

# **PLASMA DONOR POLICY**

# **INTRODUCTION**

Grifols aims to enhance the health and well-being of people around the world since its origins.

Plasma is an essential raw material in the manufacture of plasma-derived therapies, which are used to treat rare, chronic, severe, often genetically inherited and potentially life-threatening conditions.

Plasma cannot be produced in a laboratory or via small-molecule synthesis. Rather, hundreds and if not thousands of donations are needed to produce plasma-based medicines. Grifols supports Donors in several ways in appreciation of their generosity, time and effort to regularly donate plasma.

Plasma donations are voluntary and take place in specialized plasma-donation or blood centers via plasmapheresis, a process that removes plasma (source plasma) from whole blood and immediately reintroduces blood cells and platelets back into the Donor's body. Donations take approximately an hour (or more) and can be performed with greater frequency than blood donations since only the plasma is retained and the body quickly regenerates plasma.

Grifols compensates Donors monetarily, as an act of justice and return, for their commitment and solidarity, as well as the significant time, associated costs and efforts involved in donating plasma. This compensation is aligned with the economic situation of each country and/or region where Grifols' donor centers are located, as well as to legal requirements, to ensure that there is no undue influence or economic coercion of Donors.

Grifols' commitment to Donors extends to the communities where Donors centers are located. Grifols' donor centers create jobs, promote local economies and engage residents through a range of outreach activities.

#### **PURPOSE**

This Plasma Donor Policy (the "**Policy**") offers a framework to guide the interactions of Grifols with plasma donors (the "**Donors**").

#### **SCOPE**

This Policy applies to all employees of Grifols, S.A. and its subsidiaries and affiliated companies ("**Grifols**") to guide their relations with Donors.

# PRINCIPLES FOR THE INTERACTION WITH PLASMA DONORS

Grifols' interactions with its stakeholders, including Donors, are founded on a deep-seated respect for human dignity and human rights. This fundamental respect underpins Grifols' Human Rights Policy and Code of Conduct, which applies to all Grifols' employees. The safety, health and well-being of Donors is always Grifols first priority.

Grifols adheres to the principles of non-discrimination and does everything possible to protect the health and safety of everyone who plays a role in its business activities. Grifols is a staunch defender of Donors' basic human rights, integrating the ethical principles of caring, respect, bioethics and transparency in all of its interactions.

Grifols' relationship with Donors is – and always will be – based on the principle of informed consent. Before, during and after the entire plasma-donation process, Grifols aims to serve as a reliable and trusted source of information for Donors.

# **COMMITMENTS TO DONORS**

The following eight principles form the core pillars of Grifols' commitment to Donors:

- 1. Safeguard the health, safety and well-being of Donors.
- 2. Respect Donors' human rights and treat them equally following the principles of non-discrimination.
- 3. Ensure Donors provide informed consent before donating plasma.
- 4. Respect legislation in each country regarding Donor compensation and the frequency of plasma donations.
- 5. Support local communities where donor centers are located.
- 6. Comply with personal data legal requirements and implement the necessary measures to protect Donors' privacy and personal data.
- 7. Promote information exchange, open communication and awareness about the uses of plasma medicines at donor centers based on principles of transparency and mutual trust.
- 8. Ensure every interaction with Donors is professional, respectful, helpful, and engaging to create a positive and meaningful Donor experience.

# 1. HEALTH, SAFETY AND WELL-BEING OF PLASMA DONORS

#### • Donating plasma is a safe process

Grifols collects plasma from Donors through plasmapheresis, a safe medical procedure and the most effective way to separate plasma from whole blood.

Plasmapheresis is performed in highly controlled environments by professionally licensed and trained staff. The process complies with all applicable regulations and industry standards<sup>1</sup> to ensure Donors' health and safety, as well as the highest quality of donated plasma in benefit of patients.

# • Donor health and safety is a topmost priority for Grifols

Grifols only utilizes plasma from qualified Donors who undergo thorough medical evaluations in order to be classified as qualified Donors. Grifols conducts regular physical exams in its donor centers and monitors Donors' health – checking vital signs, hematocrit levels and plasma proteins, among other measures – to confirm they can safely donate plasma. Donors are informed immediately in case of abnormalities during the health check and laboratory testing.

When determining Donors' eligibility, Grifols follows the requirements established by the FDA, the EMA and any additional requirements established by the countries where our final product is distributed. Further, Grifols has a panel of physicians who monitor any changes on medications or advances in medical conditions to establish standard eligibility approaches in all our donor centers.

These eligibility criteria and medical evaluations protect Donors' health and sometimes lead to the detection of undiagnosed health issues.

# • Grifols' Plasmavigilance

Although donating plasma is a safe process, Grifols oversees a plasma surveillance program (Plasmavigilance) to monitor any adverse outcomes, in addition to ongoing statistical analyses to continuously improve the process. Grifols commits to regularly evaluate these metrics to guarantee Donors' safety both during and after the donation process.

In parallel, Grifols spearheads a range of initiatives, both directly and through scientific collaborations, to support research to further understand the physiological effects of plasmapheresis on Donors.

<sup>&</sup>lt;sup>1</sup> The collection of source plasma exclusively for fractionation purposes is regulated by the U.S. Food and Drug Administration (FDA) and other global health authorities. In addition to universal good manufacturing norms and procedures by health agencies, the Plasma Protein Therapeutics Association (PPTA) also defines and monitors additional voluntary standards as part of the voluntary IQPP (International Quality Plasma Program) certification. In Europe, it is regulated by the European Medicines Agency (EMA)

# 2. HUMAN RIGHTS

# • All interactions integrate respect for human rights

In all interactions with Donors, Grifols displays the utmost respect for their human rights and human dignity, core principles of Grifols' Human Rights Policy. This commitment is also reflected in diverse globally recognized regulations, among them, the United Nations International Bill of Human Rights –including the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights—the Helsinki Declaration and the Universal Declaration on Bioethics and Human Rights of the United Nations Educational, Scientific and Cultural Organization (UNESCO).

It is also reflected in other international frameworks like the United Nations Guiding Principles of Business and Human Rights, the Guidelines for Multinational Enterprises of the Organization for Economic Cooperation and Development (OECD) and the United Nations Global Impact.

In reflection of its intrinsic respect for human rights and human dignity, Grifols considers Donors' social and financial circumstances and the need to protect those from at-risk or socioeconomically disadvantage contexts. To this end, Grifols aspires to serve as a trusted information source and promotes initiatives that enhance their lives and communities.

#### • Grifols does not discriminate Donors

Grifols does not discriminate Donors based on gender, race, ethnicity, sexual identity or socioeconomic status, and applies the same quality and safety standards for all Donors while following the regulation from all the countries where our final product is distributed.

#### 3. INFORMED CONSENT

#### Informed consent is mandatory

Grifols ensures Donors provide informed consent before donating. Grifols rigorously follows all regulatory and other applicable legal requirements in obtaining informed consent and thoroughly briefs Donors on the benefits and potential risks of donating before receiving their consent.

# 4. RESPECT FOR COUNTRY-SPECIFIC LEGISLATION

# Frequency of plasma donations

Grifols respects all regulations in its countries of operation regarding the frequency of donating plasma. Grifols never allows Donors to exceed the maximum number of weekly and/or yearly donations and ensures Donors' compliance with stipulated rest periods in between donations.

# Grifols' compensation policy

In countries that permit Donor compensation, Grifols applies the same policy to all Donors, making no significant distinction on the volume of plasma collected or Donors' weight. Grifols recognizes Donors for their commitment to donating regularly and the effort involved.

Grifols focuses on respectful Donor compensation. Donors are compensated for their time, commitment and effort, and reflects the socioeconomic context of each country, state and/or region of operation, taking into account a variety of social determinants and other factors. Donor compensation is considered supplementary and is by no means considered wages or employment.

Grifols also positively contributes to local communities through numerous outreach and solidarity initiatives. These include Grifols Plasma Possibilities Program, which offers Donors the option of waiving part or all of their compensation to support non-profit organizations.

#### 5. SUPPORT LOCAL COMMUNITIES

# • Grifols' plasma donation-centers teams are committed to their communities

For Grifols, ongoing community participation in the plasma-donation process is critical to guaranteeing a long-term supply of this essential life-saving raw material. To this end, Grifols' donation-center employees actively take part in their communities, engaging residents and organizing awareness events on the role of plasma, the need for plasma Donors, and the manufacturing process of plasma-based medicines.

Grifols is firmly committed to improving the health, well-being, financial stability and education of its Donors, as well as promoting the economic and social fabric of communities where its donor centers are located.

#### 6. DONORS' PRIVACY AND DATA PROTECTION

# Donors' personal and medical information is always protected to maintain confidentiality

Donor personal data and medical information is required as part of Grifols regular business operations. In processing this data, Grifols complies with all relevant data-protection laws and works only with suppliers that offer sufficient data-protection guarantees and have undergone an extensive validation process in this respect.

The personal and medical information of plasma Donors is rigorously protected to maintain confidentiality. Grifols has a global privacy and data protection policy with a robust framework for processing personal data, as well as strict technical and organizational security measures and insurance policies to protect the organization's assets and users in a cyber-environment.

Grifols' members involved in processing personal data take all necessary measures to ensure Donors' information is protected and stored in a safe location, whatever its format. In addition, those who handle or have knowledge of confidential information are strictly

forbidden from using it for purposes unrelated to Grifols' operations or from disclosing it to third parties.

Grifols' relationship with Donors is further enhanced through a longstanding standard of transparency regarding its use of personal data.

#### 7. INFORMATION, COMMUNICATION AND EDUCATION

# Promoting information and communication based on transparency, trust and responsibility

Ensuring accessible and transparent lines of communication with Donors allows Grifols to better respond to their needs and expectations.

Grifols' communication channels allow plasma Donors to easily provide feedback, either directly to individual donor center employees, through a dedicated toll-free phone number, through Grifols' corporate website, via email or through various social network channels.

All Grifols' promotional and educational materials related to plasma donations comply with applicable laws and regulations; align with industry policies and codes voluntarily adopted by Grifols; adequately address the target audience and end users; and contain information that is truthful, accurate, comprehensive, clear and balanced.

Further, all Grifols' marketing and promotional materials on plasma donations (campaigns, advertisements, etc.) are clearly distinguished as such, comply with the highest ethical, medical and scientific standards, and provide comprehensive information regarding the plasma-donation process.

Grifols takes particular care in assuring the optimal tone and content for marketing campaigns and/or advertisements aimed to encourage plasma donations.

Grifols also promotes and takes part in awareness campaigns on the importance of plasma and recurrent plasma donations.

#### 8. DONOR EXPERIENCE

 Ensure every interaction with Donors digitally, online, over the phone, or in person is professional, respectful, helpful, and engaging to create a positive and meaningful Donor experience

Grifols recognizes the importance of the Donor experience to ensure an ongoing supply of plasma. Honoring and respecting the Donors must occur in every interaction.

Grifols is committed to develop and train the employees in the Grifols Academy of Plasmapheresis to ensure a complete end-to-end Donor experience solution that delivers consistent experience, service and support across all points of interaction throughout the entire Donor lifecycle.

# CRITERIA FOR OPENING PLASMA DONOR CENTERS

Grifols operates a worldwide donor centers network, with no particular concentration in any specific region. When establishing new donor centers, it considers small- and medium-sized communities with a solid commitment to being a business of choice, as evidenced by active chambers of commerce and continuous community-enhancement actions.

At the same time, Grifols seeks healthy and safe communities with low viral markers, below-average crime rates and heterogeneous populations to ensure a diverse donor pool.

# COMMUNICATION AND REPORTING CHANNELS

Grifols has several communication channels to ensure an open and fluid dialogue with Donors. Grifols offers Donors detailed information through its website, educational videos, local events, campaigns and other communication channels.

Donors can communicate with Grifols at its donor centers, dedicated toll-free feedback phone line, via the corporate website and via email or various social network channels, which also serves as a reporting channel for Donor inquiries. In addition, the website also features a section where patients express their gratitude and appreciation of Donors for their generosity. Grifols operates a Donor intranet, the Donor Hub or a mobile app, where Donors can check details of their past visits, update their personal information, and manage their donation visits.

# IMPLEMENTATION, MONITORING AND EVALUATION

Grifols' Board of Directors entrusts the Sustainability Committee to monitor and ensure the compliance of this Policy, as well as its management and associated risks, under Article 3 of the Committee's regulations.

Further, Grifols, through its office of Internal Audit, conducts regular audits of various departments and operations. As part of these audits or on an as-needed basis, Internal Audit may review and monitor compliance with this Policy, as well as any procedures derived from the same, including by identifying any appropriate enhancements to such policies and procedures or in business processes.

# **POLICY VALIDITY AND UPDATE**

This Policy is effective from February 25, 2022, date of approval by Grifols' Board of Directors.