declaration for the last 3 years (accounting document).
- For all: allowances paid by health insurance and other coverage by complementary health insurance or private insurance, if applicable.

Financial coverage for the donor is provided even if the donor's process does not ultimately result in nephrectomy for donation.

After the donation, financial coverage for the medical follow-up of all aspects related to the donation is ensured for life (systematic assessments, complications, etc.). The living donation must be noted in the person's health records (shared medical record, "My Health Space").

The establishment of 100% coverage for long-term conditions, specific and for a limited period, is under consideration, particularly to avoid additional fees by healthcare providers in the community (procedures, consultations, etc.).

Support from a social worker within the procurement and transplantation teams must be provided to the donor. Finally, information and cooperation from the financial services of the establishment are also essential.

The French Biomedicine Agency ensures compliance with this financial neutrality.

## Non-Resident Donors in France

The principle of financial neutrality applies to non-resident donors who are not covered by social security in France during their time on French soil, even though the healthcare provider responsible for the procurement cannot bill the health insurance system.

Administrative and financial rules differ according to the donor's administrative situation.

#### **Donors from European Union Member States:**

- General law applies to non-resident donors in France, subject to the recommendations of the Administrative Coordination Committee of Social Security Systems, which is responsible for nationals of the 28 EU countries, Iceland, Liechtenstein, Norway, and Switzerland.
- These donors can stay in France for 3 months without conditions and beyond 3 months if they have health insurance in their home country and sufficient resources so as not to become a burden on the French social security system.
- Non-insured donors in France benefit from the coordination of social security systems. Therefore, in most cases, medical expenses are covered by the social security system of the donor's home country.
- Non-medical expenses must be reimbursed to the donor by the procuring facility upon presentation of receipts, just like for French donors.
- Income compensation falls under the social security system of the donor's country of residence.
- The Administrative Coordination Committee of Social Security Systems recommends that the competent authorities of the organ recipient "find a humane solution and reimburse the in-kind services required for cross-border living donor organ donations if the applicable legislation for the donor does not entitle them to in-kind benefits from health insurance".

#### **Donors from Non-EU Member States:**

This situation is not described in the regulations. However, the Administrative Coordination Committee of Social Security Systems also considers that "The living donor [...] should be informed in advance about the health care coverage provided, the reimbursement methods for costs related to cross-border organ donations, and compensation for any potential loss of income."

For a non-resident and non-insured donor, several issues need to be resolved at the beginning of the donation process:

- It is important to verify the legality of the stay in France beyond the 3-month validity of the short-stay visa because 3 months is often insufficient. Therefore, the visa extension procedures must be completed. Support from a social worker may be necessary.
- The coverage of expenses, both medical and non-medical, depends in practice on the recipient's status with health insurance:
  - **When the recipient is covered by health insurance:** the foreign donor benefits from full coverage of medical expenses (assessment, hospitalisation for procurement) by the recipient's health insurance. The health facility reimburses non-medical expenses (transport), but loss of income is often difficult to justify.
  - **When the recipient is not covered by health insurance** (most often coming to France for a transplant): all related expenses must be billed to the entity potentially covering their care or, failing that, to the recipient themselves. The same applies to the donor. Because the principle of financial neutrality also applies to non-resident donors in that the donation occurs on French soil, medical expenses related to their care are practically billed to the recipient (usually in the form of a prior estimate). The same applies to non-medical expenses and loss of income, which logically should be charged to the recipient.

## **Insurability**

The principle of financial neutrality for living donors was extended to the field of insurance by the 2011 bioethics law. In other words, an insurance company cannot impose additional costs on a policy or decide to exclude coverage because the policyholder has undergone a nephrectomy as part of a living donation.

The Defender of Rights (September 2018 decision) recommends that insurers, and particularly their medical departments, ensure that living organ donors are not asked for medical documents related to their health status following their donation.

A decision by the monitoring and proposals commission of the AERAS convention (insurance and borrowing with aggravated health risks) is pending on whether or not to recognise the right for organ donors not to declare this medical history to their insurer.

## **Qualification of Living Donors Regarding Transmission Risk to the Recipient and Exceptional Transplants for HIV, hepatitis B virus, hepatitis C virus Infection**

The health safety assessment before a living kidney donation includes the following tests:

- Urinary sediment culture
- Combined HIV test (P24 antigen and HIV-1 and HIV-2 serology) and HIV viral genome detection (VGD)
- HTLV-1 and HTLV-2 serology (contraindication to donation if positive)
- HCV serology and HCV VGD
- HBsAg, anti-HBc antibodies, anti-HBs antibodies, and HBV VGD
- Syphilis serology, TPHA (no contraindication to donation if the recipient is treated and serological follow-up is ensured)
- Toxoplasmosis serology
- CMV serology
- EBV serology
- Strongyloidiasis serology
- HEV VGD within the week preceding the donation (postpone the donation if positive)
- WNV VGD and West Nile Virus serology (at least IgM) in case of recent stay in an affected area (as close to donation as possible, but results must be available before donation; defer the donation for at least 120 days if positive on at least one of the two screening methods)
- In case of emerging viruses, such as SARS-CoV-2, during epidemic periods, the recommendations of the High Council for Public Health and, if applicable, other bodies such as scientific societies and the French Biomedicine Agency, must be followed.

### **"Exceptional" Kidney Transplants with HIV, HBV, and HCV Infection**

- Such a transplant can only be performed if the patient's life is at risk and when therapeutic alternatives become inappropriate, so that waiting for a graft other than the one proposed in the exceptional context would be detrimental to the recipient's survival.
- The potential donor must be informed of the specific risks associated with this donation and must consent to the disclosure of medical information regarding their immune status concerning the virus in question to the recipient.
- The recipient must be informed both about the expected benefits and risks as well as the therapies that might be proposed and the constraints related to specific follow-up. This information must be documented in the medical record, and the recipient's consent is a prerequisite.

### **HIV-1 or HIV-2 Infection**

- A kidney donation from donors with HIV markers (HIV+) on stable antiretroviral treatment and with an undetectable viral load for HIV for at least 12 months can be considered for recipients living with HIV themselves (HIV+).

- Each case of living HIV+ donors will be evaluated individually by a specific panel of experts appointed by the French Biomedicine Agency.
- The particular case of donors co-infected with HIV and HCV is possible if the HCV PCR results have been negative for > 6 months or if the date of the HCV eradication treatment is known and is old.
- Detection by HHV-8 serology is mandatory for both the living donor and the recipient.

#### **HBV Infection**

- If HBsAg and/or HBV VGD are positive: both tests must be conducted, and the presence of either marker is a contraindication to living kidney donation.
  - In the case of a fortuitous discovery of low viral load without underlying liver disease or co-infection with hepatitis delta virus or HCV, a transient treatment of the donor may be considered solely for the purpose of kidney donation and achieving a negative viral load, under the supervision and monitoring of a hepatologist or an infectious disease specialist.
- In the case of isolated anti-HBc positivity without viral replication (anti-HBs negative, HBsAg negative, HBV VGD negative): there is an exemption to the prohibition on transplantation, regardless of the recipient's serological profile, including those considered naive (HBV serology negative).
  - The recipient requires specific monitoring: screening for HBV VGD and HBsAg at least 1 year after transplantation.
  - A donor–recipient serobank must be established.
- If anti-HBc and anti-HBs positive and HBsAg negative (profile of past and resolved infection): this case is now outside the exceptional framework, and kidney donation can be performed regardless of the recipient's serological profile.

#### **HCV Infection**

- The donor's evaluation focuses on excluding any liver disease.
  - It includes a liver ultrasound, a FibroTest, a comprehensive biological assessment including liver function tests, haemostasis tests, and alpha-fetoprotein levels.
  - The Metavir score for assessing liver fibrosis, whether histologically or by any other validated non-invasive method, must be strictly below F2.
- The favourable opinion of the specific panel of experts must be obtained before proceeding with the transplant.
- The regulatory framework specifies the virological matching procedures between the donor and recipient.
  - Confirmation of cure (HCV VGD negative > 3 months after cessation of antiviral treatment or demonstrating documented spontaneous cure): the recipient can undergo transplantation regardless of their serological and viremic status.
  - In the absence of confirmation of cure (under treatment or < 3 months after the end of treatment) and if the HCV VGD is negative before donation: only HCV-positive recipients can be transplanted.



### Specific Contexts (Foreign Donors, Travel, Epidemic Outbreaks in France, etc.)

Various transmissible agents will be investigated:

- Agents related to travel and movement: malaria, Chagas disease, chikungunya, dengue, rabies, Zika virus, West Nile virus, etc.
- Agents related to specific contexts (geography, environment, or habits): tuberculosis, Q fever, influenza, schistosomiasis, etc.

Testing for these infections is performed by the medical biology laboratories of hospitals if they have EC-marked validated tests or by the national reference center for the specific pathogen.

For specialised advice on test results or for confirmation (such as arboviruses), the national reference center should be consulted for the relevant pathogen.

To consult recommendations issued on a pathogen:

- French High Council for Public Health website ([www.hcsp.fr](http://www.hcsp.fr));
- French Biomedicine Agency professional portal ([www.sipg.sante.fr](http://www.sipg.sante.fr)), under "health alerts";
- ECDC or US-CDC websites, or the WHO, for additional or alternative guidance in the absence of advice from the French High Council for Public Health.

### The Biovigilance System

Serious incidents and unexpected adverse effects, as defined in Article R2142-40 of the Public Health Code, must be reported to the French Biomedicine Agency by the local biovigilance correspondent or their deputy, without delay, via the dedicated tele-reporting application hosted on the French Biomedicine Agency portal.

**If an event occurs** and the answer is "yes" to both of the following questions, then it is considered an adverse effect:

- Does it involve the occurrence of a harmful reaction?
- Is it possibly related to the donation procedure?

**If for an adverse effect** the answer is "yes" to at least one of the following four questions, then it is classified as a serious adverse effect or an unexpected adverse effect:

- Did it result in the death or pose a risk to the life of the donor or recipient?
- Did it cause disability or incapacity in the donor or recipient?
- Did it lead to or extend a hospitalisation or any other morbid condition?
- Is it unexpected given the health status of the involved donor or recipient?

These events must be reported without delay.

## ETHICAL ASPECTS

The general principles of bioethics law regarding living donation are as follows:

- **Human Body Integrity:** the integrity of the human body may only be compromised in cases of medical necessity for the individual or exceptionally in the therapeutic interest of others.
- **Informed Consent:** the consent of the individual must be freely given and fully informed. It can be revoked at any time.
- **Gratuitous Donation:** donation is free of charge, reflecting the principle of the inalienability and non-patrimonial nature of the human body.

Reassurance involves reformulating information in terms that are appropriate, clear, precise, and understandable to the donor according to their level of knowledge. Health literacy describes an individual's motivation and skills to access and understand information to make decisions regarding their health. The focus should be on obtaining the donor's free consent and ensuring conditions that minimise psychological impact related to the donation.

A donor's retraction is possible at any time, and confidentiality must be guaranteed. The process of obtaining consent requires an assessment of vulnerability.

The acceptance or refusal of a living kidney donation by a transplantation team must be discussed in a collegial meeting, documented, and clearly communicated to the donor. The physician–patient relationship is based on trust and shared decision-making.

Equitable access to information and transplantation teams should be pursued across the entire territory and all social classes.

In cases of difficulty, access to a second opinion from a transplantation and graft team with expertise in a specific medical or surgical field should be facilitated, with honest information provided to the donor.

Information about paired donation and desensitisation techniques must be given to all donor–recipient pairs before proceeding with an ABO-incompatible or HLA-incompatible transplant with preformed donor-specific anti-HLA antibodies (DSAs), ensuring a shared, informed, and voluntary decision.

Transplantation teams must consider the risk of inadequate post-donation follow-up, particularly when the donor resides in a country without a health insurance system and with inadequate healthcare structures.

# PATHWAY AND INFORMATION

## Information for Patients with Chronic Kidney Disease (CKD)

### When and How to Provide Information About Kidney Transplantation to Patients with CKD

For patients with progressive CKD Stage 4, for which professionals anticipate a need for renal replacement therapy or an estimated glomerular filtration rate (eGFR) < 20 ml/min/1.73 m <sup>2</sup> within the next 12 to 18 months, information should be provided about all forms of renal replacement therapy and conservative treatment.	EC
Information regarding pre-emptive kidney transplantation with a living donor should be provided during the presentation of various replacement therapy options.	B
Attention should be given to social determinants that affect access to kidney transplantation with a living donor (such as age, sex, educational level, and socioeconomic status) to ensure equitable access for all patients.	B
Patients currently on dialysis should be informed about the possibilities of kidney transplantation, whether from a living or deceased donor, and should understand whether this option represents an alternative to dialysis.	EC
Every patient should be offered the opportunity to participate in a structured, multi-professional therapeutic education program on the various forms of replacement therapy, inviting them to be accompanied by one or more of their relatives. If such a program is unavailable, information should be provided orally and supplemented with various written, visual, or digital materials; tailored to the stage of the disease and the patient's specific situation; and dated, documented, and updated in the patient's file.	B
Patients should be encouraged to connect with user associations to discuss their experiences with other patients and to inform the decisions they will make with healthcare professionals.	EC
A consultation with a clinical psychologist should be offered.	EC

## Content of Information to Provide to Patients with CKD Eligible for Kidney Transplantation

<p>For patients with CKD who are eligible for kidney transplantation, the following information should be delivered.</p> <ul style="list-style-type: none"> <li>• The stages of the pre-transplant evaluation and any potential contraindications;</li> <li>• The circle of potential living donors as outlined by the law;</li> <li>• The kidney exchange program and other therapeutic options in the case of an incompatible living donor;</li> <li>• The benefits and risks of transplants from deceased donors, compatible and incompatible living donors, as well as pre-emptive transplants, in terms of:             <ul style="list-style-type: none"> <li>○ Quality of life and life expectancy;</li> <li>○ Graft survival;</li> <li>○ Risks of complications and death;</li> <li>○ Uncertainties and risks of transplant failure with compatible and incompatible living donors as well as the risk of recurrence of some initial diseases;</li> <li>○ Constraints related to treatment and follow-up;</li> <li>○ Impact on autonomy, professional and social activities, personal relationships, family planning, psychological functioning, and financial resources;</li> <li>○ Generalities and details of the process for a potential living donor;</li> <li>○ Possibility of maintaining or suspending the status on the active waiting list for a deceased donor transplant during the pre-donation process of the potential living donor.</li> </ul> </li> </ul>	<p><b>EC</b></p>
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## Raising Awareness Among Potential Donors

<p>Offer early collective therapeutic education workshops during the course of CKD and in dialysis centers, inviting family members, to promote living donation.</p>	<p><b>B</b></p>
<p>Share experiences with resource patients in response to patient requests. Collective discussion sessions are offered within patient associations. Their development is gradual and should be supported by professionals.</p>	<p><b>EC</b></p>

## Pre-donation Process and Support for Potential Donors

<p>A pre-donation evaluation protocol must be formalised, with its implementation tailored to each donor's timing.</p> <p>Organisational support should be provided from the beginning of the process by a dedicated coordinator, typically a nurse coordinator, who is a crucial link in both the extra- and intra-hospital networks.</p> <p>Psychological support is recommended for the donor and their family throughout the process and in the event of withdrawing from the donation procedure.</p> <p>The donor must have an individual consultation. They should meet alone with the medical consultant and the referring clinical psychologist or psychiatrist from the transplantation service. In some cases, if desired, the donor may consult along with the recipient.</p> <p>A professional translator-interpreter is required in case of a language barrier.</p> <p>The donor's trusted person and the recipient's trusted person must be distinct.</p> <p>The results of the medical-surgical and psychosocial evaluations must be discussed in one or more multidisciplinary consultation meetings. Decisions should be well argued and documented in the donor's file.</p>	<p><b>EC</b></p>
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Ideally, the duration of the process from the first contact with the donor to the eligibility decision should be from 3 to 6 months, adjusted to the medical and socio-professional situation of both the donor and recipient. The evaluation of the donor candidate can be expedited in special circumstances (pre-emptive transplantation, urgent vascular access issues, cross-matching cycles, non-resident donors in France, etc.).	C
Donor and recipient transplantation are considered priority activities for operating room access and are included in the operating room charter.	
Scheduling of the donation and transplantation should ideally occur at the most favourable time for both the donor and recipient.	EC
Inter-team consultation meetings are recommended to facilitate the management of donor–recipient pairs requiring specialised expertise (e.g., surgical or immunological).	EC

## Information to be Provided to Potential Donors

### Ethical Principles of Donation

Donation is freely consented.

Donation is free from any inducement or coercion.

Donation can be refused at any time, in a protected and confidential manner.

### Pre-donation Process

The formalised process and timelines are presented and justified to the donor:

- Information;
- Medical, surgical, psychological, and social evaluation;
- Understanding the information during the Living Donor Committee meeting;
- Obtaining free and informed consent before a judicial court, after identifying the person and their declared relationship with the recipient;
  - Authorisation for kidney removal granted by the Living Donor Committee, sent to the team. The committee's decision is not explained.
- For donations from a parent to a child, the Living Donor Committee meeting serves as information to the donor rather than authorisation.
- Surgical removal;
- Lifetime follow-up post-donation.

EC

### Incidence of Complications

The incidence of complications related to donation remains sufficiently low, and quality-of-life studies are favourable enough to encourage living kidney donation.

A

## Risks

<p>Living kidney donation involves <b>surgical, medical, psychological, and social risks</b>, which may be temporary or permanent, including but not limited to the following.</p>	
<p><b>Surgical Risks</b></p> <ul style="list-style-type: none"> <li>• Death: Mortality is estimated at 3 per 10,000 within 90 days post-donation;</li> <li>• Surgical complications are estimated at about 20%, with 2% to 3% being severe complications classified as III to V on the Clavien scale: <ul style="list-style-type: none"> <li>○ Change of surgical approach (1%)</li> <li>○ Injury to neighbouring organs (0.8%)</li> <li>○ Bleeding (2.5%) and need for transfusion (0.4%)</li> <li>○ Reoperation (0.6%)</li> <li>○ Readmission (3%)</li> <li>○ Phlebitis and pulmonary embolism (0.2%)</li> <li>○ Local or systemic infection (2.6%)</li> <li>○ Cardiovascular complications (0.07%)</li> <li>○ Digestive complications (4%), ileus (0.7%), chylous ascites (0.5%)</li> <li>○ Pneumothorax (0.1%)</li> <li>○ Scrotal pain, hydrocele (11%)</li> <li>○ Risk of hernia at the incision site</li> <li>○ Various pains</li> <li>○ Allergy (0.03%)</li> </ul> </li> </ul>	<p><b>B</b></p>
<p><b>Medical Risks</b></p> <ul style="list-style-type: none"> <li>• Morbidity and mortality for living donors are influenced by age, obesity, hypertension, and all pre-existing conditions specific to the donor.</li> <li>• Although short-term cardiovascular risk and mortality do not seem increased, a longer-term study (15 years) showed a slight increase in cardiovascular mortality as compared with a "healthy" selected population.</li> <li>• Impact on kidney function with a loss of approximately 30% of initial function.</li> <li>• The risk of end-stage renal disease (ESRD) for living kidney donors does not exceed that of the general population with the same demographic profile; however, the risk of ESRD in living kidney donors was found higher than in a "healthy" selected population. This risk is estimated at 0.3% at 15 years with identified predictive factors.</li> <li>• The prediction of CKD or ESRD risk during life is more uncertain for a younger living donor than an older donor.</li> <li>• Living donors may face a higher risk of CKD or ESRD in the event of a medical issue affecting the remaining kidney.</li> <li>• The risk of pre-eclampsia is doubled in pregnancy post-donation and is from 4% to 10%, almost exclusively when the age is &gt; 32 years, with no increased risk of foetal-maternal mortality, premature birth, or low birth weight. Caesarean rates are unaffected post-donation. Studies are mostly limited to Caucasian women.</li> </ul>	<p><b>B</b></p>
<p><b>Psychological and Social Risks</b></p> <ul style="list-style-type: none"> <li>▪ Anxiety symptoms, depressive symptoms (increased risk in cases of early graft failure in the recipient);</li> <li>▪ General symptoms such as physical and emotional fatigue;</li> <li>▪ Changes in body image;</li> <li>▪ Disruption of family and recipient relationships;</li> <li>▪ Financial and/or administrative difficulties.</li> </ul>	<p><b>B</b></p>

<p><b>Risks Inherent to the Evaluation</b></p> <ul style="list-style-type: none"> <li>▪ Allergic reactions to contrast agents;</li> <li>▪ Discovery of mandatory reportable infections;</li> <li>▪ Discovery of diseases: therapeutic orientation will be organised;</li> <li>▪ Discovery of unfavourable or uncertain genetic results.</li> </ul>	EC
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**A Realistic Estimate of the Probability of Transplant Success Should be Provided**

<p>The recipient’s morbidity and mortality factors must be taken into account.  Graft survival should be estimated based on up-to-date literature data.  Risk factors for graft loss, including the risk of recurrence of the primary disease in the graft, should be disclosed to the donor.  The recipient must have agreed to share relevant medical information.</p>	EC
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**Alternative Therapies, Choices, and Decisions**

<p>The donor should be informed about alternative procedures and treatments for the recipient, including transplantation from a deceased donor.  An organ from a deceased donor may be considered during the evaluation of a living donor and before the date of the donation. The recipient may choose whether to accept an organ from a living donor or a deceased donor, following the approval of the living donor donation by the Living Donor Committee.  In the case of an ABO-incompatible donor–recipient pair and/or the presence of preformed DSAs, the kidney exchange program and the possibilities for incompatible transplantation should be presented, along with an analysis of the benefits and risks.  If a procurement and transplant team refuses the donation, the team must justify their decision and inform the donor that another team may have different eligibility criteria and/or possess expertise that could enable the donation, provided there are no validated contraindications.</p>	EC
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**Post-Donation Pathway: Coordinated Lifelong Follow-Up**

**Objectives of Postoperative Follow-Up**

<p>Monitor clinical progress and the occurrence of potential complications.  Manage pain.  Assess the duration of recovery.  Evaluate the need for psychological support and/or social assistance.  Facilitate the return to professional activities and specify the duration of exclusion from certain sports activities.</p>	EC
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## Objectives of Annual Post-Donation Follow-Up

<p>Collect clinical, biological, and therapeutic data:</p> <ul style="list-style-type: none"><li>▪ Weight, height, BMI, waist circumference, blood pressure;</li><li>▪ Serum creatinine level, albumin-to-creatinine ratio, fasting blood glucose level.</li></ul> <p>Manage therapeutic needs and establish care pathways if necessary:</p> <ul style="list-style-type: none"><li>▪ Hypertension, albuminuria, diabetes, dyslipidemia;</li><li>▪ CKD pathway according to recommendations from the Haute Autorité de Santé (HAS), if applicable.</li></ul> <p>Identify psychological impact.</p> <p>Identify socio-economic, family, or professional difficulties.</p> <p>Prevention and education:</p> <ul style="list-style-type: none"><li>▪ Vaccination follow-up.</li><li>▪ Cancer screening.</li><li>▪ Nephroprotection measures (avoiding nephrotoxic medications and substances, particularly chronic use of non-steroidal anti-inflammatory drugs and radiological contrast agents, avoiding excessive protein intake etc.).</li><li>▪ Hygienic-dietary recommendations and adapted physical activity.</li><li>▪ Therapeutic education (interpreting laboratory tests, self-monitoring blood pressure, nutrition etc.).</li></ul> <p>Support network and assistance (psychologist, social worker, dietitian, adapted physical activity, smoking cessation etc.).</p>	<b>EC</b>
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## National Register for the Follow-Up of Living Kidney Donors

Completing the Register to Enable the Evaluation and Improvement of Practices in France
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## Practical Aspects of Perioperative Follow-Up

<p>The return home should be planned in advance, with the option of home help if needed for rest and limitation of physical activities. However, early mobilisation is recommended. Prophylactic anticoagulant treatment is prescribed according to anaesthetic and surgical recommendations (see below for anaesthetic aspects).</p> <p>Nursing care is prescribed until complete healing.</p> <p>A caregiver be present at home upon postoperative return is recommended, and emergency service contact numbers should be provided to the patient, including a 24-hour emergency medical contact number. In the event of a life-threatening emergency, the emergency medical services (SAMU) should be called (dial 15).</p> <p>A work stoppage of several weeks is advised (at least 4 weeks).</p> <p>A surgical consultation is scheduled between 1 and 3 months postoperatively.</p> <p>A nephrological consultation is scheduled within 3 months postoperatively.</p> <p>An early consultation with an advanced practice nurse is recommended.</p> <p>A psychological consultation is offered at 1 and/or 3 months postoperatively.</p>	<b>EC</b>
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## Practical Aspects of Long-Term Follow-Up for Living Donors

### **Annual follow-up is mandatory.**

It can be performed by dedicated and trained staff, including advanced practice nurses trained in therapeutic education, or a local nephrologist.

It is conducted in collaboration with the primary care physician and the nephrologist from the transplantation unit.

Outpatient psychological follow-up should be offered.

Development of telemedicine and remote monitoring tools is recommended.

Specialist nephrological and obstetric follow-up should be established in case of **pregnancy** post-donation.

EC

# DONOR EVALUATION

## CARDIOVASCULAR AND METABOLIC RISK ASSESSMENT

### Hypertension

<p>Blood pressure should be measured in consultations by using standardised methods.</p> <p>In cases of hypertension, ambulatory monitoring (self-measurement or ambulatory blood pressure monitoring) is recommended.</p>	<b>A</b>
<p>Donors should be informed of the risk of hypertension after donation, especially if they have other cardiovascular risk factors.</p>	<b>B</b>
<p>For young candidates (&lt; 40 years), a blood pressure considered normal (120-129/80-84 mmHg) or even "optimal" (&lt; 120/80 mmHg) without any antihypertensive medication is recommended.</p>	<b>EC</b>
<p>Potential donors with hypertension should be excluded in the following situations:</p> <ul style="list-style-type: none"> <li>• If blood pressure is not controlled (&gt; 135/85 mmHg on self-measurement or diurnal ambulatory blood pressure monitoring) despite treatment with one or two classes of antihypertensive medications.</li> <li>• If the donor is young (&lt; 40 years old), even if hypertension is moderate and controlled, although this exclusion may be re-evaluated after weight loss and if no secondary cause of hypertension is found.</li> <li>• If there are markers of target organ damage (e.g., retinopathy, left ventricular hypertrophy, diastolic dysfunction, pathological albuminuria, or other cardiovascular history such as stroke, transient ischemic attack, or myocardial infarction).</li> <li>• If the donor is at unacceptable risk of cardiovascular events according to risk scores such as SCORE or other predictive equations for 10-year cardiovascular events.</li> </ul>	<b>C</b>
<p>All living kidney donors should be encouraged to minimise the risk of hypertension and its effects before and after donation via lifestyle changes, including smoking cessation, reducing alcohol and salt intake, frequent physical exercise, and, if applicable, weight loss.</p> <p>Care of donors with a diagnosis of hypertension during the evaluation or in whom hypertension develops after donation should follow the guidelines from the French Society of Hypertension.</p> <p>Systematic and standardised measurement or self-measurement of blood pressure should be part of post-donation follow-up.</p>	<b>EC</b>

### Obesity

Healthy individuals with moderate overweight (body mass index [BMI] 25-30 kg/m <sup>2</sup> ) may be eligible for kidney donation.	B
Obese individuals with BMI 30-35 kg/m <sup>2</sup> should undergo a thorough preoperative evaluation to exclude any cardiovascular, respiratory, and renal diseases. Regarding renal risk, the absence of pathological albuminuria and uncontrolled hypertension is essential.	C
Obese individuals with BMI 30-35 kg/m <sup>2</sup> should be informed of the increased risk of perioperative complications, including potential delays in healing, which is based on extrapolated data from the outcomes of severely obese donors (BMI > 35 kg/m <sup>2</sup> ).	B
Obese individuals with BMI 30-35 kg/m <sup>2</sup> should be warned of the potential long-term risk of kidney disease. A 5% to 10% weight loss before donation and this weight maintained after donation is recommended. Associated risk factors, as well as age and life expectancy, should be considered.	B
Data on the safety of kidney donation in individuals with BMI > 35 kg/m <sup>2</sup> are limited, and donation should be discouraged. However, in the absence of other risk factors, donation may be considered on a case-by-case basis, with careful management by an experienced medical-surgical team.	EC
Donors who have undergone bariatric surgery should be evaluated on a case-by-case basis according to their achieved BMI and the time since surgery, by an experienced medical-surgical team. Depending on the surgical technique used, the risk of lithiasis should be assessed.	EC

## Diabetes

<p>Given the prevalence of diabetes, prediabetes, and diabetes risk factors in the adult population, all potential living kidney donors should undergo the following:</p> <ul style="list-style-type: none"> <li>• Assessment of diabetes risk factors: <ul style="list-style-type: none"> <li>○ First-degree family history of diabetes,</li> <li>○ Personal history of gestational diabetes,</li> <li>○ BMI ≥ 28 kg/m<sup>2</sup>,</li> <li>○ Waist circumference &gt; 88 cm (women) and 102 cm (men),</li> <li>○ Blood pressure &gt; 140/90 mmHg,</li> <li>○ Hypertriglyceridemia &gt; 2.5 g/L, low HDL cholesterol &lt; 0.35 g/L.</li> </ul> </li> <li>• Personalised estimation of diabetes risk using predictive risk scores (e.g., FINDRISC).</li> <li>• Fasting plasma glucose and glycated haemoglobin levels.</li> <li>• Oral glucose tolerance test if: <ul style="list-style-type: none"> <li>○ Fasting glucose is 1.1–1.25 g/L (6.1–6.9 mmol/L),</li> <li>○ A diabetes risk factor is present,</li> <li>○ The 10-year diabetes risk is estimated at &gt; 30% (FINDRISC score).</li> </ul> </li> </ul>	A
A donation proposal may be reconsidered if the metabolic situation improves following sustainable lifestyle changes.	EC

<p><b>In cases of prediabetes or a high risk of diabetes</b> (e.g., FINDRISC score &gt; 30% at 10 years or a history of gestational diabetes), a multidisciplinary evaluation, including a diabetologist, is necessary for donation approval. The risk should be deemed moderate, manageable, or delayed. Decision-making should involve:</p> <ul style="list-style-type: none"> <li>Refining the estimate of diabetes progression risk based on age, obesity severity, heredity, and the severity of associated metabolic syndrome (e.g., hypertension, hypertriglyceridemia).</li> <li>Assessing other risk factors for kidney and cardiovascular diseases, including hypertension, BMI, smoking, and dyslipidemia.</li> <li>Screening for any existing cardiovascular or renal complications (5-10% in prediabetes cases).</li> <li>Evaluating the donor's ability to adhere to lifestyle or medical interventions aimed at controlling the risk of disease progression when making the donation decision.</li> </ul>	<b>EC</b>
<p>The donor should be informed of the risk of diabetes and offered education on ways to prevent this risk, including guidance on lifestyle changes, ideally supported by a dietitian, a medical sports educator, and a clinical psychologist.</p>	<b>EC</b>
<p><b>In cases of type 2 diabetes</b>, eligibility for donation is currently not well documented, and data are lacking on long-term risks. Donation may be considered in certain situations, particularly for a donor candidate who is at least 60 years old, has well-controlled diabetes with HbA1c proportion &lt; 6.5% managed by no more than two oral antidiabetic medications, has had diabetes for &lt; 5 years, is a non-smoker, and has controlled blood pressure. This consideration should follow a multidisciplinary evaluation including a diabetology team and a thorough assessment of cardiovascular and renal risks.</p>	<b>EC</b>
<p>There is no indication for routine screening for <b>type 1 diabetes</b>, but screening for a predisposition to type 1 diabetes is suggested in donors &lt; 45 years old with more than one first-degree relative with type 1 diabetes. A comprehensive autoimmune assessment is advisable, including tests for anti-GAD, anti-ICA, anti-IA2, and anti-ZNT8 antibodies, to exclude individuals from donation predisposed to type 1 diabetes.</p>	<b>EC</b>

## Dyslipidemia

<p>Evaluation of the fasting lipid profile in donors is recommended in most previous guidelines, although no specific exclusion criteria are suggested, except in extreme cases of familial hyperlipidemia due to the associated high cardiovascular risk.</p> <p>Generally, dyslipidemia should be considered within the overall assessment of the donor's cardiovascular risk.</p>	<b>EC</b>
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## Smoking

<p>Active smoking is a major cardiovascular and renal risk factor. Smoking cessation before donation is recommended. A smoking donor candidate should be encouraged to quit smoking, and medical support should be offered.</p>	<b>B</b>
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## Hyperuricemia and Gout

Donor candidates should be questioned about their history of gout symptoms. They should also be informed about the potential increase in uricemia after donation and the heightened risk of gout episodes, particularly if they have a history of gout. Kidney donors with a history of gout or those with risk factors for gout should be informed about methods to reduce the risk of gout attacks.	EC
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## Cardiovascular Assessment

All donor candidates should undergo a thorough medical history review and physical examination, focusing on cardiovascular risk factors (smoking, hypertension, diabetes, dyslipidemia, overweight, sedentary lifestyle, family predisposition), cardiovascular history, and comorbidities.	EC
No specific risk score can be recommended, and <b>the criteria for selecting additional preoperative tests are clinical</b> . The following are recommended: <ul style="list-style-type: none"> <li>• Electrocardiography (ECG);</li> <li>• Assessing functional capacity (metabolic equivalent of task [MET]);</li> <li>• Measurement of biomarkers (troponin; N-terminal pro-B-type natriuretic peptide or B-type natriuretic peptide) depending on the donor's cardiovascular risk (<math>\geq 65</math> years, hypertension, smoking, dyslipidemia, diabetes, family cardiovascular history).</li> </ul>	C
Cardiac ultrasonography is justified in cases of: <ul style="list-style-type: none"> <li>• Poor exercise tolerance (MET &lt; 7), unexplained dyspnea;</li> <li>• Abnormal ECG findings;</li> <li>• Clinical risk factors;</li> <li>• Family history of genetic cardiomyopathy (dilated, hypertrophic, arrhythmic, or restrictive cardiomyopathy);</li> <li>• To optimise perioperative management (screening for diastolic dysfunction or elevated left ventricular filling pressure).</li> </ul>	C
All donor candidates can benefit from cardiac ultrasonography. For any donor candidate > 50 years old and/or with a cardiovascular risk factor, cardiology consultation is recommended.	EC
An exercise test alone should only be considered for coronary artery disease screening if non-invasive imaging tests are unavailable or to assess functional capacity when the clinical history is ambiguous. The use of stress cardiac imaging (myocardial scintigraphy, stress echocardiography, or stress MRI) is appropriate for risk assessment in donors with clinical or biological risk factors or low functional capacity. The choice of test should be guided by local expertise.	B
A coronary CT angiogram can be considered in cases of low to intermediate clinical probability of coronary artery disease or for donors unsuitable for non-invasive functional tests.	C

# RENAL EVALUATION AND CKD RISK ASSESSMENT

## Assessment of GFR Before Donation

<p>The evaluation of a kidney donation candidate must systematically include a measurement of GFR using a reference method, such as an exogenous tracer (iothalamate, iothexol, and 99mTc-DTPA). In France, only iothexol and 99mTc-DTPA are available.</p> <p>The decision on donation eligibility is based on a GFR value, expressed in ml/min/1.73 m<sup>2</sup>, compared to the expected normal values for the donor candidate's age. The intrinsic capacity of the future graft can be assessed by the GFR value not indexed to body surface area.</p>	<b>EC</b>
<p>A GFR strictly &gt; 90 ml/min/1.73 m<sup>2</sup> is recommended for kidney donation in candidates &lt; 30 years of age.</p> <p>A GFR strictly &lt; 60 ml/min/1.73 m<sup>2</sup> is an absolute contraindication for kidney donation.</p> <p>A recommended GFR threshold can be set at the 10th percentile for age (Table 1). The British Transplantation Society guidelines also take into account sex-related variations (Table 2). These thresholds are indicative, and the decision on donation eligibility should be based on a discussion of the lifetime risk of CKD in the absence of kidney donation.</p>	<b>EC</b>
<p>In the case of renal asymmetry detected on a renal scan, performing renal scintigraphy is recommended to determine the separate function of each kidney.</p> <p>In all cases, the donor will retain the kidney deemed by the medical-surgical team to be of better quality, considering all parameters (especially anatomical ones).</p> <p>A significant asymmetry may constitute a contraindication for donation.</p>	<b>EC</b>

**Table 1: Percentiles of normal measured glomerular filtration rate (GFR; ml/min/1.73 m<sup>2</sup>) in a population of living donors in France and Switzerland by age**

Age (years)	GFR percentiles				
	5 <sup>e</sup>	10 <sup>e</sup>	50 <sup>e</sup>	90 <sup>e</sup>	95 <sup>e</sup>
18	82	88	106	125	130
20	82	88	106	125	130
25	82	88	106	125	130
30	82	88	106	125	130
35	82	88	106	125	130
40	82	88	106	125	130
45	78	83	102	120	126
50	74	79	97	116	121
55	69	74	93	112	117
60	65	70	89	107	112
65	60	66	84	103	108
70	56	61	80	98	104
75	52	57	75	94	99

*Values > 70 years have been validated in an external population of healthy individuals.*

**Table 2: Advisory thresholds: glomerular filtration rate (GFR) levels considered acceptable by the British Transplantation Society by age**

Age (years)	GFR thresholds (ml/min/1.73 m <sup>2</sup> )	
	Men	Women
20-29	90	90
30-34	80	80
35	80	80
40	80	80
45	80	80
50	80	80
55	80	75
60	76	70
65	71	64
70	67	59
75	63	54
80	58	49

## Assessment of the Risk of End-Stage CKD in Kidney Donor Candidates

<ul style="list-style-type: none"> <li>▪ The risk of end-stage CKD in living kidney donor candidates must be evaluated. Living kidney donors are at increased risk of end-stage CKD as compared with healthy non-donors.</li> <li>▪ This evaluation is based on collecting and interpreting the following clinical characteristics: age, sex, GFR, blood pressure, antihypertensive treatment, BMI, history of diabetes, albumin-to-creatinine ratio, tobacco use, and genetic relationship between donor and recipient.</li> <li>▪ If there is a first-degree genetic relationship between the donor and recipient, precautions must be taken (see genetic aspects below).</li> <li>▪ The younger the candidate, the greater the uncertainty regarding the risk of ESCKD. Total absence of ESCKD risk factors is recommended for younger candidates (&lt; 40 years old).</li> <li>▪ A favourable pre-donation assessment is not sufficient to guarantee the absence of risk. Lifelong monitoring of the donor is essential. Donors should be informed of this requirement and must agree to it.</li> </ul>	<b>EC</b>
<ul style="list-style-type: none"> <li>▪ Predicted 15-year ESCKD risk calculators are available.</li> <li>▪ The 15-year predicted risk of ESCKD should not be used alone to authorise or deny donation. The predicted 15-year ESCKD risk should be lower than that of the general population of the same age and sex as the candidate.</li> </ul>	<b>EC</b>

## Proteinuria

<p><b>Assessment of Proteinuria</b></p> <p>Urinary albumin-to-creatinine ratio measured on a urine sample is the recommended screening test.</p> <p>The urinary protein-to-creatinine ratio is not an acceptable alternative but may be used as an additional exploration.</p> <p>If the urinary albumin-to-creatinine ratio is &gt; 3 mg/mmol, it must be confirmed.</p>	<b>B</b>
<p><b>Donor Selection</b></p> <p>In the absence of new data in the literature, the following thresholds are proposed, as defined by KDIGO (Kidney Disease – Improving Global Outcomes) recommendations.</p> <ul style="list-style-type: none"> <li>▪ A urinary albumin-to-creatinine ratio &lt; 3 mg/mmol or albuminuria &lt; 30 mg/day permits donation.</li> <li>▪ A urinary albumin-to-creatinine ratio &gt; 10 mg/mmol or albuminuria &gt; 100 mg/day is an absolute contraindication to living kidney donation.</li> <li>▪ A moderate increase in the urinary albumin-to-creatinine ratio (3-10 mg/mmol) or albuminuria 30 to 100 mg/day is a relative contraindication because of the increased risk of cardiovascular morbidity and CKD associated with albuminuria. The risk of moderate albuminuria in a donor should be assessed according to the overall donor profile.</li> </ul>	<b>C</b>

## Isolated Haematuria

<p>Persistent isolated microscopic haematuria is defined by the presence of &gt; 10 red blood cells/mm<sup>3</sup> in two separate urine samples.</p> <p>Haematuria associated with albuminuria (albumin-to-creatinine ratio &gt; 3 mg/mmol) contraindicates donation and requires nephrological evaluation.</p> <ul style="list-style-type: none"> <li>• <b>Investigation Threshold:</b> The threshold of haematuria beyond which investigations are necessary is discussed. The etiological workup includes: <ul style="list-style-type: none"> <li>○ Urinary bacteriology</li> <li>○ Renal scan with four phases</li> <li>○ Cytology and cystoscopy as advised by a urologist</li> </ul> </li> <li>• <b>Negative Urological Workup:</b> If the urological workup is negative (infectious, tumour, or lithiasic pathologies) and/or glomerular haematuria is confirmed, the following steps should be taken: <ul style="list-style-type: none"> <li>○ A family history inquiry (3 generations)</li> <li>○ Screen for haematuria in donor relatives</li> <li>○ Consider genetic testing, especially if the living donor is a relative and/or the recipient's initial nephropathy is unknown</li> <li>○ Discuss the possibility of a renal biopsy (optical microscopy; immunofluorescence and, if possible, electron microscopy)</li> </ul> </li> </ul> <p><b>See Genetic Aspects Below</b></p>	<b>EC</b>
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## Urinary Stones

<p><b>Clinical Situations Contraindicating Kidney Donation</b></p> <ul style="list-style-type: none"> <li>▪ Bilateral stones regardless of their size</li> <li>▪ Genetic (monogenic) stone disease</li> <li>▪ Enteric hyperoxaluria and digestive malabsorption situations</li> <li>▪ Nephrocalcinosis with or without identified cause</li> <li>▪ Stones of infectious origin or recurrent infections associated with stone disease</li> <li>▪ Cacchi-Ricci disease</li> <li>▪ Unresolved primary hyperparathyroidism or other causes of chronic hypercalcemia and hypercalciuria (sarcoidosis or others)</li> <li>▪ Recent stone activity (&lt; 5 years) defined by renal colic</li> <li>▪ High-risk stone disease: <ul style="list-style-type: none"> <li>- Hypercalcemia (ionized calcium &gt; 1.30 mmol/l)</li> <li>- Metabolic acidosis</li> <li>- Hypercalciuria &gt; 7.5 mmol/24h (men) or 6.25 mmol/24h (women) or &gt; 1 mmol/10 kg ideal body weight/day</li> <li>- Hyperoxaluria (&gt; 0.45 mmol/24h)</li> <li>- Repeated positive crystalluria (on first morning urine)</li> </ul> </li> </ul> <p>These risk factors may be reassessed after correction of dietary errors.</p>	<b>EC</b>
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<p><b>Situations in which Kidney Donation can be Considered for a Donor with Stone Disease</b></p> <ul style="list-style-type: none"> <li>• In an asymptomatic donor or one who has been symptom-free for at least 5 years, with stones present in only one kidney and after a thorough evaluation of stone risk factors, kidney donation may be considered after treatment of the stones and absence of residual fragments.</li> <li>• Even a small proportion of uric acid in a stone composition generally indicates a metabolic syndrome.</li> <li>• Oxalocalcic stones are not a homogeneous entity, and expert opinion on stone disease is recommended.</li> </ul>	EC
<p><b>Screening and Examinations to be Conducted for any Potential Donor with Stone Disease and Specifics of Kidney Donation</b></p> <ul style="list-style-type: none"> <li>▪ The donor must be informed of the highly recurrent nature of stone disease and the risks of recurrence in a single kidney.</li> <li>▪ The history of stone disease should be specifically interrogated.</li> <li>▪ Imaging via a CT scan with urinary tract contrast should be performed.</li> <li>▪ The biological evaluation includes the following (in addition to routine biological tests): <ul style="list-style-type: none"> <li>- <b>Blood:</b> ionized calcium, total calcium, phosphate, bicarbonate, magnesium, parathyroid hormone, 25-OH vitamin D, calcitriol, uric acid</li> <li>- <b>24-hour urine collection</b> with creatinine, sodium, urinary urea, calcium, magnesium, phosphate, uric acid, oxalate, and citrate (collected in a 3-liter container with an antiseptic such as hexomedine); in the absence of stone analysis and/or whole exome, a cystinuria test is indicated.</li> <li>- <b>Morning urine:</b> urinary pH and, if available, crystalluria in a specialised facility (recommended for screening particularly for genetic disorders, such as adenine phosphoribosyltransferase deficiency).</li> </ul> </li> <li>▪ In cases of suspected genetic pathology due to a suggestive family history, to results, or to the evaluation (tubular acidosis) or type of stone (cystine etc.), whole exome analysis may be conducted. If stone disease is discovered in a related donor, the recipient's pathology should be reviewed (in the absence of a clearly identified nephropathy).</li> <li>▪ In case of stone expulsion, even if old, it should be analysed morphologically.</li> <li>▪ The removed kidney should preferably be the one with stones.</li> <li>▪ If the stone-containing kidney is to remain in the donor, it should be cleared of any stone fragments before kidney donation, ideally by flexible ureteroscopy, with stone or fragment retrieval for analysis.</li> <li>▪ If the stone-containing kidney is the one being donated, pre-donation ureteroscopy with stone or fragment analysis can be proposed. This approach has the drawbacks of additional general anaesthesia and a moderate but real risk of ureteral injury. The advantage is that the stone analysis can, according to its composition, support or oppose the kidney donation. Another approach is to propose ex vivo ureteroscopy just before kidney reimplantation.</li> </ul>	EC
<p><b>Follow-up of Donors with Stone Disease</b></p> <ul style="list-style-type: none"> <li>▪ Follow-up for stone donors should be semi-annual in the first year, then annual following the donation, and should include at a minimum the biological tests recommended by the Stone Committee of the French Urological Association, as well as oxalate and citrate measurements.</li> <li>▪ Renal ultrasonography and, if necessary, abdominal radiography for radio-opaque stones should be performed annually. In case of doubt, a non-contrast low-dose CT scan may be done. An annual consultation with a nephrologist is recommended.</li> </ul>	EC

# GENETIC ASPECTS IN LIVING DONORS

## Introduction – Prescription tests

The prescription of genetic tests should be explained in the context of incidental findings permitted by the evolution of bioethics laws in 2021.

In all cases, prescribers must be trained for these prescriptions and supported by a multidisciplinary team, including clinical geneticists, genetic counsellors, and molecular geneticists, in accordance with best practices in clinical genetics.

Each variant must be re-evaluated over time, particularly before donation, to account for advancements in knowledge.

## APOL1 Polymorphism

A test for APOL1 polymorphisms is recommended for all donors of African or Caribbean descent, regardless of their age.	A
Donation should be contraindicated in the presence of a high-risk polymorphism in homozygous or compound heterozygous state. A case-by-case discussion may be considered for donors > 60 years old in the absence of albuminuria.	B

## Autosomal Dominant Polycystic Kidney Disease (ADPKD) and Living Donation

For individuals considering kidney donation with a family risk of ADPKD, the presence of fewer than two cysts (total for both kidneys) on ultrasonography after age 40 years or fewer than 5 millimetric renal cysts on MRI after age 20 years or the absence of screening for the familial pathogenic variant allows for excluding ADPKD. In cases of diagnostic uncertainty, genetic testing is recommended.	A
Genetic diagnosis of ADPKD (next-generation sequencing panel for cystic kidney diseases) in individuals with ADPKD before reaching end-stage renal disease is a prerequisite for genetic testing of donor candidates.	A
When the recipient has no family history, the family presentation is atypical, or the clinical presentation in the recipient is atypical (e.g., small polycystic kidneys), genetic testing should be conducted in the recipient first. If the causative variant is identified, testing should then be done in related donor candidates. Diagnostic criteria based on imaging can be used only for typical forms of ADPKD (PKD1/PKD2).	B
If renal cysts are found in individuals considering kidney donation with no family history of ADPKD, a family study and genetic testing should be proposed. Donation should not proceed if the number of renal cysts (> 5 mm, total for both kidneys) identified exceeds the 97.5th percentile by age group. The thresholds are: <ul style="list-style-type: none"> <li>- 10 for men and 4 for women aged 60 to 69 years;</li> <li>- 5 for men and 3 for women aged 50 to 59 years;</li> <li>- 3 for men and 3 for women aged 40 to 49 years;</li> <li>- 2 for individuals aged 30 to 39 years;</li> <li>- 1 for individuals aged 15 to 29 years.</li> </ul>	C

## Alport Syndrome

### X-linked Alport Syndrome

Women who are heterozygous for the variation are at risk of renal insufficiency. Donation is contraindicated before age 55 years.	B
Kidney donation from older heterozygous women > 55 years old presenting isolated haematuria, without significant albuminuria, and after receiving complete informed consent may be considered after expert consultation.	C

### Autosomal Recessive Alport Syndrome

Family investigation is crucial to determine the phenotype of the ancestors carrying the candidate's variation.	A
Donor candidates who are heterozygous carriers of the variation with isolated haematuria and without significant albuminuria and after receiving informed consent may be considered for donation.	B
Referral to a specialised center is recommended.	EC

### Autosomal Dominant Alport Syndrome

Studying the co-segregation of the variation within the family, particularly in older individuals, combined with phenotypic characterisation (renal function, albuminuria, haematuria, kidney biopsy, etc.) will be crucial to better classify the variation and its causal link to renal disease.	A
If the family investigation supports the pathogenic nature of the variation in the heterozygous state, candidates carrying the variation (sometimes not yet showing albuminuria or renal insufficiency because of their young age) should be contraindicated for donation.	B
In many cases, family investigation may not be feasible, so a formal conclusion is difficult. Donors carrying the variation should be contraindicated. Referral to a specialised center is recommended.	EC

## Complement-Dependent Thrombotic Microangiopathies (CFH, CFI, C3, CD46, CFB)

### In the recipient

Screening for genetic abnormalities is recommended in cases of atypical haemolytic uremic syndrome (or typical haemolytic uremic syndrome leading to end-stage renal disease) or in cases of recurrence or episodes of thrombotic microangiopathies (TMAs) in the graft, among recipients and their related donors.	A
Identification of a molecular abnormality in the alternative complement pathway allows for anticipating the risk of TMA and recurrence for the recipient. Conversely, the absence of such abnormalities does not entirely exclude the risk.	EC

### In the donor

In all cases, seeking the opinion of a reference center is advised for complement abnormalities.	EC
If a molecular abnormality considered pathogenic or a risk factor for TMA is identified in a recipient, a systematic search should be conducted in the related donor to assess the risk of donation. If the pathogenic variant or TMA risk factor is found in the donor, the donation should be contraindicated.	A

## Segmental and Focal Hyalinosis (SFH) of Molecular Origin

<p>SFH associated with one or more pathogenic variant(s) may follow an autosomal recessive pattern (e.g., NPHS1, NPHS2), autosomal dominant pattern (e.g., WT1, INF2, TRPC6), or, more rarely, an X-linked pattern.</p> <p>The risk of recurrence is extremely low.</p> <p>Exceptions include certain truncating mutations in NPHS1 (coding for nephrin), which result in a complete absence of nephrin and lead not to actual recurrence but rather to immunisation and the production of anti-nephrin antibodies post-transplantation.</p>	<b>B</b>
<p>Molecular diagnosis is recommended in recipients &lt; 50 years old who have a cortico-resistant form, to distinguish between genetic and primary forms of SFH before transplantation.</p> <p>Identification of a causal variant in a recipient guides targeted screening in related donors.</p>	<b>B</b>
<p>In cases of recessive disease, the detection of a heterozygous variant in a relative of an index case with recessive SFH does not contraindicate donation.</p> <p>In cases of dominant disease, the identification of a causal variant in a relative contraindicates donation.</p>	<b>A</b>

## Fabry Disease

<p>Although the inheritance is X-linked, most heterozygous women exhibit symptoms of the disease, usually in a later and more variable manner.</p> <p>A family investigation is recommended after diagnosing an index case, along with consultation with an expert center to perform screening.</p> <p>Donors carrying a pathogenic variant are contraindicated.</p>	<b>A</b>
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## Crystalline or Tubular Nephropathies

<p><b>Primary hyperoxaluria</b> is an autosomal recessive hereditary disorder.</p> <p>Given the risk of recurrence post-transplantation, the diagnosis should always be considered in cases of indeterminate nephropathy, particularly in the presence of nephrocalcinosis or lithiasis.</p> <p>Heterozygous relatives are not contraindicated for kidney donation but should undergo biological and radiological phenotyping at an expert center.</p>	<b>EC</b>
<p>In the case of autosomal recessive <b>tubulopathies</b> (e.g., cystinosis, Bartter syndrome), heterozygous relatives are not contraindicated for kidney donation, but biological and radiological phenotyping at an expert center is recommended.</p>	<b>EC</b>
<p><b>Dent syndrome</b> is X-linked, but some women may be symptomatic. The relevance of the donation project should be assessed on a case-by-case basis.</p>	<b>EC</b>

## Indeterminate Nephropathies

Genetic testing for individuals with CKD of indeterminate aetiology should be proposed whenever possible before the end-stage renal failure, to clarify the risk of disease recurrence. Screening for renal risk is a prerequisite for the genetic study of related donor candidates.	EC
In cases in which the related recipient has an indeterminate nephropathy and no diagnostic test has been performed in the initial evaluation, the recipient < 50 years of age should be assessed with broad genetic tests (e.g., broad “renome” panels, exome or genome sequencing), including a study of familial segregation.	C

## Hemoglobinopathies

<p>The medical history should include a search for a family history of hemoglobinopathy.</p> <p>A haemoglobin study is recommended:</p> <ul style="list-style-type: none"> <li>• For donors not originating from Northern Europe;</li> <li>• In cases of anaemia or when the mean corpuscular volume of red blood cells is abnormally low in the absence of iron deficiency.</li> </ul>	A
This study should be conducted in qualified laboratories and include four techniques: isoelectric focusing, acid pH agarose gel electrophoresis, solubility testing, and high-performance liquid chromatography.	EC
Sickle cell disease is a contraindication for living kidney donation, as are composite heterozygous forms of HbS (Hb SC or Hb ES, etc.).	B
A sickle cell trait should not constitute a contraindication for kidney donation for donors without renal involvement, but donors must be informed of possible risks by a medical expert in sickle cell disease.	EC
Thalassemia is a contraindication for living kidney donation.	B
Heterozygous carriers of thalassemia may be eligible to donate.	EC

# NEOPLASTIC RISK ASSESSMENT, MANAGEMENT, AND PREVENTION

## Risk Assessment of Cancer or Precancerous Lesions for a Donor Candidate

### Medical History

<ul style="list-style-type: none"> <li>Collect known personal and family cancer history.</li> <li>Identify risk factors: assess tobacco and alcohol consumption, occupational exposures (asbestos), calculate BMI, etc.</li> </ul>	<b>EC</b>
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### Clinical Examination

<ul style="list-style-type: none"> <li>Perform a complete clinical examination (with a particular focus on lymphadenopathy).</li> <li>Dermatological consultation is recommended and mandatory if the individual is at high risk (fair skin type, history of sunburns especially in childhood, exposure to artificial UVs, high number of nevi, presence of atypical nevi, personal or family history of melanoma, immunosuppression, history of skin carcinoma).</li> <li>Gynaecological examination (by the patient's referring physician)</li> <li>Urological consultation for men (early detection of prostate cancer and other urological cancers according to the recommendations of the French Urological Association)</li> </ul>	<b>EC</b>
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### Screening Tests

<p>Screening is based on the general population screening guidelines in France. Regular updates consider recommendations from the Council of the European Union.</p> <ul style="list-style-type: none"> <li>Screening for colorectal cancer or precancerous lesions (polyps) according to the current recommendations of the French HAS.</li> <li>Breast cancer screening according to the guidelines from the Senology Commission of the French National College of Gynecologists and Obstetricians (CNGOF): perform a breast examination starting at age 40.</li> <li>Cervical cancer screening with detection of oncogenic human papillomavirus according to the current recommendations of the French HAS.</li> <li>In cases of family history of early cancers, genetic counselling may be suggested.</li> </ul>	<b>A</b>
<ul style="list-style-type: none"> <li>Lung cancer screening: there is no organised lung cancer screening program in France yet. Low-dose chest CT is recommended for living donors (instead of chest X-ray).</li> <li>Stomatological and ear-nose-throat examinations starting at age 50 for current smokers or those who quit &lt; 10 years ago with &gt; 15 pack-years.</li> <li>Screening for kidney cancer and other cancers: systematic abdominopelvic CT during renal anatomy evaluation pre-donation serves as screening for intra-abdominal and particularly urological tumours.</li> <li>Prostate cancer screening and prostate-specific antigen testing according to French Urological Association recommendations.</li> <li>Screening for monoclonal gammopathy by serum protein electrophoresis.</li> </ul>	<b>B</b>

## Known Cancer History Before Donation

<p>The KDIGO 2017 guidelines suggest accepting donors with a known cancer history if they present both a low risk of transmission to the recipient (&lt; 1% according to current transplantation knowledge) and a low risk of long-term recurrence for the donor (&lt; 1%, according to updated oncology results). Therefore, the donation possibility must be validated in a pre-transplant multidisciplinary team meeting with the donor’s oncologist (or the oncology reference person at the transplant center).</p> <p>Moreover, the donor must agree to share their cancer history data with the recipient, and the recipient must be informed of the risks and benefits before agreeing to proceed with the donation and transplantation project under these circumstances.</p>	EC
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## Urological Cancers

### Prostate Cancer

<p>A potential kidney donor should not be excluded, but rather urological advice should be sought on a case-by-case basis with the following:</p> <ul style="list-style-type: none"> <li>• A recent diagnosis of prostate cancer;</li> <li>• Untreated prostate cancer under active surveillance;</li> <li>• In general, any history of prostate cancer.</li> </ul> <p>Kidney donation from a living donor may be authorised in cases of limited prostate cancer or after treatment deemed effective.</p>	EC
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### Renal Carcinomas

<p>The incidental discovery of a renal mass during a pre-donation evaluation must be histologically characterised and managed similar to the general population outside the donation context.</p> <p>The possibility of a total nephrectomy with lesion removal before transplantation may be discussed in certain situations after informing the donor and recipient about the benefits and risks of the procedure.</p> <p>The shared decision for organ retrieval must be discussed in the potential donor's interest, considering all other therapeutic options (partial nephrectomy, radiotherapy, cryotherapy, etc.).</p> <p>The histological evaluation of the renal mass should first be performed by biopsy, preferably under CT guidance.</p> <p>When the lesion has favourable size and/or histological characteristics, a benefit–risk analysis should be conducted on a case-by-case basis in a multidisciplinary meeting.</p> <p>For cystic lesions, urological advice is necessary on a case-by-case basis in a multidisciplinary meeting.</p> <p>In case of a history of renal carcinoma, urological advice is necessary on a case-by-case basis in a multidisciplinary meeting.</p>	EC
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### Renal Angiomyolipoma (AML)

<p>The presence of bilateral AML is a contraindication to donation.</p> <p>The presence of a unilateral AML is not a contraindication to donation and the AML will be resected during organ retrieval.</p> <p>A small AML (&lt; 1 cm) may be left in place in a donor if the donor is not a woman of childbearing age.</p>	EC
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## Urothelial Carcinomas

A history of bladder cancer or urothelial carcinoma is considered high risk for transmission to the recipient and recurrence in the donor and represents a contraindication to donation.

EC

## Testicular Tumours

Given the good response to treatment of testicular tumours, a potential donor with a history of stage I testicular cancer in complete remission (negative markers) with a follow-up of 5 years may be accepted.

For other situations, a more cautious approach is recommended.

In all cases, urological advice in a multidisciplinary meeting is necessary.

EC

## Adrenal Tumours

If there is any doubt about the nature of an adrenal mass discovered during routine CT scanning, the case should be discussed in a multidisciplinary meeting and/or with a reference center for adrenal cancer ([www.surrenales.com/reseaux-specialises-surrenales/institut-national-du-cancer-comete/](http://www.surrenales.com/reseaux-specialises-surrenales/institut-national-du-cancer-comete/)).

EC

## Breast Cancer – Recommendations of the Senology Commission of the French National College of Gynecologists and Obstetricians (CNGOF)

In case of a personal history of breast cancer, a complete assessment (mammography, ultrasonography or breast MRI, CA 15-3 tumour marker assay, or PET-CT) is indicated. Eligibility can be determined by a network of experts from the CNGOF Senology Commission.

**Ductal carcinoma *in situ*, papillary carcinoma *in situ*, encapsulated papillary carcinoma, microinvasive ductal carcinoma:** no contraindication to donation, no follow-up period required.

**Progressive cancers,** regardless of stage: contraindication to donation.

**Stage 1a, 1b, and 2a invasive ductal carcinoma, treated more than 5 years ago,** with a recent (< 1 year) normal re-evaluation, including a head, chest, abdominal and pelvic CT scan with analysis of mammary and lymph node areas: no contraindication to donation.

**Invasive lobular carcinoma:** due to the risks of late transmission of cancer cells, collegial advice is recommended.

**Cancers with a good histological prognosis** (e.g., tubular cancer, secretory cancer): favourable opinion even if < 5 years have passed, with a recent and normal re-evaluation.

**Stage 1a, 1b, or 2a breast cancer in men,** treated > 5 years ago, with a recent (< 1 year) normal re-evaluation: collegial advice is recommended. Other situations of breast cancer in men are contraindications to donation.

**Distant family history of breast cancer** (sporadic case in the family, second-degree relative), without identified genetic mutation: does not constitute an exclusion criterion for a female donor.

**In case of high familial risk:** history of early-onset breast cancer, bilateral cancers, breast cancer in first-degree relatives, or associated with ovarian or male breast cancer, or if a deleterious mutation in a breast cancer susceptibility gene is identified, expert advice with oncogeneticists present is recommended.

EC



## Lung Cancer

<p>According to patient survival tables and recurrence-free survival, donors with a history of microinvasive adenocarcinoma T1aN0, with a follow-up of &gt; 5 years after surgery and without neoadjuvant therapy, may be considered. The decision on eligibility for donation requires presenting these cases in an oncology multidisciplinary meeting with the referring oncologist of the patient or the transplant center.</p> <p>Genetic testing should be considered if the carcinoma occurred at a young age in the donor (&lt; 40 years), and the recipient relative should be screened.</p>	EC
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## Digestive System Cancers

<p>According to patient survival tables and recurrence-free survival, donors with a history of T1N0M0 or T2 or T3, N0M0 gastric or rectal carcinoma before any neoadjuvant treatment and those with a history of T1N0M0 or T2 or T3, N0M0 colon cancer after surgery and without neoadjuvant therapy, with a follow-up of &gt; 5 years, may be considered. The decision on eligibility for donation requires presenting these cases in an oncology multidisciplinary meeting with the referring oncologist of the patient or the transplant center.</p> <p>Genetic testing should be considered if the carcinoma occurred at a young age in the donor (&lt; 40 years), and the recipient relative should be screened.</p>	EC
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## Non-Melanoma Skin Carcinomas

<p>A history of <b>basal cell carcinoma</b> is not a contraindication to donation.</p> <p>A history of <b>cutaneous squamous cell carcinoma</b> (non-mucosal) without severe risk factors and fully resected is not a contraindication to donation (2020 Guidelines, under revision in 2023, from the European Association of Dermato Oncology).</p> <p><b>Merkel cell carcinoma</b> is a contraindication to donation.</p> <p>A history of <b>adnexal carcinomas</b> should be discussed on a case-by-case basis.</p> <p>A history of <b>Kaposi's sarcoma</b> is a contraindication to donation.</p>	EC
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## Melanomas

<p><b>The discovery</b> of a melanoma during pre-donation examinations should contraindicate donation, except for strictly in situ lesions with a re-evaluation of the slides.</p> <p><b>A history</b> of <i>in situ</i> melanoma does not contraindicate donation.</p> <p>Donors with a lesion diagnosed &gt; 5 years ago, with a Breslow thickness &lt; 0.5 mm, with a zero mitotic index, without ulceration, or lymph node dissemination may be considered after obtaining precise dermatological data (histopathology with re-evaluation of slides, staging, and treatment) and in oncological-dermatological consultation.</p> <p>Other melanomas carry a high risk of transmission because of the possible long-term dormancy of tumour cells and are a contraindication to donation.</p>	EC
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## Thyroid Cancers

Except for anaplastic cancers, which have a poor prognosis, thyroid cancers generally have an excellent 10-year survival rate of 95%.

Donation will be allowed without restriction in cases of a history of microthyroid carcinoma (< 10 mm). For other thyroid cancers, expert advice is necessary.

EC

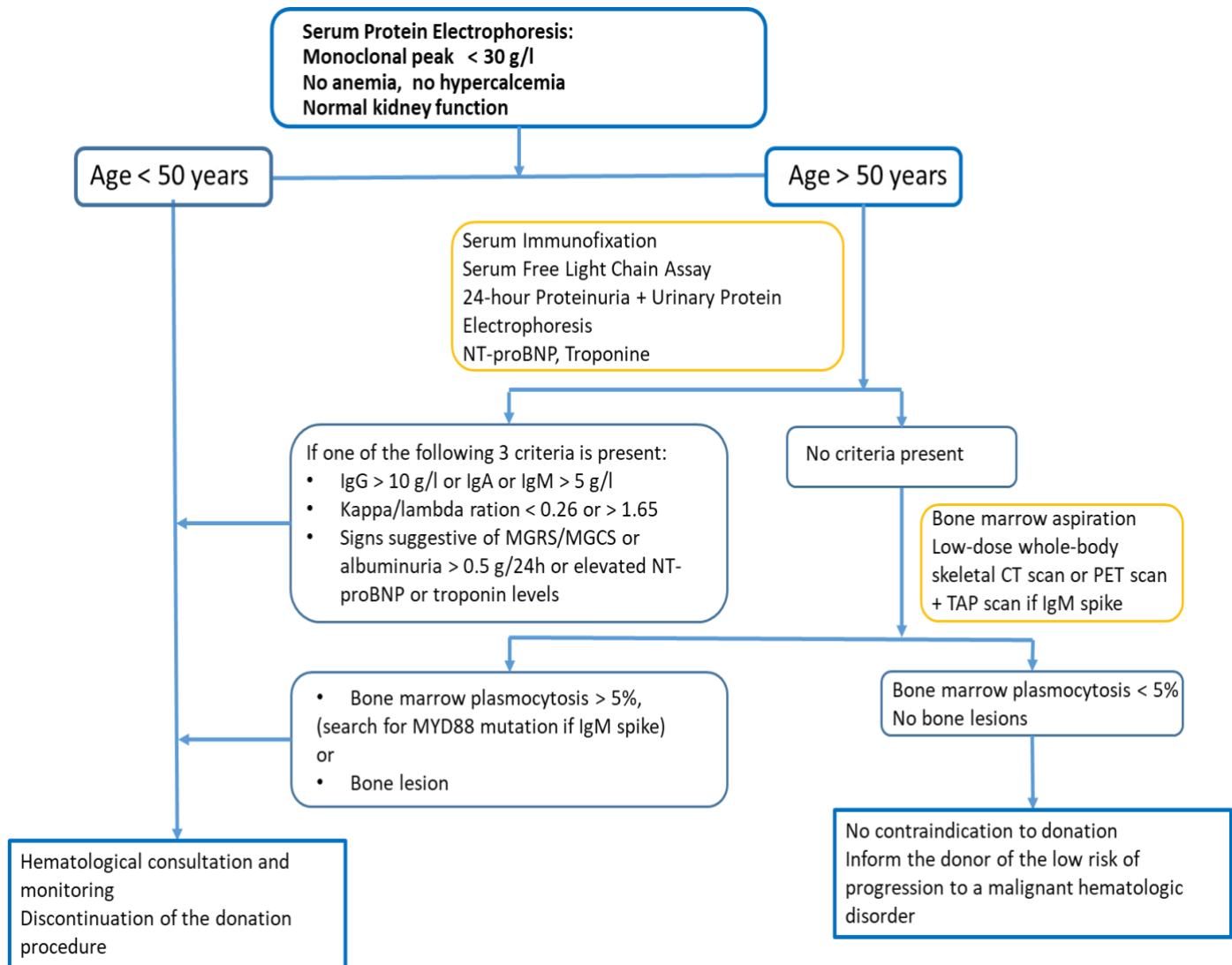
## Monoclonal Gammopathies of Undetermined Significance (MGUS)

MGUS does not contraindicate donation in a potential donor > 50 years old with a low risk of progression to malignant hemopathy, who is informed of this risk and wishes to proceed with the donation process.

Donation is not recommended if MGUS is discovered in a potential donor < 50 years old. A multidisciplinary meeting is essential.

The prospective recipient will be informed of the very low risk of developing a malignant hemopathy transmitted by the donor's lymphoplasmacytic cells.

EC



Decision-making flowchart for the management of a newly discovered monoclonal gammopathy

## SURGICAL ASPECTS

*Extract from the French Recommendations of the Transplantation Committee of the French Association of Urology (CTAFU): Nephrectomy for Kidney Donation. Prog Urol, 2021*

<b>Anatomical Evaluation of the Donor</b>	<b>Grade</b>
A multi-detector abdominopelvic CT scan with four phases (without contrast, arterial, tubular, and delayed) is the reference pre-donation examination.	Moderate
The left kidney is preferably harvested.	Moderate
The right kidney can be harvested, if necessary, without increased risk of complications.	Moderate
A functional difference of > 10% should be considered in the decision of which side to harvest.	Low
Multiple arterial or venous vascularisation is not an absolute contraindication to donation.	Low

<b>Nephrectomy Technique for Kidney Donation</b>	<b>Grade</b>
Minimally invasive nephrectomy techniques for kidney donation provide functional transplant outcomes equivalent to those of open surgery.	Moderate
Minimally invasive techniques allow for faster recovery and reduced postoperative pain for the donor.	Low
The use of Hem-o-lok® clips should be accompanied by an additional control method (ligation) for the control of the main left renal artery in nephrectomy for kidney donation.	Low

## PSYCHOLOGICAL AND SOCIAL ASPECTS

At least one meeting or consultation with a clinical psychologist affiliated with the transplant service is recommended.	B
A consultation with a psychiatrist is recommended in cases of personal or even family psychiatric history, or if there are suspected mental health issues.	EC
<p><b>In the case of paediatric kidney transplantation</b> with a living donor, the following is recommended:</p> <ul style="list-style-type: none"> <li>▪ Systematically offer a family meeting with the parents and the child with a clinical psychologist from the paediatric service and a one-on-one meeting with the child as soon as they are able to express themselves;</li> <li>▪ Systematically offer a meeting for the donor parent with a clinical psychologist from the adult service;</li> <li>▪ Ensure coordination between the adult retrieval team and the paediatric transplant team.</li> </ul>	EC
Standardised assessment scores can be useful in more effectively identifying individuals at psychological or social risk post-donation, allowing for enhanced care pathways before and after donation, such as involving a social worker or providing increased psychological support.	B
Beyond the pre-donation evaluation, psychological support for the donor and their family, as well as for the recipient, should be considered throughout the entire process, particularly during the postoperative period and follow-up care.	EC

# ANAESTHETIC MANAGEMENT

## Pre-Donation Anaesthesia Consultation and Criteria for Thrombophilia Screening

The anaesthesia consultation and risk assessment should be performed according to the recommendations of the French Society of Anaesthesia and Resuscitation (SFAR), the French Society of Cardiology, and the European Society of Cardiology: <b><i>Preoperative Cardiovascular Assessment of Patients Undergoing Non-Cardiac Surgery.</i></b>	EC
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### Transfusion Risk

The donor should be informed of the potential risk of bleeding and the use of blood and blood products, as well as the possible complications of transfusion. This risk can be reduced by implementing a personalised blood management program following the July 2022 recommendations of the French HAS on pre-, peri-, and postoperative blood management.	B
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### Thrombophilia Screening

In the absence of a personal history of thromboembolism, biological thrombophilia screening is not necessary before kidney donation unless there is an informative family history (i.e., two or more first-degree relatives with a history of venous thrombosis or pulmonary embolism).	C
According to the 2021 French guidelines for the management of venous thromboembolic disease, when constitutional thrombophilia screening is indicated in asymptomatic relatives, the individual should be referred to a certified thrombosis expert center.	B
Constitutional thrombophilia screening should be limited to testing for Factor V and prothrombin mutations and measuring antithrombin, protein C, and protein S levels.	B
The presence of a major constitutional thrombophilia, such as antithrombin deficiency, contraindicates donation even without a personal history of thromboembolism.	C
The presence of biologico-clinical thrombophilia, such as antiphospholipid syndrome, contraindicates donation.	C
In the absence of a personal history of thrombosis, the detection of minor thrombophilia, such as heterozygous Factor V Leiden or heterozygous 20210A mutation, does not contraindicate donation.	C
In cases of a history of a single distal thrombosis, subpopliteal, without pulmonary embolism, in the context of oestrogen-progestin contraception or after major surgery, there is no contraindication to donation because the risk of recurrence is very low.	C
Personal multiple thromboembolic events or a history of pulmonary embolism with significant residual obstruction or severe unprovoked pulmonary embolism constitute a contraindication to donation.	C
In other cases, an updated recurrence risk assessment should be performed by referring the patient to a multidisciplinary thrombosis team.	C

## Smoking Cessation Counselling

The recommendations drafted under the auspices of the French SFAR and the French Office for Tobacco Prevention should be implemented. All healthcare professionals involved in the care pathway should inform smokers about the positive effects of quitting smoking and offer them tailored care and personalised follow-up.	B
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## Perioperative Management of the Donor

Units should have a written protocol detailing the specific points of perioperative management of kidney donors and their perioperative pathway, including periodic pain assessment during the first postoperative days and postoperative analgesia techniques. This protocol should be reviewed regularly and updated if necessary.	EC
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## Thromboembolism Prevention

The risk associated with nephrectomy surgery by laparoscopy in a living donor with a low risk of venous thromboembolic disease (VTE) is considered low.	EC
In cases of laparoscopic nephrectomy, after consultation with the Perioperative Hemostasis Interest Group, the following is recommended: <ul style="list-style-type: none"><li>No pharmacological thromboprophylaxis if the pathway is optimised (in terms of short operative time and early mobilisation) in a low-risk donor (absence of VTE risk factors);</li><li>Pharmacological thromboprophylaxis if the pathway is not optimised (in terms of operative time or delayed mobilisation) or in a donor with a VTE risk factor. Pharmacological prophylaxis should begin the day after surgery and continue for 7 days.</li></ul>	C
No mechanical thromboprophylaxis (elastic compression) is recommended. Early mobilisation is recommended. Intermittent pneumatic compression prophylaxis may be an alternative to pharmacological thromboprophylaxis.	EC

## Antibiotic Prophylaxis

To date, the expert formalised recommendations for antibiotic prophylaxis in surgery and interventional medicine published by the French SFAR in 2018 do not recommend routine perioperative antibiotic prophylaxis for nephrectomy (an update is scheduled for 2023).	EC
Urine must be confirmed sterile before nephrectomy (French Urological Association 2010).	C

## Type of General Anaesthesia: Inhalation versus Total Intravenous Anaesthesia

Current literature does not support a recommendation for a specific type of general anaesthesia.	EC
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## Fluid Resuscitation and Vasopressors

The application of a targeted fluid resuscitation strategy guided by a hemodynamic monitoring device to assess preload reserve is particularly desirable.	EC
Synthetic colloids no longer have a role in fluid resuscitation in patients.	B
Some studies have shown a benefit in using a balanced crystalloid solution rather than 0.9% sodium chloride to reduce renal adverse events in recipients, although this strategy is not documented in living donors.	B

## Analgesia

Perioperative and postoperative analgesia management largely depends on the surgical approach and technique used.

Multimodal analgesic management of the living donor is essential. The patient should have access to a range of therapeutic options, combining analgesics of all levels, administered systemically with early oral transition, and regional analgesia techniques. The benefit for chronic pain remains debated.

The use of non-steroidal anti-inflammatory drugs is an integral part of opioid-sparing strategies, with a favourable benefit–risk balance.

C

## Enhanced Recovery After Surgery: Pre-, Peri-, and Postoperative

The implementation of an enhanced recovery after surgery (ERAS) program is recommended in the care pathway for living donors.

C

# IMMUNOLOGICAL COMPATIBILITY BETWEEN DONOR AND RECIPIENT

## Molecules Involved in Donor–Recipient Compatibility

The compatibility assessment between a recipient and a living donor is based exclusively on ABO and HLA compatibility.	A
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## HLA Compatibility Analysis

<p>Performing two HLA typings is recommended for both the recipient and the donor:</p> <ul style="list-style-type: none"> <li>▪ <b>First Typing:</b> Perform high-resolution typing for all loci, if possible, or at least for A, B, C, DRB1, DQB1, DQA1, and DPB1.</li> <li>▪ <b>Second Typing:</b> Perform low-resolution typing to rule out sampling errors for A, B, DRB1, DQB1.</li> </ul>	EC
Optimising HLA matching is recommended between the recipient and living donor, particularly for DQ and DR molecules, to minimise the risk of humoral rejection and improve the survival of kidney allografts (considering older recipients). If there are multiple donor candidates, prioritise the donor with the best HLA and ABO compatibility, considering other risk factors, especially medical and socioeconomic ones.	A
Molecular analysis of HLA incompatibilities using available software (HLA Matchmaker, PIRCHE, HLA-EMMA, HLA EMS/HMS, etc.) can assist in selecting the best living donor.	A

## Anti-HLA Humoral Response Analysis Against the Donor

<b>Initial Testing:</b> Conduct an initial search for anti-HLA antibodies when the recipient is placed on the transplant waitlist by using sensitive techniques with Luminex screening and single antigen identification, regardless of screening results. Preserve the serum in a serum bank. The concept of negative screening and single antigen negativity is defined locally between the HLA laboratory and the transplant team.	B
<p><b>Monitoring of anti-HLA antibodies in individuals on the wait list</b> (recommendations from the Francophone- Society of Transplantation and the Francophone Society of Histocompatibility and Immunogenetics)</p> <ul style="list-style-type: none"> <li>▪ Perform blood draws every 3 months for building a serum bank and testing for anti-HLA antibodies using screening techniques and/or single antigen every 3 months.</li> <li>▪ Conduct a single antigen test within <b>15 days before</b> transplantation.</li> </ul>	B
<b>In the event of an immunising event</b> (transfusion, pregnancy, miscarriage, transplantectomy, or cessation of immunosuppressive therapy), take a blood sample to search for anti-HLA antibodies by single antigen technique and for the serum bank 1 month after transfusion and 3 months after delivery or miscarriage.	A
<b>On the day of transplantation</b> (without waiting for results): take a blood sample for the serum bank and/or to analyse anti-HLA antibodies using the single antigen technique.	EC



<b>Threshold for pathogenicity of DSAs:</b> There is no consensual threshold of mean fluorescence intensity in the literature to determine the pathogenicity of preformed DSAs.	A
Testing for the ability of antibodies to fix complement using single antigen tests is not recommended before kidney transplantation.	B
Testing for donor-specific T/B cells is not recommended before kidney transplantation.	B
<b>Assessing adaptive cellular memory</b> in the recipient is important for stratifying the immunological risk of transplantation. The following is recommended: <ul style="list-style-type: none"> <li>Investigate the presence of DSAs in historical* sera for patients without DSAs on Day 0.</li> <li>Review the recipient's pregnancy and miscarriage history to potentially perform HLA typing of the partner.</li> <li>Examine transplantation history to identify the HLA type of previous donor(s).</li> <li>Consider history of transfusions (red blood cells and platelets).</li> </ul>	EC
The presence of historical* DSAs not found on Day 0, repeated HLA incompatibilities without DSAs, and transplantation of a woman with a graft having HLA antigens identical to foetal-paternal antigens are <b>situations of immunological risk</b> but should not necessarily contraindicate transplantation.	C

\*All patient sera except the serum from the day of transplantation.

## Crossmatch

<b>Virtual Crossmatch:</b> During the initial assessment of the compatibility of candidate donors and the immunological risk of the recipient, check all sera of interest and a serum sample < 3 months old from the recipient for the absence of antibodies directed against antigens of the potential living donor(s), including all loci.	B
<b>Cellular Crossmatch:</b> A cellular crossmatch using lymphocytotoxicity (LCT) testing and/or flow cytometry (FCM) should be performed within 15 days before transplantation on T and B lymphocytes, including an examination of relevant historical sera and recent serum. <b>In case of an immunising event</b> between the crossmatch and transplantation, the transplantation should be postponed.	A
If a desensitisation protocol with rituximab is used, perform the crossmatch before rituximab administration (or perform rituximab inhibition).	C

## HLA-incompatible Transplantations with Preformed DSAs

If a recent serum crossmatch is positive on LCT testing, pre-immunisation desensitisation is essential to achieve a negative LCT crossmatch and permit kidney transplantation after a case-by-case discussion.	A
A kidney transplantation with a positive recent serum crossmatch on FCM is not an absolute contraindication but requires adjustments to the immunosuppressive strategy and a case-by-case discussion.	A
HLA-incompatible kidney transplants should be performed in a center with apheresis techniques available 7 days a week.	B
Inform the donor–recipient pair about the immunological risks associated with HLA-incompatible transplants.	EC

## ABO-incompatible Transplants

ABO-incompatible kidney transplants require preconditioning with apheresis and rituximab, which must be available 7 days a week. The specifics of this preconditioning will depend on the level of isohaemagglutinins.	A
For an A donor, A1 and A2 typing is advisable to help stratify the risk of rejection.	C
Measure IgG and IgM levels of isohaemagglutinins.	EC
Failure to achieve a sufficiently low level of isohaemagglutinins after preconditioning may contraindicate the transplant.	A
Inform the donor–recipient pair that ABO-incompatible kidney transplantation is associated with increased risk of humoral rejection, graft losses in the initial years, infections, and surgical complications (notably haemorrhagic) as compared with ABO-compatible transplants.	EC

## Paired Exchange Donation

Inform any immunologically incompatible donor–recipient pair about various transplantation options and their benefit–risk ratios: compatible transplantation within the paired donation program, ABO-incompatible transplantation, or HLA-incompatible transplantation.	EC
Register any immunologically incompatible donor–recipient pair in the paired donation program for a few months before considering ABO- or HLA-incompatible transplantation, depending on the chances of access and urgency.	C
Paired exchange donation can also help find better HLA compatibility, particularly Class II, between the recipient and donor.	B
Estimate each pair’s chances of access to a paired donation to assist clinicians and patients in making informed decisions and avoid directing pairs with a low chance of finding a possible exchange to this program.	EC

# LIVING KIDNEY TRANSPLANTATION IN PAEDIATRICS

Kidney transplantation from living donors is the preferred therapeutic option given the long-term outcomes and the improved access to pre-emptive grafting. Because of the extended lifespan of recipients, particular attention to donor quality in terms of age and HLA compatibility is required in paediatric cases.	A
ABO-incompatible transplantation should only be considered for paediatric recipients who have poor access to transplantation from a deceased donor, despite the implementation of possible priorities and exceptions.	EC
HLA-incompatible transplantation with preformed DSAs should only be considered with no access to an HLA-compatible graft from a living or deceased donor.	EC
Systematically identifying ABO-incompatible or HLA-incompatible living donors is recommended to assess the feasibility and potential impact of paired donation in paediatric cases.	EC

## Special Considerations for Paediatric Recipients Weighing < 20 kg

Kidney transplants for young children weighing < 20 kg who receive a kidney from an adult donor should be performed by an experienced transplantation team.	EC
A preoperative multidisciplinary meeting should be held to confirm the donor choice and the surgical approach with the surgeon performing the transplantation.	EC
A written protocol outlining the monitoring and specific hemodynamic management goals for these children (refer to the scientific rationale for specific management details) is recommended.	EC
Ultrasonography and Doppler examination are recommended in the operating room after closing the abdominal wall to verify proper kidney perfusion.	C

# RECOMMENDED PATHWAY FOR A LIVING KIDNEY DONOR CANDIDATE

## Preliminary Evaluation

Ionogram, calcium, phosphate, uric acid, bicarbonates, protein levels

Fasting glucose, HbA1c

Complete blood count, platelet count, prothrombin time, activated partial thromboplastin time, fibrinogen level, C-reactive protein level

Serum creatinine level and eGFR using the CKD-EPI or EKFC formula

Albumin-to-creatinine ratio, urine sediment measurement

AST, ALT, Gamma-GT, alkaline phosphatase, bilirubin levels

ABO grouping, Rh factor

Renal and pelvic ultrasonography

## Nephrology-transplantation Consultation

## Therapeutic Education Session

## Immunological Compatibility Assessment

Isohaemagglutinins if ABO incompatible

HLA Typing:

- Two determinations with two separate samples
- First determination: high-resolution typing for all loci if possible, or at least A, B, C, DRB1, DQB1, DQA1, and DPB1
- Second determination: low-resolution typing to rule out sampling errors for A, B, DRB1, DQB1

Anti-HLA Antibodies in the Recipient:

- Screening by Luminex and identification by single antigen technique regardless of screening results.
- Follow-up every 3 months for serum storage and antibody testing by Luminex and/or single antigen
- Within 15 days before transplantation: testing by single antigen technique

Compatibility Testing:

- Virtual crossmatch: during initial compatibility assessment of donor candidate and recipient immunological risk, check for antibodies against donor antigens in all relevant sera and a serum sample from the recipient < 3 months old, including all loci.
- Cellular crossmatch: before transplantation, perform LCT testing and/or FCM crossmatch on T and B lymphocytes, including analysis of relevant historical sera and a recent serum sample (< 15 days old).
- If using a desensitisation protocol with rituximab, perform the crossmatch before rituximab injection (or perform rituximab inhibition).

## Renal Evaluation

Measure eGFR using a reference technique (Iohexol, 99mTc-DTPA)

Albumin-to-creatinine ratio, urine sediment (second evaluation)

Urine cytobacteriological examination

Renal angiography (CT scan with 4-phase imaging)

### **Cardiovascular Assessment:**

Standard blood pressure measurement

Ambulatory blood pressure measurement (self-monitoring or 24-hour ambulatory blood pressure monitoring) if hypertension present

ECG

Troponin I/T hs, BNP or NT-proBNP if at least one cardiovascular risk factor

Echocardiography

Cardiology consultation if age  $\geq$  50 years or at least one cardiovascular risk factor

If multiple cardiovascular risk factors, including age  $\geq$  65 years:

- Physical or pharmacological stress imaging: myocardial scintigraphy, stress echocardiography, or stress MRI
- Coronary CT scan may be considered for low or intermediate clinical probability of coronary artery disease or in patients unable to undergo non-invasive functional tests.

### **Metabolic Assessment**

Fasting glucose and HbA1c

Oral glucose tolerance test if:

- Fasting glucose is 1.1–1.25 g/L (6.1– 6.9 mmol/L)
- Presence of diabetes risk factors:
  - First-degree family history of diabetes,
  - Personal history of gestational diabetes,
  - BMI  $\geq$  28 kg/m<sup>2</sup>,
  - Waist circumference > 88 cm (women) and 102 cm (men),
  - Hypertension > 140/90 mmHg,
  - Hypertriglyceridemia > 2.50 g/L, low HDL < 0.35 g/L.
- Estimated 10-year diabetes risk > 30% (using prediction scores, e.g., FINDRISC)

Cholesterol: total, LDL, HDL, triglycerides

### **Oncological Screening**

Family cancer history

Serum protein electrophoresis

Abdominopelvic CT scan with contrast

Low-dose chest CT scan

Ear-nose-throat, dental consultation based on smoking history

Dermatology consultation recommended and mandatory if high risk

Urology consultation for early prostate cancer detection per French Urology Association recommendations and urological cancer screening

Gynaecology consultation, Pap smear per French HAS recommendations; mammography for women > 40 years old

Colorectal cancer screening per French HAS recommendations

## **Screening for Transmissible Infectious Diseases**

- Urine cytobacteriological examination
- HIV Testing: combined HIV test (including HIV-1 and HIV-2 serology and P24 antigen test) and HIV viral genome detection (VGD)
- HTLV-1 and HTLV-2 serology
- HCV serology and HCV VGD
- HBV serology and HBV VGD
- Syphilis serology, TPHA test
- Toxoplasmosis serology
- CMV serology
- EBV serology
- Strongyloidiasis serology
- HEV VGD within the week preceding donation.
- WNV VGD and West Nile Virus serology (at least IgM) in case of recent stay in an affected area (as close to donation as possible)
- In case of emerging viruses, such as SARS-CoV-2, during epidemic periods, the recommendations of the High Council for Public Health and, if applicable, other bodies such as scientific societies and the French Biomedicine Agency, must be followed.
- HHV-8 serology if donor tests are positive for HIV markers
- Depending on the travel history, movements, and non-resident donors, other transmissible agents may be screened, including tuberculosis screening by Quantiferon based on context and habitus.

## **Psychological Evaluation by a Clinical Psychologist or Psychiatrist and Social Assessment**

### **Anaesthesia Consultation and Screening for Thrombophilia as Applicable**

### **Geriatric Consultation if the Donor is $\geq$ 70 Years Old**

### **Consultation with the Surgeon Performing the Donation**

### **Urology Consultation if There are Urological Anomalies (including anatomical variations in the urinary tract, kidney cysts, or stones)**

### **Multidisciplinary Team Discussion including the Medical-surgical Team**

### **Appointment for Hearing with the Living Donor Committee and Court Registration by the Donor.**

# ORGANISATION AND PARTICIPANTS

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Francophone Society of Nephrology, Dialysis and Transplantation (SFNDT)

Francophone Society of Histocompatibility and Immunogenetics (SFHI)

French Society of Anaesthesia and Resuscitation (SFAR)

## Consulted patient and user associations and professional organisations

The following patient and user associations, as well as professional organisations, were consulted to ask experts invited individually to participate in the working and/or review groups:

- **Patient and User Associations:** Association pour l'Information et la Recherche sur les Maladies Rénales Génétiques (AIRG), Association Française des Familles pour le Don d'Organes (AFFDO), France ADOT, France Rein, Greffe de Vie, Renaloo, Transform.
- **Professional Organisations:** Collège National des Gynécologues et Obstétriciens Français (CNGOF), Comité de Transplantation et d'Insuffisance Rénale Chronique de l'Association Française d'Urologie (CTAFU), Groupe d'Intérêt en Hémostase Périopératoire (GIHP), Société Française de Médecine Vasculaire (SFMV).

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