



14th

**International Donor Registry Conference
& WMDA Meetings**

25 – 29 June, 2024 – Cape Town, South Africa

All patients & donors matter

www.capetownidrc.co.za



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A nation-wide consent for the collection of donor stem cells, endorsed by all transplant centres for both family donors and unrelated donors.

No disclosures



Case

- Your role: Donor physician
- 19-year-old unrelated donor
- 23- year old patient
- Transplantation was successful
- 1 year later patient participates in research
- Genetic testing of the peripheral blood of the patient
- BRCA mutation was found
- Relevant information for donor's health



Would you inform the donor?

Join at menti.com | use code 2906 7271

Mentimeter



Yes No



- Join at menti.com and use code: 8909 9792

Yes, I informed the donor

- Mother of donor calls
- Anxiety and distress
- Affect ability to obtain life insurance
- Donor wasn't aware that this could be a result of
- Complaint

YES.

No, I did not inform the donor

- 10 year Follow-Up
- No previous issues
- Patient made full recovery
- Diagnosed with stage 4 breast cancer, no curative options
- Donor has found out she is BRCA positive
- Inform the patient about this

NO.

Why a national consent?

1. TC → use of leftover donated cells for research
 2. COVID-19 Pandemic → Cryopreservation
 3. Increase in genetic testing
 4. SoHo → equal rights (un)related donors
- Matchis and TC's united in SCT HOVON working group.



MATCHIS

HET NEDERLANDS CENTRUM
VOOR STAMCELDONOREN

Further implementation

- One template, different section applicable for (un)related donors
- SCT working group → Document control
- Matchis → development of donor information

What is the goal of this consent?

A donor needs to be aware of:

- Conditions and risks of procedure
- Voluntary nature of the donation
- The purpose of the donated cells
- Consent for other purposes (research/cryopreservation)
- When to be informed in case of relevant findings in the genetic material. (always vs only treatable/preventable diseases)



Legal and ethical considerations

- GDPR
- Dutch act of scientific research (WMO)
- Ethical consideration
- White papers



Content of the donor consent

- General donation rules
- Consent for the type of procedure
- Scientific research (optional consents)
- Informed about relevant unexpected findings

Scientific research - optional consents

All scientific research discussed in this context must meet certain conditions. For example, the research must be carried out in accordance with approved protocols and aim to improve the outcome of stem cell transplantation or alternative treatments in the future.

The human tissue and the data used for this research cannot be traced back to your person by organisations other than Matchis. When exchanging data or material with a country outside the EU, we ensure that at least the privacy rules that apply in the EU are complied with.

We ask you to tick what you give permission for:

- I give my donor physician and the transplant centre permission to use residual material for scientific research. This may involve washings from the transfusion bags after the transplant, or frozen cells that can no longer be used for the treatment of the intended recipient patient.
- If a large portion of my frozen donated cells can no longer be used for the treatment of the intended recipient patient, I give permission to store these cells for possible use for the treatment of another patient.
- I give permission to be approached for participation in scientific research that requires additional data, extra human tissue or extra effort from me, or which has a purpose other than described above. I will then be informed about this separately and I will then decide whether I want to participate in the proposed research.

Consent to inform about relevant unexpected discoveries

I know that, very occasionally, unexpected information about my health or heredity may emerge from tests done on the patient's blood after the stem cell transplant or from scientific research for which I have given permission.

We ask you to tick what you give permission for:

- I want to be informed in any case.
- I only want to be informed about this if the abnormality found can be treated or (for future children) can be prevented. If this information could be important for me or my family members, I want to be informed about this.

Dilemma's

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Strongly disagree

The WMDA should establish standards regarding genetic testing in patient research

After donation, the donor needs to be able to withdraw their consent

Strongly agree



Further steps

- Dutch donors → All donors
- International collaboration
- Incorporation into standards?



Thank you.

