

PATIENT SCREENING REPORT

ID No.				
Form Type	S	R		

PART I: IDENTIFICATION

1. Patient's initials: \_\_\_\_\_

2. Screening date: FO2-DAYS  
Month Day Year

5. Has the patient's blood specimen been sent to the Core Laboratory? Yes No  
----- (1) (2)  
1 BLD. Sent

PART II: SCREENING INFORMATION

3. Does the patient meet all eligibility criteria except antinuclear antibody (ANA)? Yes No  
----- (1) (INEL)  
ELIG

Blood specimens for patients believed to be eligible must be sent to the Core Laboratory and ANA titer results must be received at the Coordinating Center within one week of the screening date (Item 2).

A. Date blood specimen sent: BLOOD-DY  
Month Day Year

- Check all that apply.
- A. Patient is under 18 years of age ----- (1) EXCL
  - B. Patient does not have Raynaud's phenomenon - (1) EXCL
  - C. Patient did not have at least 14 Raynaud's attacks per week in the previous cold season - (1) EXCL
  - D. Patient has not had Raynaud's for at least one previous cold season ----- (1) EXCL
  - E. Patient does not have normal nailfold capillaries ----- (1) EXCL
  - F. Patient does not have a method of regular contact ----- (1) EXCL

6. Has the patient been given a four-week supply of the Raynaud's Attack Cards (Form 08) and the Daily Diaries (Form 10)? Yes No  
----- (1) (2)  
Four-wk

Patient must complete the Attack Cards and Daily Diaries for month before he/she can be enrolled in the RTS.

4. Does the patient meet any of the exclusion criteria? Yes No  
----- (INEL) (2) EXCL

A. Start date of Attack Cards and Daily Diaries: Start-DY  
Month Day Year

Advise patient that if his/her ANA titer is above 1:320, he/she will not be eligible for the RTS.

- Check all that apply.
- A. Patient has a history of digital ulcers or digital gangrene or has digital pits ----- (1) EXCL
  - B. Patient has indications of secondary Raynaud's phenomenon ----- (1) EXCL
  - C. Patient is unreliable ----- (1) EXCL
  - D. Patient has another illness which is likely to interfere with the conduct of the study --- (1) EXCL
  - E. Patient is planning to move within the next 24 months ----- (1) EXCL
  - F. Patient is using a disallowed medication --- (1) EXCL  
Specify: EXCL-Rok
  - G. Patient is intolerant of nifedipine or nifedipine XL ----- (1) EXCL
  - H. Patient has previously been treated for Raynaud's with biofeedback therapy ----- (1) EXCL

PART III: ADMINISTRATIVE MATTERS

7. Research Coordinator:  
Signature: \_\_\_\_\_ RTS Staff No.: \_\_\_\_\_

8. Date form completed: \_\_\_\_\_  
Month Day Year

This form should be **FAXED** (410-435-0689) to the RTS Coordinating Center within two days of screening the patient.

PATIENT SCREENING REPORT

ID No.		-		
Form Type	S	R	0	1

Part I: Visit Identification

1. Patient's initials: -----
2. Screening date: ----- FOUR DAYS -----  
Month Day Year

Part II: Screening Information

3. Does the patient meet all eligibility criteria except antinuclear antibody (ANA)? ----- ( 1 ) ( STAY ) ELIG  
Yes No
4. Does the patient meet any of the exclusion criteria? ----- ( STAY ) ( 2 ) EXCL  
Yes No
5. Has the patient's blood specimen been sent to the Core Laboratory? ----- ( 1 ) ( 2 ) BLOOD SENT  
Yes No

A. Date blood specimen sent: BLOOD-DY -----  
Month Day Year

Blood specimen must be sent to the Core Laboratory and ANA titer results received at the Coordinating Center within one week of the screening date (Item 2).

6. Has the patient been given a four-week supply of the Raynaud's Attack Cards (Form 08) and the Daily Diaries (Form 10)? ----- ( 1 ) ( 2 ) FOUR WK  
Yes No

A. Start date of Attack Cards and Daily Diary: START-DY -----  
Month Day Year

Patient must complete the Attack Cards and Daily Diaries for one month before he/she can be enrolled in the RTS.

Advise patient that if his/her ANA titer is above 1:320, he/she will not be eligible for the RTS.

Part III: Administrative Matters

7. Research Coordinator:  
Signature: ----- RTS Staff No.: -----

8. Data form completed: -----  
Month Day Year

This form should be FAXED (410-435-0689) to the RTS Coordinating Center within two days of screening patient.

## FORM 02 (Rev. 0, 1)

## PATIENT SCREENING REPORT

<u>ITEM</u>	<u>NAME</u>	<u>TYPE AND LENGTH</u>	<u>CODES OR UNITS</u>
HEADER	NEWID*	I(4)	Patient ID
2	FO2_DAYS	I(4)	Screening date Days from Randomization
3	ELIG	I(1)	1 = Yes, 2 = No
3A	ELIGA	}	1 = Yes, 2 = No
3B	ELIGB		
3C	ELIGC		
3D	ELIGD		
3E	ELIGE		
3F	ELIGF		
4	EXCL	I(1)	1 = Yes, 2 = No
4A	EXCLA	}	1 = Yes, 2 = No
4B	EXCLB		
4C	EXCLC		
4D	EXCLD		
4E	EXCLE		
4F	EXCLF		
4G	EXCLG		
4H	EXCLH		
4F	EXCL_RMK	CHAR(1)	1 = Remark written on form
5	BLD_SENT	I(1)	1 = Yes, 2 = No
5A	BLOOD_DY	I(4)	Date blood sample sent to lab Days from Randomization
6	FOUR_WK	I(1)	1 = Yes, 2 = No
6A	START_DY	I(4)	Date patient is to start filling out Attack Cards and Daily Diaries. Days from Randomization

\* Persons randomized will have ID numbers 1 – 313; persons not randomized will have id numbers 314 – 556.

CONTENTS PROCEDURE

Data Set Name:	RTS.FORM02	Observations:	556
Member Type:	DATA	Variables:	23
Engine:	V612	Indexes:	0
Created:	11:06 Thursday, April 27, 2000	Observation Length:	102
Last Modified:	11:06 Thursday, April 27, 2000	Deleted Observations:	0
Protection:		Compressed:	NO
Data Set Type:		Sorted:	NO
Label:			

-----Engine/Host Dependent Information-----

Data Set Page Size:	8192
Number of Data Set Pages:	8
File Format:	607
First Data Page:	1
Max Obs per Page:	80
Obs in First Data Page:	49

-----Alphabetic List of Variables and Attributes-----

#	Variable	Type	Len	Pos	Format	Informat	Label
18	BLD_SENT	Num	4	65	1.	BEST22.	f02q5 Blood sent to Core Lab
22	BLOOD_DY	Num	8	86	4.		f02q5a Day blood sent to Core Lab
1	ELIG	Num	4	0	1.	BEST22.	f02q3 All elig. criteria except ANA
2	ELIGA	Num	4	4	1.	BEST22.	f02q3a < 18 years old
3	ELIGB	Num	4	8	1.	BEST22.	f02q3b No Raynaud's phenomenon
4	ELIGC	Num	4	12	1.	BEST22.	f02q3c < 14 attacks per week
5	ELIGD	Num	4	16	1.	BEST22.	f02q3d < 1 previous cold season
6	ELIGE	Num	4	20	1.	BEST22.	f02q3e Abnormal nailfold capillaries
7	ELIGF	Num	4	24	1.	BEST22.	f02q3f No regular contact
8	EXCL	Num	4	28	1.	BEST22.	f02q4 Any exclusion criteria
9	EXCLA	Num	4	32	1.	BEST22.	f02q4a Digital ulcers or gangrene
10	EXCLB	Num	4	36	1.	BEST22.	f02q4b Secondary Raynaud's
11	EXCLC	Num	4	40	1.	BEST22.	f02q4c Patient is unreliable
12	EXCLD	Num	4	44	1.	BEST22.	f02q4d Patient has another illness
13	EXCLE	Num	4	48	1.	BEST22.	f02q4e Patient will be moving
14	EXCLF	Num	4	52	1.	BEST22.	f02q4f Patient on disallowed medication
16	EXCLG	Num	4	57	1.	BEST22.	f02q4g Intolerant to Nifedipine
17	EXCLH	Num	4	61	1.	BEST22.	f02q4h Previous biofeedback therapy
15	EXCL_RMK	Char	1	56			f02q4f Specify disallowed medication
20	F02_DAYS	Num	5	73	4.		f02q2 Days from randomization
19	FOUR_WK	Num	4	69	1.	BEST22.	f02q6 4 week supply of attack cards
21	NEWID	Num	8	78	4.		Patient ID
23	START_DY	Num	8	94	4.		f02q6a Start day of attack cards

Variable	Label	N	Mean	Std Dev	Minimum	Maximum
ELIG	f02q3 All elig. criteria except ANA	556	1.2	0.4	1.0	2.0
ELIGA	f02q3a < 18 years old	115	2.0	0.0	2.0	2.0
ELIGB	f02q3b No Raynaud's phenomenon	115	1.6	0.5	1.0	2.0
ELIGC	f02q3c < 14 attacks per week	115	1.8	0.4	1.0	2.0
ELIGD	f02q3d < 1 previous cold season	115	2.0	0.1	1.0	2.0
ELIGE	f02q3e Abnormal nailfold capillaries	115	1.6	0.5	1.0	2.0
ELIGF	f02q3f No regular contact	115	2.0	0.1	1.0	2.0
EXCL	f02q4 Any exclusion criteria	554	1.9	0.3	1.0	2.0
EXCLA	f02q4a Digital ulcers or gangrene	64	2.0	0.2	1.0	2.0
EXCLB	f02q4b Secondary Raynaud's	64	1.5	0.5	1.0	2.0
EXCLC	f02q4c Patient is unreliable	64	1.8	0.4	1.0	2.0
EXCLD	f02q4d Patient has another illness	64	1.8	0.4	1.0	2.0
EXCLE	f02q4e Patient will be moving	64	2.0	0.0	2.0	2.0
EXCLF	f02q4f Patient on disallowed medication	64	1.9	0.2	1.0	2.0
EXCLG	f02q4g Intolerant to Nifedipine	64	2.0	0.2	1.0	2.0
EXCLH	f02q4h Previous biofeedback therapy	64	2.0	0.0	2.0	2.0
BLD_SENT	f02q5 Blood sent to Core Lab	556	1.3	0.4	1.0	2.0
FOUR_WK	f02q6 4 week supply of attack cards	556	1.3	0.4	1.0	2.0
F02_DAYS	f02q2 Days from randomization	313	-41.4	12.5	-121.0	-27.0
NEWID	Patient ID	556	278.5	160.6	1.0	556.0
BLOOD_DY	f02q5a Day blood sent to Core Lab	313	-41.4	12.5	-121.0	-27.0
START_DY	f02q6a Start day of attack cards	313	-40.5	12.5	-120.0	-26.0

f02q4f Specify disallowed medication

EXCL_RMK	Frequency	Percent	Cumulative Frequency	Cumulative Percent
1	3	75.0	3	75.0
8	1	25.0	4	100.0

Frequency Missing = 552