



SLEEP HEART HEALTH STUDY

FIELD SITE CERTIFICATION

Instructions: After completion, send this form along with appropriate IRB materials to the Certification Coordinator at the SHHS Coordinating Center.

A. Identifying information

1. Field Site (*check one*):

- Framingham
- Johns Hopkins
- Minnesota
- NYU/Cornell
- Sacramento
- Pittsburgh
- Strong Heart - Dakota
- Strong Heart - Phoenix
- Strong Heart - Oklahoma
- Tucson

2. Name of person completing this form (*please print*):

3. Certification # (PIN) of person completing this form:

____ _

4. Date form completed:

__ __ - __ __ - 2 0 0 __
month day year

5. Satellite sites included in this certification (if more than one field site)

B. IRB approval

6. Date IRB approved participation in SHHS-2 (attach a copy of notification and approved consents to this form.)

__ __ - __ __ - 2 0 0 __
month day year

7. Parent Study approval obtained, if needed.

Yes No Not Applicable

C. Facilities and materials

8. Documents, equipment, and facilities available for conduct of the study:

- | Yes | No | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | a. Manual of Operations, Volume 3 (Protocol) |
| <input type="checkbox"/> | <input type="checkbox"/> | b. Manual of Operations, Volume 4 (Procedures) |
| <input type="checkbox"/> | <input type="checkbox"/> | c. Manual of Operations, Volume 5 (Data System Manual) |
| <input type="checkbox"/> | <input type="checkbox"/> | d. Manual of Operations, Volume 6 (Forms) |
| <input type="checkbox"/> | <input type="checkbox"/> | e. Policy and Procedures Memoranda (PPMs) |
| <input type="checkbox"/> | <input type="checkbox"/> | f. Designated, secure (locked) storage space for forms |
| <input type="checkbox"/> | <input type="checkbox"/> | g. Data system housed in secured location |
| <input type="checkbox"/> | <input type="checkbox"/> | h. Equipment to measure height (Handistat) |
| <input type="checkbox"/> | <input type="checkbox"/> | i. Scale to measure weight (SECA Integra 815 or Tanita BWB 8005) |
| <input type="checkbox"/> | <input type="checkbox"/> | j. Blood Pressure cuffs and sphygmomanometer - portable, standard mercury |
| <input type="checkbox"/> | <input type="checkbox"/> | k. ECG MAC® 1200 (Marquette) |
| <input type="checkbox"/> | <input type="checkbox"/> | l. Compumedics portable polysomnograph |
| <input type="checkbox"/> | <input type="checkbox"/> | m. Doppler for AAI - Parks Medical 841A pencil probe |
| <input type="checkbox"/> | <input type="checkbox"/> | n. Tape measure for neck circumference |

D. Study personnel

9. List of all personnel involved in the study and their study role (If PIN not yet assigned, leave blank. PIN will be assigned by the Coordinating Center after a PC form is submitted)

name	role	PIN
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name	role	PIN

10. At least one coordinator or technician from your site attended the study training meeting in Cleveland (6-10 November 2000).

Yes

No

11. At least one staff member has been certified as a:

Yes

No

a. PSG technician

b. Anthropometry technician

c. BP technician

d. AAI technician

e. ECG technician

f. Interviewer

g. Consenter

h. Clinic coordinator

i. Data system operator

E. Site director's assurance

12. I have reviewed the information on this form and attest to its accuracy:

Yes

No

13. Site director's signature:

14. Date signed:

__ __ - __ __ - 2 0 0 __
month day year

F. CC use

15. Review of checklist:

Yes

No

a. All items reviewed

b. All items approved for certification

16. Items needed for certification:

17. CC reviewer (*please print*):

18. Date reviewed:

__ __ - __ __ - 2 0 0 __
month day year