SENSEWEAR ARMBAND

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SENSEWEAR ARMBAND

1. Background and rationale

The equipment that will be used for this study, the Body Monitoring System, includes an activity-based device called the SenseWear Pro® armband (BodyMedia Inc., Pittsburgh, Pa) which measures energy expenditure. The armband is a small comfortable device worn on the back of the upper arm and monitors various physiological and movement parameters. The activity monitor will be worn on the participant's upper right arm against the skin (at triceps level) for the 12-16 days between their first clinic visit (ingestion of doubly-labeled water) and their follow-up energy expenditure visit.

The device utilizes a unique combination of sensors that continuously gather the following data: movement, heat flow, skin temperature, ambient temperature, and galvanic skin response. Total energy expenditure (TEE), active energy expenditure (AEE), metabolic equivalents (METs), total number of steps, physical activity duration (PAA), sleep duration, and lying down, can all be calculated from the data the sensors gather. The Body Monitoring System and the SenseWear armband has been scientifically validated and has been used successfully by clinical and research departments worldwide.

2. Training and certification of armband examiners

Armband examiners charged with the responsibility of initializing, downloading, or any other handling of the armband will be required to meet performance standards that indicate an understanding of the InnerView software, the SenseWear armbands function, and cautions related to the armband's sensitive inner workings. Only examiners who meet these standards will be certified and approved to handle the armbands and instruct the participants.

Examiners will be required to attend a training session, or undergo local training by a certified technician. Training will consist of:

1. Overview of Operations Manual

2. Web-based training for initializing, wearing of the armband, and downloading/saving of files. Transfer of the armband data file to the Coordinating Center will also be shown but may not be required for each examiner (this requires a secure web site with limited access.) Each examiner involved with the armbands will be required to wear an armband for one over-night period. They will be required to download/save the file and print out the activity report, and discuss results. There will be a discussion of some common questions from participants, armband problems, battery problems, and other situations that may occur. Monthly armband conference calls are suggested.

3. Besides completing the web-based training, each examiner needs to successfully complete the following sequence three times: a) initialize the armband; b) wear the armband for 20 to 30 minutes; and c) download and save data from the armband. In addition, any

examiners who will be uploading participant data files to the Coordinating Center need to upload at least three test data files for practice. The first time this sequence is completed, the three data collection forms (Prescreener for SenseWear Armband, SenseWear Armband Distribution form, and SenseWear Armband Return and Reading form) should be completed. Clinic project directors will be asked to notify the CC when all of their examiners have completed these training requirements.

3. Participant safety and exclusions

Participants in the energy expenditure substudy will be excluded under four general criteria (below):

1. Insulin using (dependent) diabetes mellitus

2. A requirement for supplemental oxygen

3. Blood transfusions, administration of blood products, or administration of intravenous fluids in excess of 500 mL in the week previous to the first energy expenditure visit or an expectation of same during the period between the first and second energy expenditure visit

4. Travel in excess of 200 miles away from home during week prior to energy expenditure visit 1 or an expectation of same during the period between visits 1 and 2.

Two extra exclusion criteria are needed for wearing the armbands.

1. Disability in the right arm (e.g., paralysis, amputation)

2. Participation in water recreation or sports (e.g., swimming, water aerobics) three or more times per week

There are additional precautions that should be communicated to the participant. These are included in the Information Sheet for participants (Appendix 3).

1. Do not over-tighten the armband while on your arm. If, at any time, you feel constriction or loss of circulation, simply loosen the adjustable strap and re-fasten to a more comfortable setting.

2. Do not immerse the armband in water. The armband should be removed for bathing and participation in water sports.

4. Equipment and supplies (per box)

- One Monitor SenseWear armband
- Two adjustable straps (normal and large) with velcro tabs (extra straps can be ordered)
- One USB cable
- Two AAA batteries (only needs one at a time)

- Getting Started Guide
- InnerView software with on-line help guide (used for initializing the armband and downloading data)

5.   Copying InnerView software to computer

Each field center will receive an InnerView software CD that they can install on their clinic computer. A representative from BodyMedia will be available by telephone to support each field center to install the InnerView software.

6.   Pre-exam procedures

6.1   Pre-screen participants

The Prescreener for Energy Expenditure will be administered before the participant comes into the clinic for their Year 10 clinic visit. The participant will have already been told about the armbands during the prescreening.

In addition, please administer the Pre-screener for SenseWear Armband to determine each participant's eligibility to wear the SenseWear armband.

6.2   Armband initialization procedures

We recommend that all armbands be checked once prior to use by participants. Examiners should initialize and wear each armband for approximately 30 min and then retrieve data to ensure the device is collecting data. Each armband should be cleared after being checked.

Participant's current height, weight, and enrollment ID# are required to initialize the armband. The following procedures should be followed for optimal armband use and output:

1. Prior to initialization, verify that the AAA battery in the armband is new. A new battery should be placed in the armband for each participant. Do NOT use rechargeable batteries.

2. Clean the device sensors with a soft cloth dampened with 70% isopropyl alcohol. Allow to dry for 5 to 10 minutes before wearing.

3. The adjustable straps should be hand washed with mild soap and water and air dried.

4. Connect one end of the USB cable to the armband and the other end to the computer. You should hear a beep which confirms a connection. If you do not hear a beep, press the button on the front of the device once.

5. Open InnerView program and check the box "Via USB Cable" (this should be the default).

6. Click on Configure SenseWear and then Retrieve Configuration.

7. SenseWear Parameters will pop up and possibly a warning that states the computer clock is out of sync with the armband clock. Confirm that computer clock is correct and then click Apply to update the armband clock.

8. Check that both Battery Life and Memory Available are 100%. If they are not at 100%, replace battery and clear the data and participant information from Sensewear armband. This can be done by clicking on "Clear Data & Subject Info" on the SenseWear Maintenance drop down menu.

9. Write down the participant's name and their armband serial number on the SenseWear Armband Distribution form. The serial number can also be placed on the front of the armband using a removable sticker (this will be a clinic-based decision).

10. Record the date and time the device was initialized on the SenseWear Armband Distribution form.

11. Click on Subject Info tab and enter participant's information. Participant ID + ACROSTIC should go in the Subject field (e.g., HB5000ABCD).

12. Click Apply and OK to finish initializing the device.

Please note:

The initialization procedure for the participant should take place as close as possible to the time the armband is given to the participant (within at most 5 hours). The initialization process should take less than 5 minutes per armband. We recommend completing the armband initialization as soon as possible after you have measured the participant's current height and weight.

7.   Wearing the armband (data collection)

The participant will be instructed to wear the armband until they return for their follow-up energy expenditure visit (12 to 16 days after they receive the armband). Each participant should be oriented to procedures for wearing the armband. The armbands will be distributed at the participant's clinic visit. Place the armband on the participant at the same as you attach the other three monitors (ActiGraph, Actiheart, and Polar heart rate monitor).

At the visit, the participant will receive:

• SenseWear Armband
• Adjustable strap
• Information Sheet (Appendix 3)

The procedure for wearing the armband should be explained to the participant while they are in the clinic and any questions should be answered at that time. Items to be explained to the participant include:

1. Wearing the armband: The armband should be worn on the back of the upper **right** arm (the triceps muscle), touching the skin. The skin should be clean. The Timestamp button is located near the top of the device and should be facing up when positioned on the arm. Adjust the strap so that it fits on the arm comfortably, and then secure the oval pull-tab. Ensure that the sensors maintain continuous contact with the skin at all times and that the armband does not slide off the arm. Be careful not to secure it too tightly. Once it fits comfortably you will not need to readjust the strap. The armband should be worn at **all** times except when bathing or performing water sports. If the participant absolutely refuses to wear it while sleeping, ask them to continue wearing it while awake.

2. Making sure the armband is on and working: There is no on/off button on your armband. When the device makes secure contact with the arm, it automatically performs a "turning on" sequence. This may take up to 5 minutes for some people.

    The "turning on" sequence is as follows:
    - Welcome: Four distinct notes descending in tone (do-de-do-deet). This sound indicates the armband has made contact with the skin.
    - Warming Up: Two-second vibration. The participant will feel a series of light vibrations as it settles to the body.
    - Ready: Three notes (de-de-deet). This sound indicates that the armband is collecting data.
    - In order to check if the armband is working properly, press and hold the Time-stamp button until you here the three note sound (de-de-deet). This means the device is working properly.
    - Once activated, the device will start collecting data while on the participant's arm and will only stop collecting data when removed. Once put back on the participant's arm the device will resume collecting data.

Please note:

Write down the time the device was activated on the SenseWear Armband Distribution form (this is the time the device performs the "turning on" sequence once it has been placed on the participant's arm).

3. While wearing the armband: If the armband beeps and vibrates occasionally the participant should not worry about it; however, if it beeps and vibrates often, the armband strap should be tightened a bit.

4. Removing the armband: The armband can be simply slid on and off (again no need to adjust the band). The device should be removed when bathing and/or during water sports (such as swimming or water aerobics). This is to avoid damaging the device. It is also advised to remove the armband one hour for every 24 hours worn. Make sure both your arm and the sensors are cleaned daily, especially after vigorous exercise. To clean the sensors wipe with a soft damp cloth. If a rash develops where the armband comes into contact with the skin, the participant should immediately discontinue use. If the participant does not want to wear it while sleeping have them continue wearing it while awake.

5. <u>Things to note</u>:

- If the "memory" light on the armband is red this means the memory is full. The data should be retrieved.
- If the "battery" light on the armband is red this means the battery is very low. Battery should be replaced. We are not asking participants to replace the battery. If the battery life expires while they are wearing it, that is OK. Examiners will retrieve the data that was collected.

6. A summary of the above information with critical points should be provided to the participant. An example of an information sheet can be found in Appendix 3. The information sheet should be reviewed with the participant before they take it home with them. The sheet will provide them with a phone number to call should they have further questions after leaving the clinic.

The armband should be collecting data when the participant puts it on at their clinic visit. The participant will be wearing the armband the day of their visit, so that they get used to wearing it. At first, the participant will likely be very conscious of the device and will be more inclined to alter activity or fidget with it. However, the participant's awareness of the armband will likely diminish within about a day, so the measurement bias will be minimized.

8.   Retrieving data from the armband

When an armband is returned after a participant has worn it for the specified time, the data needs to be downloaded from the device to the clinic computer.

If the armband did not collect data, a message will pop up when trying to retrieve the data that states no data was collected. If this occurs, the armband needs to be checked to see if it is working properly. A staff member can wear the armband for 30 minutes to see if data is being collected. If the monitor does not seem to be working, please contact Dawn Mackey at the Coordinating Center.

Dawn Mackey
San Francisco Coordinating Center
185 Berry Street, Lobby 4, Suite 5700
San Francisco, CA 94107-1762
Email: dmackey@sfcc-cpmc.net
Phone: 415.600.7429
Fax: 415.514.8150

If the armband collected any data, then it needs to be saved and sent as a .swd file (this is the default file extension) to the Coordinating Center for analysis.

8.1 Steps to retrieve data

To retrieve data:

1. Press the Timestamp/Status button (blue button on top front of armband). If the battery light blinks green or amber, proceed with data retrieval. **If the battery light blinks red, replace the battery and then proceed with data retrieval** (see Section 11.1).

2. Connect armband to the computer using the USB cable (similar to what was done when initializing the device).

3. Double click on the armband icon on your desktop to open InnerView software.

4. Click "Retrieve SenseWear Data." Click "Via USB Cable." Click "Retrieve."

5. Unclick the box "Clear SenseWear for next use." We want to be sure the data is correct and saved properly before we clear the device.

6. Name and save file as "HealthABCIDAcrostic" (using the ID and Acrostic of the participant who most recently wore the armband, e.g., HB5000ABCD). Save with the extension .swd.

Once data is saved, a screen will appear that summarizes the armband information. Look at this file and make sure the participant ID and Acrostic are correct (matches the participant who wore the armband), that the number of days are correct, that the armband collected data (if data was not collected a message will pop up), and that the start and end times are correct.

Generate an activity report by clicking on the 'Generate Report' tab at the bottom of the screen. A sample report is shown below. Print a copy of the report for the participant and keep a copy of this report in the participant's chart. You d**o not** need to save the report on the computer.

Once the data file has been saved the armband can be cleared by going to the drop down list at the top of the screen under SenseWear Maintenance and clicking on "Clear Data & Subject Info."

A sample activity report:

InnerView Report   Created Mon Mar 12, 2007   Page 1 of 1

Clinician / Physician	Hospital / Organization	Practice / Department

Subject 200_008_VFA	Age 48	Gender Female	Weight 154.0 lbs	Height 5' 5"	Handed Right	Smoker No	BMI 25.67

Start Time Tue Sep 12, 2006 08:24 AM	End Time Tue Sep 19, 2006 07:05 AM	Duration of View 6 days 22 hrs 41 min	Duration on-body 6 days 15 hrs 31 min (95.7%)

* Partial Day. Value is not representative of a 24-hour timeframe.

8.2   **Completing the SenseWear Armband Return and Reading form**

Record on the SenseWear Armband Return and Reading form the:

1. Date the participant returned the armband to the clinic.

2. Number of days and hours the armband was collecting data. This information is shown on the activity report under the heading "Duration of View." Round times to the nearest hour. For example, 12 days, 3 hours, and 15 minutes would be recorded as 12 days, 3 hours, while 10 days, 5 hours, and 49 minutes would be recorded as 10 days, 6 hours.

9.   **Sending the data to the Coordinating Center**

At the end of each month, upload all data files from that month, regardless of the amount of data collected, to the Coordinating Center at the Neoteris website. There will be one data file (.swd) per participant, and you will have to upload one file at a time. To help stay organized, you may wish to create separate directories on your clinic computer for each month (e.g., March, April, May). At the end of each month you can upload all of the files in that month's directory. See Appendix 6 for uploading instructions.

Retain a copy of each file on the clinic computer hard drive until you receive notification from the Coordinating Center that it is ok to delete the file.

If the wrong ID and/or Acrostic were used in the Subject Field (when initializing the device) or when naming the file, please email Dawn Mackey (dmackey@sfcc-cpmc.net) at the Coordinating Center to let her know this happened. Please provide her with the correct ID# and/or Acrostic, and she will take care of it.

Please note

For the first week, upload all data files at the end of the week so that the Coordinating Center can check the data.

10.   **Maintaining an activity monitor log**

A log should be maintained at the clinic so that the location of the armbands is known at all times. An example log is included in Appendix 5; it can be modified as individual clinics see necessary. A serial number for each armband can be found when initializing the device. This should be used as the Armband ID.

11.   Data collection considerations

11.1 Battery life

A new AAA battery can collect up to 14 days of continuous data (24/7). The battery life is typically reduced under colder conditions. A new battery should be placed in the device for each participant. Do not use rechargeable batteries.

To check the status of the battery, press the Timestamp/Status button. The following sequences will occur:

- Green (solid) = More than 24 hours of battery life remains.
- Amber (flashing) = Less than 24 hours of battery life remains.
- Red (flashing) = Battery life is very low and the armband will not collect data. Change the battery before continuing use.

We recommend that participants DO NOT press the Timestamp/Status button, but examiners may press the Timestamp/Status button to check the status of the battery.

When you push the Timestamp/Status button on the armband and both the battery level and memory level are OK, it will play the A-OK sequence, which can best be described as a series of three notes (de-de-deet) the first two of which are the same note, followed by a third ascending note. This sequence of notes is also accompanied by a short vibration, and then both green lights will flash.

When you push the Timestamp/Status button on the armband and the battery level is low, it will play the battery LOW sequence, which can best be described as a series of two notes repeated three times in an alarm fashion (de-do de-do de-do). This sequence of notes is also accompanied by a short vibration, and the battery light will flash yellow.

When you push the Timestamp/Status button on the armband and the battery level is insufficient to power the device, it will play the battery OUT sequence, which can best be described as a series of two notes repeated three times in an alarm fashion (de-do de-do de-do). This sequence of notes is also accompanied by a short vibration, and the battery light will flash red.

When there is less than 24 hours of battery life remaining, the armband will produce a subtle vibration and sound to alert the user. When the battery is too low to operate, the alert will become more urgent, but only last for a few seconds.

When a participant returns an armband, the examiner should press the Timestamp/Status button. If the battery light blinks green or amber, the examiner can proceed with data retrieval. **If the battery light blinks red, the examiner should replace the battery prior to retrieving data.**

To replace the battery, lift and rotate the top hatch counterclockwise. Remove the drained AAA battery and replace it with a new AAA battery immediately. **Once you remove the AAA battery, you have 30 seconds to replace it with the new one. Failure to do so may lead to loss of data.**
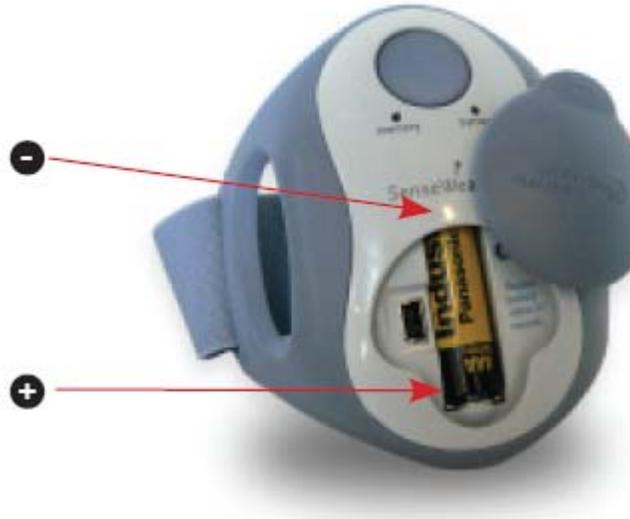
11.2 Memory capacity

Under default configurations, the armband has approximately 20 days of data collection memory. To check the memory status, remove the armband and press the Timestamp/Status button. The light above the word "memory" will turn on as follows:

- Green (solid) = More than 24 hours of memory remains.
- Amber (flashing) = Less than 24 hours of memory remains.
- Red (flashing) = Available memory is low and the armband will not collect data. Retrieve data before continuing use.

We recommend that participants DO NOT press the Timestamp/Status button, but examiners may press the Timestamp/Status button to check the status of the memory.

When there is less than 24 hours of memory life remaining, the armband will produce a subtle vibration and sound to alert the user. When the memory is full, the alert will become more urgent, but only last a few seconds.

12. Acknowledgment

The material in this document was modified from the Osteoporosis in Men (MrOS) Study. Stephanie Harrison created the original manual of operations for the MrOS Study.

Appendix 1 Pre-screener for SenseWear Armband

HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
		Month / Day / Year	

Health ABC

PRE-SCREENER FOR SENSEWEAR ARMBAND

1. What is your...?

First Name   M.I.   Last Name

2. Does the participant have any disability in their right arm, such as paralysis or amputation?

○ Yes   ○ No

NOT eligible. Go to Question #6.

3. Do you swim or do water aerobics three or more times per week?

○ Yes   ○ No   ○ Don't know   ○ Refused

NOT eligible. Go to Question #6.

4. Do you have a surgically implanted defibrillator (a defibrillator is a device that jump starts your heart to bring it back to a normal rhythm)?

○ Yes   ○ No   ○ Don't know   ○ Refused

5. Do you have a surgically implanted heart pacemaker that helps to control your heart rhythm?

○ Yes   ○ No   ○ Don't know   ○ Refused

6. Is participant eligible to wear the SenseWear armband?

○ Yes   ○ No

Complete SenseWear Armband Distribution Form.

Year 10 Prescreener for SenseWear Armband
Version 1.0, 3/9/07

Appendix 2 SenseWear Armband Distribution Form

HABC Enrollment ID #   Acrostic   Date Visit Completed   Staff ID #

Month   Day   Year

SENSEWEAR ARMBAND DISTRIBUTION

1. What is your...?

First Name   M.I.   Last Name

2. Did the participant receive an armband?

   O Yes   O No

   Please record serial number:

   Why didn't participant receive an armband?
   (Note: Mark __all__ that apply.)

   O Participant refused

   O Cognitive impairment

   O Physical/medical problem
       (Please specify:_____)

   O No device available/schedule problem

   O Other   *(Please specify:_____)*

3. Date and time the armband was initialized:

   Month   Day   Year   Hours   Minutes   O am   O pm

4. Time armband was activated: Hours   Minutes   O am   O pm

Year 10 SenseWear Armband Distribution
Version 1.0, 3/9/07

Appendix 3 Armband Information Sheet

SenseWear Armband Information Sheet

The armband will go on your **right** upper arm held in place by Velcro strap. Once the straps fits your arm comfortably there is no need to readjust, simply slide it on and off your arm.

Step 1

Make sure small circle is facing up.

Step 2

Slip armband over your hand.

Step 3

This is how it should look when it's on the right way!

- The armband should be worn at all times, except when bathing or participating in water sports. In addition, you can remove the armband for one hour a day if you wish.

- Clean the armband with a soft damp cloth after exercise that causes your arm to sweat. Make sure arm is clean and free of lotion or other products at this time.

- The armband will activate when in contact with your arm. This activation may take up to 5 minutes. You will know it is on when you hear four beeps, feel a two second vibration, and then hear another three beeps. The device will stop collecting data when removed and start up again this same way when placed back on your arm.

- Do not worry if armband beeps and vibrates occasionally; however, if this happens often, then the armband should be tightened a bit.

- Please do not open the tab on the front of the armband.

- You will wear the armband home from your visit.

- Please wear your armband to your follow-up appointment.

Contact Information:
If you have questions about wearing the armband please call: _____

Appendix 4 SenseWear Armband Return and Reading Form

HABC Enrollment ID #	Acrostic	Date Visit Completed			Staff ID #
		Month	Day	Year	

SENSEWEAR ARMBAND RETURN AND READING

1. What is your...?

First Name   M.I.   Last Name

2. Date participant returned armband to clinic:

Month   Day   Year

3. What was the number of days and hours the armband was collecting data?
(Examiner Note: After retrieving the data from the armband, generate an activity report, and record days and hours as seen on the "Duration of View" screen.)

Days   Hours   *(Round to the nearest hour.)*

Year 10 SenseWear Armband Return and Reading
Version 1.0, 3/9/07

Appendix 5 Log for SenseWear Armband

Armband ID _____

Armband ID	Date Initialized	Initialized By	ID/Acrostic	Date Downloaded	Downloaded By	Date Cleared	Cleared By

Appendix 6 Data Backup and Transfer

Data Transfer Using the Secure Web Gateway

The following instructions explain the process for transferring data securely to the SF Coordinating Center.

In your initial connection, you may be requested to download an ActiveX control.   This takes only a few seconds and is required for access to the secure site.

To Start:

In any browser go to site https://ive.psg-ucsf.org/ and enter your username and password.

Prevention Sciences Group

Username JDoe   Please sign in to begin your secure IVE session.
Password *********

Sign In

You will see a page similar to the page below. Most of you will only have a single role listed, although you may have more as does the user below. Select the appropriate project/task based on the data you wish to transfer.

For HABC Transfer at Pittsburgh: HABC Data Transfer (Pitt)
For HABC Transfer at Memphis: HABC Data Transfer (Tenn)

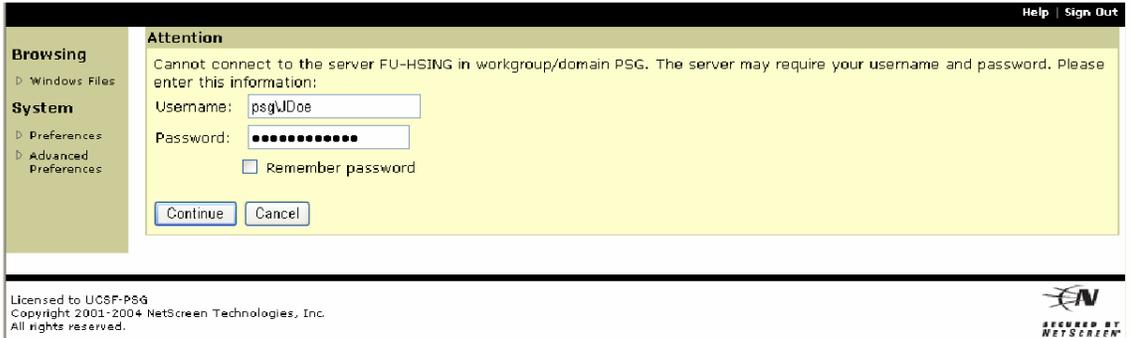**Prevention Sciences Group**

You have access to the following roles through the secure gateway:

HABC Accelerometry
OAI Clinics
HABC Data Transfer (TENN)
HABC Data Transfer (PITT)

Each role allows you to access certain resources. Click on the role you want to join for this session. Please contact your administrator you need help choosing a role.
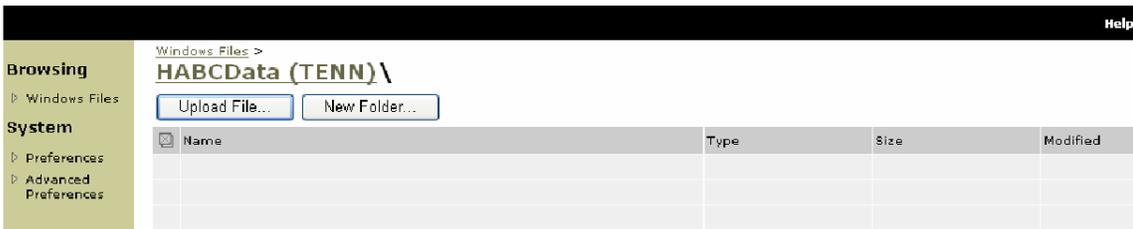
Some users may receive a request to type their username and password in again. Please do so, using the "**psg**" prefix as shown below.
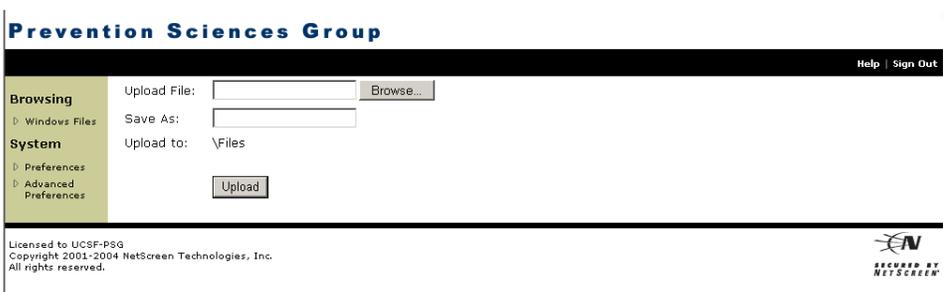

To upload data:

Select "Upload File"

Select "Browse" to locate the files for uploading. If you wish to rename the file, use "Save As" to enter the new name (otherwise this field can be left blank). Select "Upload".

Once the file has been transferred, the upload status should reflect "Done". Click "Close". You should now see the file you uploaded in the Name column. To upload additional files, click "Upload File" and repeat the above process.

Once you are finished, click "Sign Out" and close your browser.