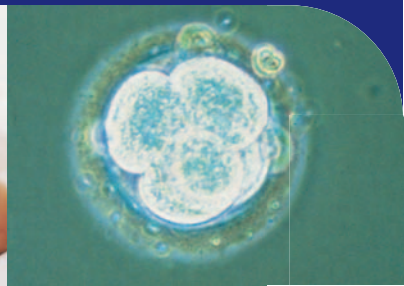
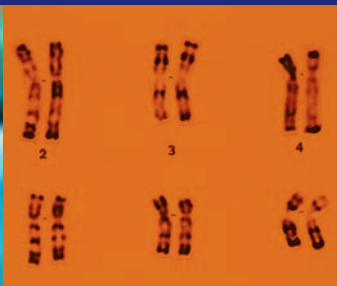


The French Biomedicine Agency:  
**missions** and objectives





## Safety and quality

Drawing on the skills of medical and scientific experts, the French Biomedicine Agency works with professionals to develop guidelines for harmonizing and developing medical practices. By issuing opinions, approvals and authorizations, and ensuring that they are properly applied, the agency guarantees that patients throughout France benefit from the highest levels of safety and quality.

## Ethics

The agency contributes to the development of homogeneous quality treatment that is accessible to all. It ensures that health professionals respect the legal provisions on using parts of the human body and the French rules concerning the free, anonymous and consenting donation of organs, tissues, cells, gametes and embryos. It calls for and contributes to public debates on topics under its responsibility.

## Transparency

The agency accords an important role to civil society in its constitutive organisation. It evaluates medical activities and makes these evaluations available to the government, parliament,

professionals and society as a whole. It conducts information campaigns to foster understanding of its activities and the ensuing challenges. Each year, the agency publishes a report of its activities.

## Looking forward

By closely tracking evolving knowledge and techniques, the French Biomedicine Agency raises authorities' awareness about new possibilities and makes recommendations. It participates in drafting regulations and defining new scenarios for organising health care in France. It encourages research and promotes international cooperation in its fields of activity.

## Eight priorities for 2005-2008

- Continue improving access to organ, tissue and cell transplants
- Improve care for assisted reproductive technologies, prenatal diagnosis and the examination of genetic characteristics
- Develop and ensure the quality, safety and evaluation of medical activities and practices
- Deliver authorizations and approvals, and monitor them
- Contribute to ethical debate, and to the dissemination and respect of ethical principles in activities within the agency's scope
- Promote research in the agency's areas of activity and foster respect for ethical principles in embryo research
- Develop information for authorities, health professionals and French citizens
- Contribute effectively to regulatory and international activities as well as public health policies

**The French Biomedicine Agency is the only agency in Europe covering the four areas of transplantation, procreation, embryology and genetics. It has forged close links with medical teams and patients, thanks to its 24/7 operational role of managing the list of patients awaiting transplants, and distributing and allocating transplantable organs.**

# Fields covered by the French

<b>Reproductive cells</b>	<ul style="list-style-type: none"><li>• <b>Assisted reproductive technologies:</b> artificial insemination, in vitro fertilization and all other non-natural procreation techniques, including gamete donation</li></ul>
<b>In vitro embryos</b>	<ul style="list-style-type: none"><li>• <b>Pre-implantation genetic diagnosis:</b> genetic diagnosis on a cell procured from the in vitro embryo, carried out before implantation in the uterus</li></ul>
<b>In vivo embryos and foetuses</b>	<ul style="list-style-type: none"><li>• <b>Prenatal diagnosis (PND):</b> chromosome genetic diagnosis (study of the shape and number of chromosomes), molecular genetic diagnosis (research on the DNA structure), or biochemical, infectiological</li></ul>
<b>Birth or abortion</b>	<ul style="list-style-type: none"><li>• <b>Cells procured from the blood in the umbilical cord</b></li></ul>
<b>Any living persons</b>	<ul style="list-style-type: none"><li>• <b>Genetic diagnosis</b> on persons with symptoms (cystic fibrosis, Duchennes muscular dystrophy, haemophilia, etc.) or without symptoms (late appearing diseases such as Huntington's Disease)</li></ul>
<b>Deceased persons</b>	<ul style="list-style-type: none"><li>• <b>Procurement of organs, tissues and cells</b></li></ul>

1. A stored embryo can be donated to a couple from parents no longer requiring assisted reproductive technologies.

# Biomedicine Agency

- **Storage of human gametes**

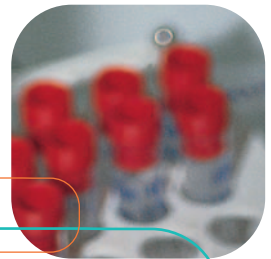
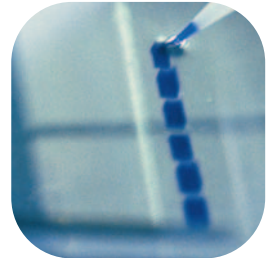
- **Storage and donation<sup>1</sup> of human embryos**
- **Research on embryos and human embryonic stem cells**

and immunological diagnosis using samples from a foetus, its related tissues or the mother

- **Procurement of tissues and cells from an aborted foetus** for transplants or research

- **Genetic diagnosis** based on predisposition factors (breast cancer) or the study of risks in families
- **Procurement of organs, tissues and cells**
- **Organ, tissue and cell transplants**

- **Storage of tissues and cells**



## Procurement and transplants of organs, tissues and cells

Every year, **11,000 patients** require organ transplants in France and yet in 2004 only **4,000** were carried out, indicating a serious shortage. The Bioethics Law of August 6, 2004 raises the question of organ procurement and transplants to the level of national priority, whereby every health institution is required to participate in organ procurement.

### Mobilize all resources to increase the number of transplants

This was a key priority of L'Établissement français des Greffes (the French Transplant Agency), and the French Biomedicine Agency will pursue the objective. Working with health professionals, the agency contributes to a more effective territorial organisation for procurements and transplants. It works towards improving the quality of transplant organs and expanding the circle of potential organ donors. It also develops training on how to assist mourning families in hospitals. In addition, the agency ensures that surgical teams have the means to carry out a higher number of transplants. Finally, it aims to encourage the general public to express to family and friends their position on organ and tissue donation.



### 3,945 organ transplants in 2004

In 2004, France performed 3,945 organ transplants, including 2,421 kidney transplants, 931 liver transplants, 317 heart transplants, 145 lung transplants and 102 pancreas transplants.

In addition, more than 4,000 cornea transplants were carried out.

Medical teams carry out more than 900 haematopoietic allografts every year, of which a third involve donors unrelated to the patient.





## Ten years of progress

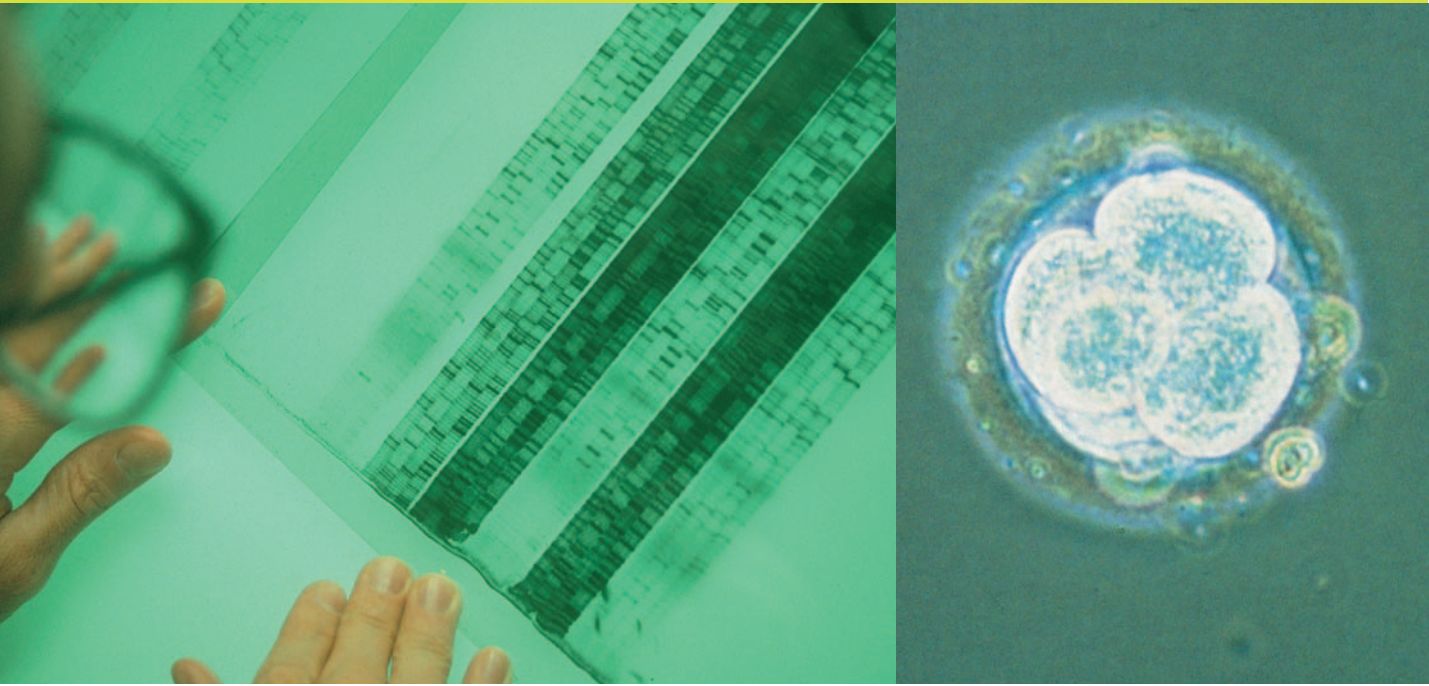
The progress achieved by L'Établissement français des Greffes (the French Transplant Agency, now the French Biomedicine Agency) includes:

- Adapting rules for organ distribution
- Organising tissue banks
- Publishing centre-specific organ and cell transplant results
- Acknowledging and increasing the budget for organ procurement and transplants
- Working continuously with transplant teams, leading to achievements such as doubling the 2004 number of lung transplants
- Setting up a kidney transplant team in the French West Indies



## The French Biomedicine Agency's role in organ procurement and transplants

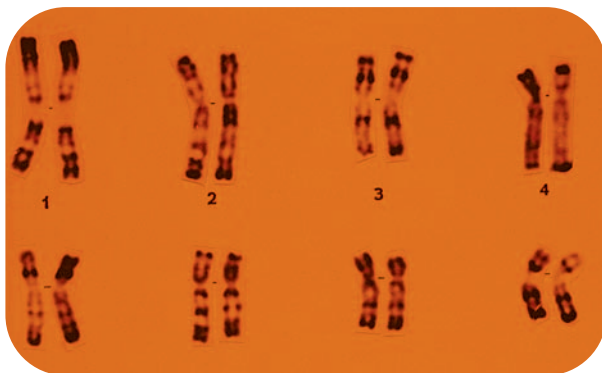
- Managing the nationwide list of patients awaiting transplants
- Managing the national register of those who refuse to be donors
- Developing the national database of volunteer donors of haematopoietic stem cells
- Developing rules for distributing donor organs
- Coordinating organ procurement, and their distribution and allocation in France and abroad
- Evaluating procurement and transplantation activities
- Organising expert committees for authorizing procurement from living donors
- Developing information on donating, procuring and transplanting organs, tissues and cells



## Assisted reproductive technologies, prenatal and genetic diagnosis

### Fast developing practices

Assisted reproductive and diagnosis activities have developed rapidly due to progress in knowledge and techniques, as well as social pressure. This underlines the need to monitor medical practices and make patient care efforts more consistent.



Practitioners also wish to pool opinions on the social issues raised by these topics.

### Ensuring the safety of healthcare

The French Biomedicine Agency represents the first grouping under one authority of assisted reproductive technologies with prenatal and genetic diagnosis. Its task is to approve the practitioners concerned, authorize such activities as multidisciplinary prenatal diagnosis centres, and verify compliance with the legal framework. It must also establish and publish a detailed inventory of the resources deployed and the results in France.

The agency must also compile registers to monitor the health of women who have undergone in vitro fertilization, children born using this technique, and women who donate oocytes.

A further priority is to upgrade the quality of treatment and harmonize patient care. The agency must work with practitioners towards establishing medical best practice. It will identify areas for progress, such as improving the

## > THOUSANDS OF PEOPLE CONCERNED

Recorded every year in France:

- 780,000 births
- 9,500 births following in vitro fertilization
- 4,000 births following artificial insemination
- 80,000 amniotic samples taken for chromosome diagnosis
- 600,000 serum tests on pregnant women's blood (to evaluate the risk of a chromosome abnormality in the foetus)
- 5,000 medical abortions linked to a prenatal diagnosis



quality of embryos transferred during in vitro fertilization so that their number can be limited and the risks of multiple pregnancies reduced, or evaluating the impact on families of systematic genetic screening.

The agency must act as an opinion leader in the ethical debate through a steering committee. Numerous questions are raised by health professionals and patients: Is there a specific age beyond which assisted reproductive technologies should no longer be offered? Which recommendations for parents who suffer from serious genetic diseases and wish to have healthy children?

## The French Biomedicine Agency's **specific remit** for assisted reproductive technologies and for diagnosis

- Authorize multidisciplinary centres for prenatal diagnosis
- Authorize pre-implantation genetic diagnosis centres and approve practitioners
- Approve biologists to carry out prenatal diagnosis
- Approve practitioners for clinical and biological activities in assisted reproductive technologies
- Deliver official opinions on authorizations granted to centres for assisted reproductive technologies
- Set up a monitoring scheme for clinical and biological activities associated with assisted reproductive technologies
- Evaluate activities in assisted reproductive technologies, prenatal and genetic diagnosis
- Set up a health monitoring service for women undergoing assisted reproductive technologies, children conceived by this method, and oocyte donors
- Provide information about gamete donation
- Authorize imports and exports of gametes or embryos

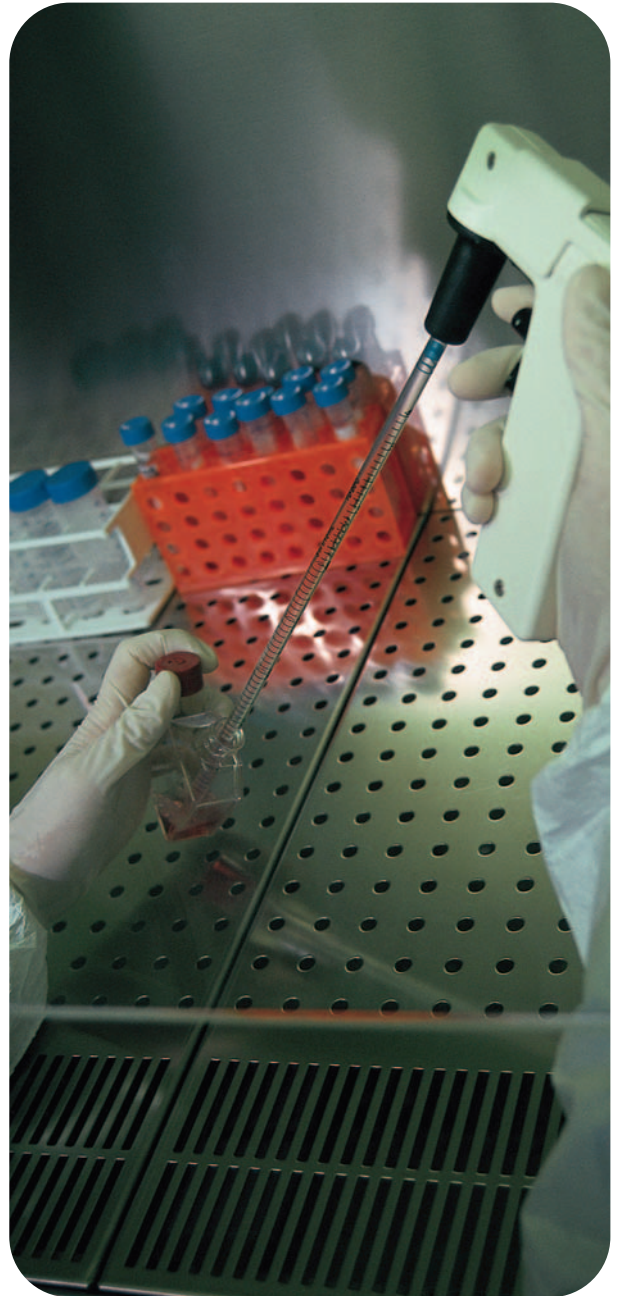
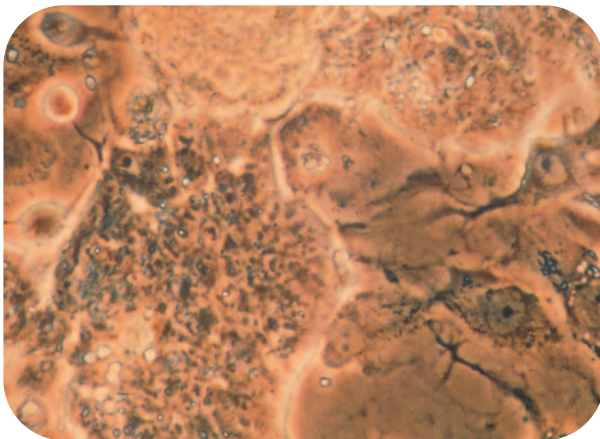
## Research on embryos and embryonic stem cells

### Enabling controlled research

Research on embryos is in principle prohibited in France. Exceptionally, the Bioethics Law of August 6, 2004 permits therapy-driven research under highly controlled conditions for a period of five years. Authorized researchers can work on supernumerary embryos from in vitro fertilization that are no longer required by parents, under the protocols authorized by the French Biomedicine Agency.

The agency ensures that this work complies with the conditions of authorization and ethical rules. It also delivers authorizations for importing, storing and disposing of embryo tissues and cells required for research purposes. If the conditions of authorization are not respected, the agency can suspend or withdraw a permit.

After five years' experience, the agency will evaluate the results and publish a report that will act as the basis for any possible extension of these authorizations.



# The French Biomedicine Agency: organisation

**The French Biomedicine Agency has its head office in Saint-Denis near Paris, where two main policies are defined:**

- the agency's medical policy and monitoring of its application, in relation with a number of expert groups,
- information and communication policy towards professionals and the general public.

**The head office also houses:**

- the computer systems required to carry out agency missions and evaluate care activities,
- the management of existing or future national registers: patients awaiting organ and cornea transplants, those who refuse to be donors of organs and tissues, volunteer donors of haematopoietic stem cells, children born of in vitro fertilization, oocyte donors, etc.,
- a training and information centre.

**In the provinces, regulation and support departments represent the agency and ensure 24/7 missions for procurement and transplantation.**

**The French Biomedicine Agency is equipped with:**

- an executive board of representatives from different ministries and public health bodies, together with key figures qualified in the agency's fields of activity,
- a steering committee which supervises the consistency of the Agency's medical and scientific policy, and compliance with the regulatory and ethical principles applicable to its activities. It comprises scientific and medical experts, representatives from associations, qualified key figures, members of different institutions (e.g., the French Consultative Committee for Ethics, and the French Consultative Commission for Human Rights), as well as Members of Parliament.

The agency draws on a medical and scientific committee and on groups of experts for its medical and scientific expertise.

Working closely with these different experts, the French Biomedicine Agency organises discussions with doctors, scientists, authorities and the general public.



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