TABLE 3. Regression models for the change in log(TfR/F)

Predictor	Coefficient	95-percent confidence interval	p value
Male donors			
20 mg Fe^{2+}	−0.074	−0.121 to −0.028	0.002
40 mg Fe^{2+}	−0.118	−0.168 to −0.068	<0.001
Constant	0.091	0.058 to 0.123	<0.001
Female donors			
20 mg Fe^{2+}	−0.150	−0.238 to −0.061	0.001
40 mg Fe^{2+}	−0.209	−0.292 to −0.127	<0.001
Constant	0.086	0.018 to 0.153	0.012

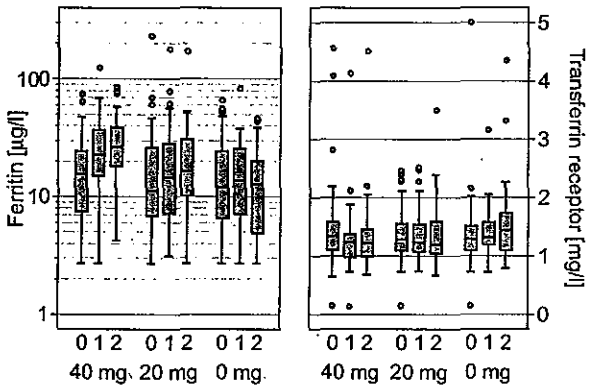

Fig. 4. Box-plot for the concentration of serum ferritin and soluble transferrin receptor in female donors.

DISCUSSION

Regular blood donation frequently leads to iron depletion, and it has been shown that iron supplementation can prevent this complication.[8,10,11] However, the exact dose needed to compensate for this type of iron loss remains unclear, and there is uncertainty as to whether iron supplementation is required in both male and female donors. Attempting to elucidate this complex issue more precisely, we monitored the logarithm of the TfR/F ratio as a measure of body storage iron in regular male and female whole-blood donors. The donors were randomly assigned to receive daily supplements containing selected vitamins plus 40 mg, 20 mg, or 0 mg of elemental iron. Dropout rates were marginally (male) or significantly (female) higher in the placebo group than in both iron groups. The reason for this finding is obscure.

Daily doses of 40 mg and 20 mg of elemental iron resulted in both a positive iron balance and an increase in storage iron in female donors and compensated for iron loss in males. This indicates that 20 mg of elemental iron per day is indeed sufficient to compensate for iron loss in both males and females. The differences in storage iron responses may be due to the shorter donation intervals in males (every 2 months) compared to females (every 3 months). It is likely that the ascorbic acid in the capsules may have increased the iron absorption by roughly 50 percent.[19] The question of whether the other vitamins may play any role in this context is speculative. The only reason for including these vitamins in the investigational products was our desire to improve the compliance rate.

In the present study, we monitored ferritin and soluble transferrin receptor levels as well as the logarithm of the TfR/F ratio. The latter variable, which was shown to have a highly linear correlation with body storage iron, is the most precise measure of body storage iron available.[14,15] Until now, body iron of blood donors was assessed mainly by measuring serum ferritin.[1,3,5-7] However, this variable is somewhat unspecific and may give false-high results in the presence of various underlying diseases.[2] In fact, if ferritin had been the only variable used for assessment of body storage iron, the effects of 20 mg elemental iron in males would have been underestimated in our study.

Interestingly, the number of side effects in the two groups treated with iron(II)-gluconate was only slightly higher than the number observed in the placebo group. In particular, the incidence of gastrointestinal side effects in the iron groups was very low (12%). Due to the slight risk of poisoning in children, iron capsules should be delivered in individual packages. Elemental iron preparations like carbonyl iron are preferred as an alternative by many experts due to the much higher lethal doses.[9,10,20,21] However, carbonyl iron is not available in the European countries. In comparison, bioavailabity of carbonyl iron is slightly lower than that of ferrous salts,[21] but side effects seem to be comparable: The incidence of gastrointestinal complaints for both preparations was reported much higher in two previous studies, probably due to the supplementation with higher doses of iron.[9,21] The utility of iron supplements for prevention of iron deficiency in menstruating female blood donors is currently being discussed.[20,22] However, others and we prefer a supplementation of iron for a short-term period after blood donation but not in general.

In conclusion, our results indicate that daily doses of 20 mg Fe^{2+} can adequately compensate for iron loss resulting from whole-blood donation in males who donate up to six times a year and in females who donate up to four times a year.

REFERENCES

1. Finch CA, Cook JD, Labbe RF, Culala M. Effect of blood donation on iron stores as evaluated by serum ferritin. Blood 1977;50:441-7.
2. Skikne B, Lynch S, Borek D, Cook J. Iron and blood donation. Clin Haematol 1984;13:271-87.
3. Alvarez-Ossorio L, Kirchner H, Klüter H, Schlenke P. Low

ferritin levels indicate the need for iron supplementation: strategy to minimize iron-depletion in regular blood donors. Transfusion Med 2000;10:107-12.
4. Punnonen K, Rajamäki A. Evaluation of iron status of Finnish blood donors using serum transferrin receptor. Transfus Med 1999;9:131-4.
5. Sayers MH. Predictions for the effect of serum ferritin screening on the deferral rate of regular blood donors. Transfusion 1982;22:433.
6. Simon TL, Garry PJ, Hooper EM. Iron stores in blood donors. JAMA 1981;245:2038-43.
7. Worwood M, Darke C. Serum ferritin, blood donation, iron stores and haemochromatosis. Transfus Med 1993;3:21-8.
8. Cable RG, Morse EE, Keltonic J, et al. Iron supplementation in female blood donors deferred by copper sulfate screening. Transfusion 1988;28:422-6.
9. Gordeuk VR, Brittenham GM, Hughes MA, Keating LJ. Carbonyl iron for short-term supplementation in female blood donors. Transfusion 1987;27:80-5.
10. Gordeuk VR, Brittenham GM, Bravo J, et al. Prevention of iron deficiency with carbonyl iron in female blood donors. Transfusion 1990;30:239-45.
11. Simon TL, Hunt WC, Garry PJ. Iron supplementation for menstruating female blood donors. Transfusion 1984;24: 469-72.
12. Lieden G. Iron supplement to blood donors. I. Trials with intermittent iron supply. Acta Med Scand 1975;197:31-6.
13. Lieden G. Iron supplement to blood donors. II. Effect of continuous iron supply. Acta Med Scand 1975;197:37-41.
14. Skikne BS, Flowers CH, Cook JD. Serum transferrin receptor: a quantitative measure of tissue iron deficiency. Blood 1990;75:1870-6.
15. Cook JD, Flowers CH, Skikne BS. The quantitative assessment of body iron. Blood 2003;101:3359-64.
16. Punnonen K, Irjala K, Rajamäki A. Serum transferrin receptor and its ratio to serum ferritin in the diagnosis of iron deficiency. Blood 1997;89:1052-7.
17. Boulton F, Collis D, Inskip H, et al. A study of the iron and HFE status of blood donors, including a group who failed the initial screen for anaemia. Br J Haematol 2000;108: 434-9.
18. Twisk JWR. Applied longitudinal data analysis for epidemiology. Cambridge: Cambridge University Press, 2003.
19. Brise H, Hallberg L. Iron absorption studies II. Effect of ascorbic acid on iron absorption. Acta Med Scand 1962; 171(Suppl 376):51-8.
20. Bianco C, Brittenham G, Gilcher RO, et al. Maintaining iron balance in women blood donors of childbearing age: summary of a workshop. Transfusion 2002;42:798-805.
21. Devasthali SD, Gordeuk VR, Brittenham GM, et al. Bioavailability of carbonyl iron: a randomized, double-blind study. Eur J Haematol 1991;46:272-8.
22. Simon TL. Iron, iron everywhere but not enough to donate. Transfusion 2002;42:664-5.

2. 貧血と採血基準を考える
～血液学的立場から～

香川県赤十字血液センター
内田 立身

1．貧血の定義

貧血の定義について血液学の代表的な教科書をみると、①a reduction below normal in the concentration of hemoglobin or red blood cells in the blood[1] ②anemia is functionally best characterized by a hemoglobin concentration below normal[2] などの記載があり、健常人のヘモグロビンの下限値から判断するのが一般的である。米国人においては表1のような数字が用いられている[1) 2) 3) 4)]。この際、健常人として選ばれる対象のうち特に鉄欠乏状態の多い女性では血液学的に正常でない人が含まれ、下限域が低く算定される可能性があった。

表1 米国健常人のヘモグロビン(g/dL)下限値

	男性	女性	文献番号
WHO	13.0	12.0	3
Beutler E	14.0	12.3	1
Lee GR	13.2	11.6	2
NHANESⅢ	13.5	12.0	4

最近、Beutlerら[5] は米国人の貧血の定義としてNHANES-Ⅲ(The Third US National Health and Nutrition Examination Survey)[4] が行なったように、トランスフェリン飽和率16%以上、血清フェリチン10ng/mL以上の人を健常人として正常域の5%値未満を貧血としている(表2)。血液学的な貧血の定義として妥当な決め方である。

日本人の貧血の頻度について、私たちは「1981年～1991年」までの鉄欠乏の頻度を検索したことがあるが[6]、このデータをもとに鉄欠乏のない健常人を対象としてヘモグロビン値を求めたところ表3のとおりとなった。同じ方法で求められた斎藤ら[7] の成績とあわせると、鉄欠乏のない日本人のヘモグロビン下限値は男性12.8～13.2g/dL、女性11.8～12.1g/dLとなり、日本人成人の貧血の定義は男性13.0g/dL未満、女性12.0g/dL未満が妥当と考えられた。最近の日本人については鉄欠乏に関する正確なデータがなく、厚生労働省が行なっている「国民健康・栄養調査報告」などから鉄欠乏のない健常人のヘモグロビン値を求め、日本人の貧血の定義を定める必要がある。

表2 健常米国人のヘモグロビン(g/dL)下限値 (Beutler, 2006)

	男性(20～59歳)	女性(20～49歳)
白 人	13.7 (6,907人)	12.1 (2,966人)
アフリカ系	12.8 (434人)	11.1 (205人)

表3 鉄欠乏のない健常日本人のヘモグロビン値

	平均ヘモグロビン値	1標準偏差	5%正常分布値	文献
男性(284例)	14.8	1.0	12.8	6
女性(390例)	13.9	0.9	12.1	
男性 (26例)	15.0	0.9	13.2	7
女性(134例)	13.4	0.8	11.8	

2．日本人の貧血の頻度

私たちは、1981～1991年にかけて3,015名の女性で貧血の調査を行なった。その成績は、健常者43.6%、貯蔵鉄欠乏33.4%、潜在性鉄欠乏8.4%、鉄欠乏性貧血8.5%、その他6.5%

表4　日本人の貧血の頻度(%)（平成16年度国民健康・栄養調査報告から）

年齢	男性			女性		
	平均Hb±SD	Fr<10(%)	Hb下限値	平均Hb±SD	Fr<10(%)	Hb下限値
20～29	15.1±1.0	1.6	13.1	12.9±1.0	30.5	10.9
30～39	15.1±0.8	1.2	13.5	12.7±1.2	36.5	10.3
40～49	15.2±1.0	1.2	13.2	12.5±1.6	37.5	9.3
50～59	14.9±1.2	1.8	12.5	13.2±1.1	10.0	11.0
60～69	14.5±1.4	2.5	11.7	13.1±1.0	3.9	11.1
70≦	14.0±1.5	2.8	11.0	12.6±1.2	5.6	10.2
計	14.6±1.4	2.1	11.8	12.9±1.2	17.3	10.5

男性1,537名、女性2,634名の調査。

で40歳台前半では17.2％の鉄欠乏性貧血がみられた[6]。

その後、日本人についての詳細なデータがなく、特に女性の鉄欠乏性貧血の頻度をみるには毎年厚生労働省が行なっている国民健康・栄養調査から類推するのがよいと思われる[8]。表4はその成績である。高齢者を除くと男性の貧血は5.8％以下、鉄欠乏の頻度も2.5％以下であるが、女性は16.8％が貧血であり血清フェリチン低値(鉄欠乏)の頻度も高率であることから、ほとんどが鉄欠乏性貧血である。40歳台では25.0％に貧血があり同年代の半数（47.5％）が鉄欠乏状態にある。

また、香川県赤十字血液センターにおいて平成17年度に400mL献血を申し込んだ女性のうちヘモグロビン不足(Hb12.5g/dL未満)で献血ができなかった女性の比率[9]を表5に示すが、30～40歳台女性の約35％が献血できていない。また、日本赤十字社による全国的な調査によると[10]、平成17年に比重不足で献血できなかった人は485,746人で、これは東京都で１年間に献血できた人の数407,235人をはるかに凌駕するほどである。

表5　ヘモグロビン不足で献血できない女性の割合
（平成17年：香川県赤十字血液センター）

年齢	Hb<12.5g/dL
16～19	28.6%
20～29	32.6%
30～39	35.6%
40～49	35.3%
50～59	18.9%
60～69	17.5%
全体平均	19.4%（申込者数 9,963人）

わが国の女性の貧血の頻度は欧米に比して高い。米国の国民健康・栄養調査報告によると、20～40歳台の女性の鉄欠乏性貧血の頻度は5％、鉄欠乏状態は11％[11]、米国24血液銀行における2003年度の女性ヘモグロビン不足(12.5g/dL未満)の割合は平均で6.6％(1.3～13％)、Wisconsin州において17～49歳では21～23％である[12]。わが国のこれに対応する成績は400ml献血ができなかった女性が該当し、16～19歳で28.6％、20～29歳で32.6％、30～39歳で35.6％、40～49歳で35.3％であり[13]、どの調査をみても頻度は高いといわざるを得ない。

わが国で鉄欠乏の多い原因は鉄摂取量の不足にある。平成16年国民健康・栄養調査によると、男性の１日平均鉄摂取量は8.1mg、女性の１日平均は7.7mg（20～39歳で6.9～7.0mg)で必要量に比して少ない[8]。日本人の必要鉄摂取量は男性10mg、月経のある女性12mgであるが、その差2mgは全血にして10～12mLにしか相当せず、平均的月経量を30～40mLとして外国並に15～18mgは必要であろう。となるとわが国の月経のある女性は必要量の半分の鉄しか摂取していない。しかも鉄摂取量は過去の上記の調査によると年々減少してきている。

他方、米国における調査によると、白人男性で１日あたり17.2±0.3mg、女性で13.4±0.4mgで相当の開きがある[8]。採血基準を考える際には、以上のようなわが国の事情を勘案して決める必要がある。

3．採血基準をどう決めるか

日本の現状を踏まえて、わが国の採血基準をどう決めたらよいかについて以下に私見をまじえて述べたい。

代表的な国の採血基準を表6に示す。このうちEU諸国とオーストラリアは男女差があるが、米国とわが国は男女差がない。わが国の採血基準は1986年に改定され、200mL献血と400mL献血に分け、比重法かヘモグロビン法で判定するようになっている。現在、貧血の定義はヘモグロビンで記載されており、わが国の医療機関のすべてがヘモグロビン法で貧血を診断しているので、ヘモグロビン法に統一することが望ましい。また献血も400mL献血が主流になりつつあるので諸外国に倣い200mL、400mLを一本化して表記するのがよいと考えられる。

表6　各国の採血基準（400mL相当）

	男性	女性
Council of EU	13.5	12.5
Australia	13.0	12.0
U.S.A	12.5	12.5
日本	12.5	12.5

1)　ヘモグロビンの正常範囲から決める

鉄欠乏のない健常者から正常分布域を定め、5％正常値を求めると男性13.0g/dL、女性12.0g/dLとなり、これ以上を採血基準とする方法はわかりやすく貧血の定義とも一致する。

2)　貧血状態にない人から採血する

赤血球は鉄欠乏の進展に伴い、小赤血球化、低色素性化する。図1、図2は男性および女性におけるヘモグロビンと赤血球恒数との関係で、MCV・MCHが低下するのは男性で12.5g/dL、女性で12.0～12.5g/dLである[14]。また、鉄欠乏性貧血82例の私達の検討から、ヘモグロビンの分布域の上限は13.0g/dLであることをみると、現行の米国やわが国の基準である12.5g/dLは矛盾しない数字となってくる。

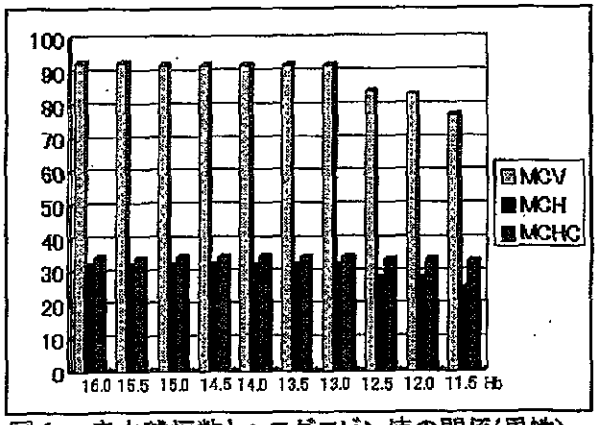

図1　赤血球恒数とヘモグロビン値の関係(男性)

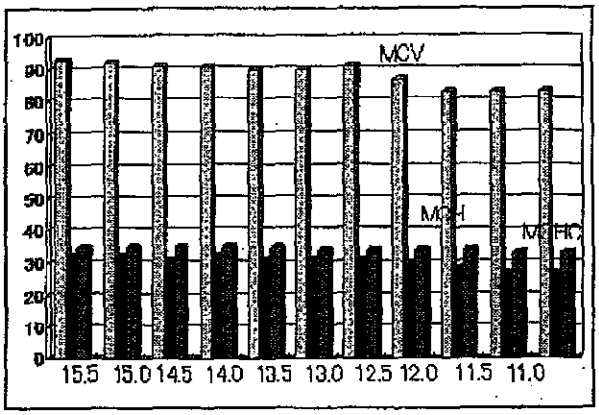

図2　赤血球恒数とヘモグロビン値の関係(女性)

3)　現在考えられる適切な採血基準は

上記を踏まえて採血基準について考察すると、わが国では鉄欠乏状態にある女性の頻度が高く、抜本的対策の見出せない現状では、貧血のない鉄欠乏からの採血をできるだけ避けるために女性の基準は12.0g/dLよりは12.5g/dLのほうが妥当と思われる。また、男性については貧血のない鉄欠乏はほとんどないが、12.5～13.0g/dLは貧血の人から採血することになり矛盾を生ずるので、13.0g/dLが妥当ではないかと思われる。

いずれにしても、採血基準の改定には正確なデータに基づく議論が必要である。それには、日本人の鉄欠乏性貧血、貧血のない鉄欠乏、鉄欠乏のない健常人の頻度（これは現行の国民健康・栄養調査の個々のデータから算出可能である）、献血申込者のヘモグロビン不足による男女別、年齢別不適格者の頻度などの解析によって決められるべきであろう。

文　献

1) Lee GR et al:Anemia:General aspects. In Wintrobe's Clinical Hematology. Williams & Wilkins, Baltimore, 1999, p897

2) Beutler AJ:Clinical Manifestations and Classification of Erythrocyte Disorders. Williams Hematology (6th ed), McGraw-Hill, New York, 2001, p369

3) Blanc B, Finch CA, Hallberg L et al: Nutritional Anemia: Report of WHO Scientific Group. WHO Tech Rep Ser 405: 1-40, 1968

4) Cook JD Flowers CH, Skikne BS: The quantitative assessment of body iron. Blood 101: 3359-3364, 2003

5) Beutler E, Waalen J: The definition of anemia: what is the lower limit of normal of the blood hemoglobin concentration. Blood 107: 1747-1750, 2006

6) 内田立身、河内康憲、坂本幸裕ほか：日本人女性における鉄欠乏の頻度と成因にかんする研究-1981年～1991年の福島・香川両県での成績。臨床血液33:1661～1665, 1992

7) 日本鉄バイオサイエンス学会編：鉄欠乏・鉄欠乏性貧血の予防と治療のための指針、響文社, 札幌、2004

8) 健康・栄養情報研究会編：平成16年度国民健康・栄養調査報告、第一出版、東京、2006

9) 内田立身：鉄欠乏性貧血、わが国の頻度と予防対策。カレントテラピー(2007年2月発行予定)

10) 日本赤十字社血液事業本部編：血液事業の現状、平成16年度統計表、2004

11) Locker AC: Prevalence of iron deficiency in the United States. JAMA 277: 973-976, 1997

12) Gottschall JL, Adamson J: Iron metabolism, anemia and blood donation. AABB Annual Meeting Presentation, 2006/10/14, Miami Beach.

13) 内田立身、窪田明美、中西幸美ほか：事前検査におけるヘモグロビン測定の導入。血液事業 28: 393-399, 2005

(17)

American Red Cross

Mid-America Division
Badger-Hawkeye Region
Heart of America Region
Midwest Region
North Central Region

Dear Parent or Guardian,

Your 16-year-old has expressed an interest in donating blood at an upcoming American Red Cross blood drive. The states of Illinois, Iowa, Kansas, Nebraska, Minnesota, Missouri and Wisconsin allow 16-year-olds to donate blood with written parental/guardian consent. We are asking for your support by completing the attached consent form.

Please read the attached forms: "What You Must Know Before Giving Blood" and "What You Must Know About NAT – A New Blood Test." If you have any questions about the information contained in these documents, please call 1-800-448-3543 – M-F: 8 am - 9 pm, Sat: 9 am - 1 pm, Sun: 4 pm - 8 pm – and press Option 6 to speak to a Red Cross donor health consultant.

We support each student's willingness to give blood and ask that you offer your encouragement too. Much like voting and driving a car, the opportunity to donate blood and save a life has become a right of passage for thousands of high school students. Becoming a blood donor is a very personal decision, and we understand that parents and students may be somewhat apprehensive about taking this step. This is completely natural, so we want to provide you with some additional information about donating blood.

Blood donation is a safe procedure using single-use sterile needles and supplies. To ensure that your student has a positive experience, we recommend that they follow these guidelines:

- Get a good night's sleep before the blood drive.
- Eat well and drink plenty of fluids in the days leading up to the blood drive, especially the day of the drive.
- Drink at least 16 oz of caffeine free fluid (2 cups) 3-4 hours before the donation and after.
- Be honest and accurate about their weight (donors must weigh at least 110 lbs).

While the donation process is safe, reactions can occur. Most reactions are mild and can include fainting or small bruises. Our staff is fully trained to work with first-time and younger blood donors, and to respond to any reactions. We hope you will encourage your student to support our blood drive. Since one blood donation can be separated into three components, your student has the potential to save as many as three lives with a single donation.

Please note that the FDA requires that donors are asked specific questions about their health history. This information helps ensure the safety of the blood donor and the blood recipient. These questions are asked privately and are completely confidential.

You should be very proud of your son or daughter's decision to donate at the upcoming drive. *Please help support this act of generosity by completing the consent form prior to the drive.* If you are not currently a blood donor, please consider making an appointment for yourself. For more information call 1.800.GIVE.LIFE or visit our website at givebloodgivelife.org.

Sincerely,

David C. Mair MD

David C. Mair, M.D., Senior Medical Director

Form:
Informed Parental Consent for Persons Not of a Legal Majority

What this form is about

This form provides staff with a mechanism for documenting a parent or legal guardian's informed consent for someone not of legal majority to donate blood or blood components.

Who should use this form

This form applies to all staff who obtain informed special consent from donors or parent/legal guardian.

Instructions

- Ensure the region-identifying information is on the form.
- Instruct the parent/legal guardian to
  - Print the name of the son, daughter, or ward in the space provided.
  - Print his or her name.
  - Sign the consent form.
  - Date the consent form.
- Affix a Whole Blood Number/Donation Identification Number (WBN/DIN) to the form.

Revision History

Revision Number	Summary of Revisions
1.0	Initial version
1.1	Developed and released prior to revision history requirement
1.2	Revised instructions for completion of form Reformatted signature, date, and WBN lines

Informed Parental Consent for Persons Not of a Legal Majority

Information

This form must be completed by a parent or legal guardian for blood donations by any person who has not yet reached the age of legal majority as defined by the laws of the state in which the donor makes the blood donation.

Questions or concerns about the blood donation process should be directed to

Department: **Donor Health Consultants**

Phone Number: **(800) 448-3543 (Press Option 6)**

Hours of operation: **M-F: 8am-9pm, Sat: 9am-1pm, Sun 4-8pm**

Parental Consent

I have received and read a copy of "What You Must Know Before Giving Blood" describing the overall blood donation process.

I have received and read a copy of "What You Must Know About NAT- A New Blood Test" describing additional test procedures and any research-related attachments.

I understand that in the event it becomes necessary to notify my son, daughter, or ward of test results, the American Red Cross will send those results directly to my son, daughter, or ward.

I understand the information provided to me and have had an opportunity to ask questions about the information it contains. I hereby give permission for my son, daughter, or ward, to make a voluntary donation of blood to the American Red Cross during his or her legal minority.

A signed consent from the Parent/Guardian will be required for each donation until the donor reaches the age of majority.

Donor Name [son, daughter, or ward] (print) _____

Parent/Guardian Name (print) _____

Parent/Guardian *Signature* _____ **Date:** MM / DD / YY

WBN/DIN →

American Red Cross Blood Services Washington, DC 20006	American Red Cross

WHAT YOU MUST KNOW ABOUT NAT

Possible Use of Donor Information and Blood Samples in Medical Research

The American Red Cross Blood Services mission is to provide a safe and effective blood supply for patients who need blood transfusions. As part of this mission, the American Red Cross may conduct research. Some research is conducted with other institutions, such as academic centers and biomedical companies.

Some examples of the types of research are:

- Studies relating to testing, storing, collecting and processing blood to increase the safety of the blood supply.
- Studies of new test methods for infectious agents carried in the blood, like Nucleic Acid Testing (NAT).
- Studies of ways to recruit blood donors and to evaluate donor eligibility.

Participation does not require additional blood to be collected or additional time.

By signing your Blood Donation Record, you are giving consent to allow us to use a portion of your blood donation and donor information for research like that listed above. Donor information for research will not include anything that would identify you as the donor, such as your name or Social Security Number (SSN).

Confidentiality

American Red Cross policy requires protection of the confidentiality of your donor identifying information, results of tests on your blood samples and information collected at the time of donation. Strict procedures are observed at all blood collection facilities to maintain the confidentiality of donor information.

Your donor identifying information will not be released to other institutions for research purposes without your consent. Your age, gender, general geographic location, and test results may be used to evaluate important information about disease or donor recruitment, but this information is combined with information about other donors and not identified with you.

While study results may be published, donor names and other identifying information will not be revealed, except as required by law. Records are kept, as required by State and Federal Laws. The Food and Drug Administration (FDA) may need to review and copy donor records in order to verify study data. The FDA, however, is committed to protection of the confidentiality of donor identity.

Testing and Storage

Blood samples used by researchers are coded. This means that your donor identifying information, including name and SSN, is not used in connection with research. Coded samples can be linked to information about donors' identity only by authorized Red Cross personnel who are required to follow Red Cross procedures to maintain confidentiality.

Some of your sample or information may be saved for future research on viruses or other agents that may be carried in blood. Samples linked to your identifying information may be used, either

now or in the future, for infectious disease testing, as described in What You Must Know Before Giving Blood or in other information about a specific research study that is being conducted today. Your identified sample and information will not be used for genetic testing or for research unrelated to blood safety without your consent.

You will be notified in person, by phone, or by letter, about any test results that may impact your health. You will receive information about how these test results may affect your health and future eligibility as a blood donor.

Possible Participation in a Follow Up Study
If your test results are positive or unexpected, Red Cross staff may ask you to participate in a follow up study. Participation is voluntary and of no cost to you.

Benefits
By using new infectious disease tests like NAT, you may find out sooner if you are infected by one of the agents being tested. This may be important to your health.

Risks
There is a very low chance that your blood sample may give a false positive or true positive infectious disease result. If this happens, the blood that you donate will not be used for transfusion and there is the likelihood that you may not be able to donate again. If you are donating for a specific patient and have a positive test result, your blood donation will not be available for that patient. If you are donating blood for yourself and have a positive result, your blood donation may not be available to you.

Your Right Not To Participate
You may refuse to participate now or at any time during the donation process. If you decide that you do not want your donation or donor information to be used for possible research like that listed above, you will not be able to donate today. It is very important to include all donors in such research in order to provide a safe and effective blood supply.

If you decide not to participate at this time, your decision will not change your future relationship with the Red Cross.

If you begin donating and then decide that you do not want to participate, you must notify the blood collection staff before you leave the collection site. If you decide to withdraw in the future, contact the Scientific Support Office at (301) 212-2801. However, test information collected before your withdrawal may still be used or disclosed after your withdrawal.

Questions
If you have any questions about your donation, please feel free to ask the ARC staff member performing your confidential health history interview. If you have questions later, you can contact the Blood Center at 1-800-652-9742.

If you have scientific questions, you can call the Scientific Support Office at (301)212-2801. If you have any questions about your rights as a research participant, call the American Red Cross Institutional Review Board Administrator at (301)738-0630.

You have been given this information sheet to read and will be offered a copy to keep.