FLU SUBSTUDY

TABLE OF CONTENTS

FLU SUBSTUDY

1. Background and hypotheses

The long-term impact of respiratory illness accompanied by fever on the physical functioning of the elderly is unknown. Simple inactivity associated with the recuperative process leads to substantial lean body mass (LBM) losses (Buchner & Wagner, 1992; LeBlanc et al, 1992). More importantly, the body's response to the physiologic stress of infectious disease involves accelerated catabolism of skeletal muscle (Wilmore, 1991). In healthy young volunteers infected with pyrogenic pathogens, average weights declined from 3 to 6 pounds depending on the infection, and the weight loss persisted at least 2 weeks following the development of symptoms (Beisel, 1967). The study ended before it could be determined whether or when lost weight was recovered. Average nitrogen losses from the catabolism of skeletal muscle ranged from 20 to 50 grams. Nitrogen loss correlated with the duration and severity of fever and differed from pair-fed controls. Not only did the pair-fed controls lose less nitrogen; they also regained it quite readily (unlike infected volunteers) upon the return to normal feeding patterns.

The loss of skeletal muscle resulting from infection may have direct functional effects and also confer increased risk for future ailments. Direct effects of catabolic illness would include a loss of general strength which is an important component of overall functional status and can lead to need for assistance in ambulation, gait instabilities and increased risk of falls (Bjorntorp & Evans, 1992; Buchner & Wagner, 1992). The indirect consequences derive from increased frailty due to the loss of protein reserves necessary to face future physiologic insults (Buchner & Wagner, 1992). These might include an increased risk of secondary infection following subsequent illness and increased risk of complications following surgical interventions (Windsor & Hill, 1988; Tellado et al, 1989). These losses may be of particular consequence in the elderly, since lower levels of physical activity may lead to incomplete recovery of skeletal tissue and, hence, retarded recovery of functional capacity (Buchner & Wagner, 1992).

The substudy will provide information complementary to that being collected for the main study. The main study will be able to examine the role of LBM and changes in LBM as a predictor of incident disability. If, as hypothesized by the overall study, decreased LBM is a predictor of incident disability; the next step will be to examine risk factors for LBM decline. Understanding the determinants of decline may help in designing novel interventions to forestall the development of disability. The proposed substudy will provide important and specific information regarding the role of a common exposure, respiratory illness with fever, in causing the acute loss of lean body

mass through the catabolism of skeletal muscle during the symptomatic phase of the disease. Furthermore, it will provide specific information regarding when and whether LBM is regained following an acute illness episode and what the correlates of the recovery of LBM might be. Moreover, the functional impact of respiratory illness in the community dwelling elderly is poorly understood. However, it is known that acute respiratory illness with fever (ARIF) is common in elderly persons and often leads to extensive periods of inactivity. ARIF is also frequently associated with complications such as severe bronchitis, pneumonia, falls, and hospitalization. This substudy will provide novel information regarding respiratory illness and functional limitations in the elderly.

Hypotheses:

Three hypotheses will be tested.

1. Participants experiencing an acute respiratory illness with fever (ARIF) will lose more lean body mass and grip strength and will have a greater decrease in walking speed, compared to participants not experiencing such an illness;

2. The severity of an ARIF, as defined by bed-days and symptom-days will predict the extent of change in the physiologic and functional variables assessed above;

3. In those experiencing an ARIF, recovery, as measured by increasing muscle strength, regain of LBM and increased walking speed will be related to the level of physical activity following the illness.

2. Case ascertainment

2.1 Surveillance based on existing contacts

Cases will be identified based on self-report of respiratory illness with fever on either the semi-annual call or the annual clinic visit interview. Those reporting that they had a cold or flu that kept them in bed for most of a day that was accompanied by a fever of at least 100° F would qualify for the substudy. The questions read:

Since we last spoke to you about 6 months ago, have you had a cold or flu that was bad enough to keep you in bed for all or most of the day?

If "yes": Was your temperature taken?
If "yes": Was your temperature 100° or higher?

Those answering "yes" will be asked additional questions to determine eligibility.

2.2 Additional information collected from qualifying cases

2.21 Establishing eligibility

Eligibility determination is based on a questionnaire (see attached). In order to be eligible for the study, participants must have had a respiratory illness with a measured fever of more than 100° F no more than 2 months and 3 weeks before the date of phone contact. The timing is important because the study will collect blood samples that will help identify the infecting illness. Blood samples taken too soon or too late after the infecting illness may be misleading in this regard. Also, the physical assessments for the study need to be obtained in an interval that is not so close to the illness so that the participant may not have recovered, but not so far from the illness that the recovery process is nearly completed.

The first two pages of the Flu Substudy Eligibility Assessment form guide the interviewer in determining whether or not the participant is eligible to be part of the flu substudy:

- The examiner will write in the illness cutoff date (transcribed from the Flu Substudy Illness Cutoff Date and Target Window Log (see Appendix 1) provided for each clinic) on the first page of the Flu Substudy Eligibility Assessment data collection form in order to ask Question #2 (page 1): "Did this illness start after [illness cut-off date]?" If it did occur after this date, the participant is not eligible to be part of the flu substudy.
- The participant will then be asked if their temperature was taken during this illness (Question #4, page 2). If their temperature was not taken, they are not eligible to be included in the flu substudy.
- The answer to Question #5 (page 2) regarding how high the participant's temperature was, will also determine whether or not the participant is eligible to be in the flu substudy. If the temperature is 100° F or lower, they are not eligible.

The participant may have had more than one febrile illness in this time period, but a minimum of one illness is required.

2.22 Severity of illness

The second portion of the Flu Substudy Eligibility Assessment form includes questions about the illness experience, including how long it was until the participant felt

completely recovered, specific symptoms, highest temperature, and number of days with fever, number of days in bed, number of days with restricted activity, number of days with no or limited appetite, consultation with a physician or other health professional and number of illness episodes. The second portion of the Flu Substudy Eligibility Assessment form also includes questions about the participant's other illnesses during the previous 6 months.

3. Scheduling flu substudy visit

Two visits are required for the flu substudy; one visit taking place from 4 to 12 weeks after the illness episode, and one 6 to 9 months following the illness episode (i.e., 3 to 6 months after the first flu substudy contact). It is intended that at least one of these visits be the routinely scheduled annual clinic visit.

If a participant has had multiple ARIF's in the previous 12-week period, visits should be scheduled based on the occurrence of the most recent episode.

3.1 Eligibility for additional assessments

3.1.1 First flu substudy contact

The first flu substudy visit should take place between 4 and 12 weeks after the date of onset of the qualifying illness. If the illness is ascertained during the Semi-annual Telephone Contact, the examiner should determine whether an appointment could be scheduled in this interval. To determine the time parameters within which the participant should be seen, refer to the Flu Substudy Illness Cutoff Data and Target Window Log (Appendix 1) to find the target window for that participant. For example, if a participant's Semi-annual Telephone Contact is on 2/11/ /01, their Flu Substudy Eligibility Assessment form is completed on this call, and they are eligible to be part of the flu substudy, you would look at the column across from 2/11/01 entitled: "Target Window to schedule first flu substudy visit if eligibility assessment is done as part of the Semi-annual Telephone Contact" and see that this participant has to be seen between 2/11/01 and 2/25/01. If an appointment cannot be made within this window then no substudy visit should occur. The first flu substudy contact should be done at the clinic, if possible. Its components include:

CES-D
Weight
Grip Strength
Chair Stands

Standing Balance
4-Meter Walk
Isometric Strength (Chair)
DXA
Blood for one 5 ml red top tube (serum to be aliquoted and stored)

If the illness is ascertained at the annual clinic visit and the annual clinic visit is occurring between 4 and 12 weeks after the onset of the qualifying illness additional components may need to be added to the in-clinic exam. Specifically, these are home exam components that may not be in a given year's clinic visit (short walk, lower extremity performance tests, certain questionnaire items, grip strength and isometric chair, and serum collection). There are clear instructions in the Flu Substudy Workbook for the examiner regarding which components of the Flu Substudy exam to administer (see Section 5 below). If the visit is outside of this window, continue with the annual visit as specified in that year's protocol and do not administer the Flu Substudy Workbook at that time.

3.1.2 Second flu substudy contact

The second flu substudy contact should occur 6 to 9 months after the end of the qualifying illness episode (i.e., 3 to 6 months after the first flu substudy contact). If the original post-illness assessment was done as a special visit following the Semi-annual Telephone Contact, the recovery assessment (second flu substudy contact) should be the next annual clinic visit with the additional components if not already included in the annual exam.

The components of the second flu substudy contact are the same as the first flu substudy components except physical activity questions are added and no blood for serum is collected. Its components are:

CES-D
Physical Activity questions
Weight
Grip Strength
Chair Stands
Standing Balance
4-Meter Walk
Isometric Chair
DXA

If the original assessment was done as a part of an annual clinic visit, a special visit should be scheduled 3 to 6 months after the annual exam. The same Flu Substudy

Workbook is used for both the first flu substudy contact and the second flu substudy contact. The instructions on the Flu Substudy Workbook are clear about which components to administer at each contact.

3.2 Expected number of extra visits

Based on data from 763 18-month phone visits, 26 participants reported having had an illness accompanied by fever in the past 3 months. Assuming this sample is representative, one may project that the proposed surveillance will identify up to 208 eligible cases per year. Sample size estimates (see below) indicate that the sub-study will require approximately 200 ARIF participants. Spreading this number out over the remaining years of the study and leaving a cushion for ineligible cases, refusers and attrition, the substudy will require an extra 66 additional clinic visits per year study-wide.

4. Sample size requirements

The first study hypothesis will compare the mean lean body mass (LBM) change in ARIF to non-ARIF participants. The expected change in non-ARIF sufferers will be derived from data from the parent cohort. Based on data from Year 1 and Year 2 in a subset of Health ABC participants, the standard deviation of the change is expected to be 1.7 kg. The number of ARIF participants needed to detect a 0.5 kg difference in the change in LBM between ARIF participants and non-ARIF participants with 80% power is 122, assuming a Type I error rate of 5% and the use of two-tailed significance test. The other measures specified in the first hypothesis are not as central, so no sample size calculations are provided.

The second two hypotheses will correlate amounts of body composition and functional change with either illness severity or physical activity among those suffering an ARIF. The sample size therefore is driven by the proportion of variation in change that can be accounted for by the independent variables. A sample size of 200 will permit the detection of a univariate R-square of .04 with 80% power. Thus, with 200 qualifying cases even relatively modest associations will be able to be detected.

5. Administration of Flu Substudy Workbook

5.1 First flu substudy contact at annual contact

1. Mark “First flu substudy contact” and “at annual contact” on page #1 of the Flu Substudy Workbook. Record whether this is a home visit or a clinic visit. Record the month or year of contact.

2. Follow the directions on the Flu Substudy Workbook. For example, on Question #1, you will be asked if this visit is in conjunction with an Annual Clinic Visit. Mark "Yes" and determine whether or not the physical activity questions are being asked during this year's annual clinic visit. If "Yes" you will be directed to go to question #6; if "No" you will ask the physical activity questions. When you get to the testing portion of the workbook (starting with Weight), you will be directed to go to Grip Strength since weight is always taken at each clinic visit. You will then be asked whether or not Grip Strength is part of this year's clinic visit and if it is you will not have to administer the grip strength test. You would go to the next test in the workbook and repeat the same procedure for each test – i.e., determine whether or not that test was being done at this year's clinic visit and skip the test if it is already part of the clinic visit workbook for that year.
3. When you get to page 17 (Phlebotomy), you will be asked whether this visit is in conjunction with a Year 4 or Year 6 annual clinic visit, and if it is, you will skip the phlebotomy and go to page 20 (DXA), mark that this visit is in conjunction with an annual clinic visit, and complete the Flu Substudy Procedure Checklist on page 1 of the Flu Substudy Workbook.

5.2 First flu substudy contact at semi-annual contact

1. Mark "First flu substudy contact" and "at semi-annual contact" on page #1 of the Flu Substudy Workbook. Record whether this is a home visit or a clinic visit. Record the month or year of contact.
2. You will start on Question #1 on page 2; i.e., the entire questionnaire component of the Flu Substudy Workbook will be administered.
3. Administer all of the tests in the Flu Substudy Workbook, including the blood draw. One 5 mL serum tube should be drawn. This serum sample should be allowed to clot, should be centrifuged, and aliquoted into a single 1 mL aliquot that will be frozen and sent to McKesson. Special barcode labels with a distinct series of barcode numbers (1000-xx and up for Memphis and 2000-xx and up for Pittsburgh) have been sent to each field center. Make absolutely sure that the Phlebotomy and Laboratory Processing Forms in the Flu Substudy Workbook (pages 17-19) accompany the cryovials to McKesson. Please put the flu substudy samples in the same freezer boxes as the regular annual clinic visit samples. Do not make blind duplicate aliquots with these samples.

5.3 Second flu substudy contact at annual contact

1. Mark "Second flu substudy contact" and "at annual contact" on page #1 of the Flu Substudy Workbook that. Record whether this is a home visit or a clinic visit. Record the month or year of contact.
2. Follow the directions on the Flu Substudy Workbook. For example, on Question #1, you will be asked if this visit is in conjunction with an Annual Clinic Visit. Mark "Yes" and determine whether or not the physical activity questions are being asked during this year's annual clinic visit. If "Yes" you will be directed to go to question #6, if "No" you will ask the physical activity questions. When you get to the testing portion of the workbook (starting with Weight), you will be directed to go to Grip Strength since weight is always taken at each clinic visit. You will then be asked whether or not Grip Strength is part of this year's clinic visit and if it is you will not have to administer the grip strength test. You would go to the next test in the workbook and repeat the same procedure for each test – i.e., determine whether or not that test was being done at this year's clinic visit and skip the test if it is already part of the clinic visit workbook for that year.
3. When you get to page 17 (Phlebotomy), you will be asked whether this visit is a first visit, and since it is not, you will mark "No" and go to DXA.
4. Since this is an annual visit, you will mark "yes" on question #1 on page 20 (DXA), and complete the Flu Substudy Workbook Procedure Checklist on page 1 of the Flu Substudy Workbook.

5.4 Second flu substudy contact at semi-annual contact

1. Mark "Second flu substudy contact" and "at semi-annual contact" on page #1 of the Flu Substudy Workbook. Record whether this is a home visit or a clinic visit. Record the month or year of contact.
2. You will start at Question #1 on page 2; i.e., the entire questionnaire component of the Flu Substudy Workbook will be administered.
3. Administer all of the tests in the Flu Substudy Workbook, with the exception of the blood draw, and complete the Flu Substudy Workbook Procedure Checklist on page 1 of the Flu Substudy Workbook.

6. Quality assurance

6.1 Training requirements

The examiner requires no special qualifications or prior experience to perform this assessment. Training should include.

- Read and study operations manual chapter on the Flu Substudy
- Read and study operations manual chapters on each individual component of the Flu Substudy Workbook
- Discuss protocol and data collection forms with local expert or QC Coordinator

6.2 Certification requirements

- Complete training requirements
- Recite eligibility criteria for cases
- Observation and evaluation of two to three *mock* Flu Substudy eligibility assessments by the QC Coordinator or their designate.
- Observation and evaluation of one *actual* Flu Substudy eligibility assessment by the QC Coordinator or their designate.
- Complete recent (within the year) certification is required for any examiner administering any particular component of the flu substudy: i.e., Interview, Weight, Grip strength, Performance Measures, Isometric strength; Phlebotomy; Laboratory processing; DXA
- Complete two Flu Substudy Eligibility Assessment forms and two Flu Substudy Workbooks and have reviewed by QC Coordinator:

6.3 Quality assurance checklist

ELIGIBILITY

- ☐ Records correct month or year of contact on Flu Substudy Eligibility Assessment form
- ☐ Records correct type of contact on Flu Substudy Eligibility Assessment form
- ☐ Correctly determines whether the participant should or should not be included in the Flu Substudy, i.e., administered the Flu Substudy Workbook
- ☐ Correctly completes Question #15 on the Flu Substudy Eligibility Assessment form regarding how many colds or bouts of flu the participant reported having.

FLU SUBSTUDY WORKBOOK

- ☐ Correctly records Type of Substudy Contact.
- ☐ Correctly follows skip pattern to determine which tests to administer
- ☐ Reads questions exactly as written on the Flu Substudy Workbook (same order, same wording).
- ☐ Response options read / not read when appropriate
- ☐ Follows skip pattern in Flu Substudy Workbook.
- ☐ Accurately records participant's responses on Flu Substudy Workbook.

☐ Follows the guidelines for recording data on scannable forms.
☐ At the end of interview, reviews Flu Substudy Workbook for completeness.
☐ Correctly completes form

INTERVIEWING TECHNIQUES

☐ Reads slowly, speaks clearly and uses appropriate inflection when speaking
☐ Reduces the chance of bias by maintaining a neutral attitude towards the participant
☐ Is able to elicit accurate and complete information using non-directive probes
☐ Keeps interview on track by presenting questions at a regular pace.
☐ Focuses participant's attention on questions while always being polite.
☐ Treats participant with respect
☐ Maintains a professional and friendly manner

WEIGHT

☐ Check box if a Year 5 Weight certification form for the examiner has already been sent in to the Coordinating Center. If the examiner is certified to administer the Year 5 Weight measurement, skip to Grip certification on page 4.

Training Requirements

No special qualifications or experience are required to perform this assessment. Training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers (Goal: minimize differences between repeat measurements)
- Discuss problems and questions with local expert or QC officer

Certification Requirements

__ Completes training requirements
__ Conducts exam on two volunteers while being observed by QC officer:
  __ According to protocol, as demonstrated by completed QC checklist

Quality Assurance Checklist

- ☐ Participant is encouraged to use bathroom prior to measurement
- ☐ Measurement is made without shoes, heavy jewelry, or heavy objects in pockets
- ☐ Immediately records weight to nearest 0.1 kg if using kg scale
- ☐ Ensures that participant stands still in center of platform
- ☐ Tells participant weight in pounds (and kilograms if using a kilogram scale)
- ☐ Reviews form for completeness
- ☐ Correctly completes form
- ☐ Checks Data From Prior Visits Form and determines if participant has lost ≥10% of their weight since the last annual visit

GRIP STRENGTH

Training Requirements

The technician requires no special qualifications for performing this assessment. The training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

Certification Requirements

__ Completes training requirements

__ Demonstrates maintenance check of dynamometer and adjustment of dynamometer handles

- **Posts**: Remove the adjustable handle and check that each post moves up and down freely (through a very small distance, about 1/8") within the plastic aperture (the guide) even when you exert pressure on the side of the post.
- **Hydraulics**: Remove the adjustable handle. While watching the top post, push down on the bottom post. Normally, both posts should move about 1/8", with top and bottom posts moving in opposite directions. Movement less than 1/16" indicates a probable leak in the hydraulic system, which requires service.
- **Handle**: Grasp the instrument normally and look carefully at the way the forks of the adjustable handle are supported on the posts. Each fork should touch the post at approximately its mid-point.

- **Peak-Hold Needle**: Check for excessive friction in the peak-hold assembly by turning the peak-hold knob counter-clockwise. If the peak-hold needle causes the gauge needle to move, return the gauge for service.
  If the peak hold needle is knocked off its support pin, it can readily be repositioned. Unscrew the crystal and turn it upside down. Locate the brass pin in the center of the crystal (the pin is part of the chrome knob on the outside of the crystal). Locate the slot on the brass pin and place the peak-hold needle into this slot.

__ Demonstrates the calibration check procedures

- Every week: Check the calibration of the grip strength dynamometer by hanging 5 kg and 20 kg (or 10 lb and 50 lb) weights across the handle using two velcro straps, one strap on each side of the dynamometer handle, or one wide strap that covers the whole handle. Lift the weights slowly from the floor while they are strapped to the dynamometer handle and record the maximum kilograms registered. The lifting motion should be very slow and smooth, and the weight should remain evenly distributed between the two sides of the handle. Repeat the procedure three times and record each result.
- Average the three calibration trials. The dynamometer should be accurate within ± 2 kgs for the average of the three calibration trials. If the calibration check is not within these limits, notify the QC officer.

__ Recites exclusions

- Has undergone fusion, arthroplasty, tendon repair, synovectomy, or other related surgery of the upper extremity in the past 3 months.

__ Conducts exam on two volunteers while being observed by QC officer:

__ According to protocol, as demonstrated by completed QC checklist

__ ± 2 kgs on repeat assessment of volunteer

Quality Assurance Checklist

☐ Participant is asked about recent surgery on hands
☐ Participant is asked about pain and arthritis in hands
☐ Correct instructions are given while demonstrating procedure
☐ Recording dial is reset to zero after sub maximal practice
☐ Sub maximal practice; grip adjusted if necessary
☐ Forearm is resting on table, elbow bent to approximate right angle
☐ Standard encouragement (motivation and feedback) is offered to participant
☐ Recording dial (peak hold needle) reset to zero after first trial
☐ Measurement is taken twice on each side (unless contra-indicated)
☐ Key points from script delivered clearly

☐ Reviews form for completeness
☐ Correctly completes form

PERFORMANCE TESTS

Training Requirements

The examiner requires no special qualifications or experience to perform this assessment. Training should include:

- Read and study manual
- Attend Health ABC training session on techniques (or observe administration by experienced examiner)
- Practice on other staff or volunteers
- Discuss problems and questions with local expert or QC officer

Certification Requirements

__ Completes training requirements
__ Recites exclusions
  - problems from recent surgery, injury, or other health conditions that would prevent participant from standing up from a chair, standing on one leg, or walking
  - participant feels it would be unsafe to try test
__ Conducts exam on two volunteers while being observed by QC officer:
  __ According to protocol, as demonstrated by completed QC checklist
  __ Times within ± 1 s of QC officer, step counts agrees with QC officer
  __ Assessment of "deviations" on narrow walks agrees with QC officer

Quality Assurance Checklist

Standing balance

Semi-tandem stand

☐ Script correctly and clearly delivered
☐ Correctly demonstrates position
☐ Timing started coincident with participant release and stopped when participant took a step or held on
☐ If task was not performed, recorded reasons

Tandem stand

- ☐ Script correctly and clearly delivered
- ☐ Correctly demonstrates position
- ☐ Timing started coincident with participant release and stopped when participant took a step or held on
- ☐ If task is not performed, records reasons
- ☐ Repeats (second trial)

One-leg stand

- ☐ Script is correctly and clearly delivered
- ☐ Correctly demonstrates position
- ☐ Timing starts coincident with participant release and stops when participant takes a step or holds on
- ☐ If task is not performed, records reasons
- ☐ Repeats (second trial)

Chair stands

- ☐ Back of chair is against a wall
- ☐ Script is correctly and clearly delivered for each test
- ☐ Correctly demonstrates single stand, emphasizing
  - keeping arms tight across chest
- ☐ Correctly demonstrates two stands, emphasizing
  - full stand and return to complete sit
- ☐ Says “ready, go.” for each test
- ☐ Counts each chair stand, and stops timing after participant sits down on fifth stand
- ☐ Records and explains unusual values
- ☐ If tasks are not performed, codes and explains reasons

4-meter Walk

☐ Main points of script correctly and clearly delivered
☐ Correctly demonstrates
☐ Toes touching start line
☐ Timing starts coincident with participant's first footfall
☐ Repeats (second trial)
☐ Rapid pace is correctly tested

ISOMETRIC CHAIR

Training

The examiner requires no special qualifications or experience to perform this assessment. Training should include:

- observe measurement by experienced examiner
- read manufacturer's user's guide and Health ABC operations manual to understand:
  - the proper use of equipment
  - the proper calibration and adjustment of equipment
  - exclusions and safety considerations
  - detailed testing procedures
- practice on colleagues and volunteers who have no previous knowledge of the protocol

Certification Requirements

___ Completed training requirements
___ Recited exclusion criterion (Bilateral knee replacement)
___ Recited stop criterion (Knee pain that stops the participant from pushing hard)

Quality Assurance Checklist

☐ Participant is questioned regarding knee replacement
☐ Checks Data from Prior Visits report to determine side to test
☐ Participant is correctly positioned in chair with knee joint at a 90-degree angle
☐ Appropriate connecting rod is chosen and recorded on data collection form
☐ Vertical seat adjustment correctly made
☐ Back support is moved to provide maximum lower back support
☐ Sensor is parallel with the shaft of the participant's thigh
☐ Padding is placed under the non-tested knee

- ☐ Participant is strapped into chair properly
- ☐ Lower leg length is measured from mid-knee joint to base of the trolley
- ☐ Kim-wipe is placed on the trolley heel
- ☐ Participant's heel correctly is placed into the trolley and strapped into place using shin pad (not too tight)
- ☐ Performs final check for participant positioning (90 degree angle, thigh parallel to connecting rod)
- ☐ Practice trial is completed successfully
- ☐ Standard level of encouragement (motivation and feedback) is offered to participant
- ☐ Key points from script are stated and clearly delivered
- ☐ 25 seconds passed between each trial
- ☐ Data is completely and accurately recorded:
  - ☐ leg being tested
  - ☐ leg length
  - ☐ maximum torque
  - ☐ maximum rate torque
  - ☐ reaction time
  - ☐ time to 50% MVTD
  - ☐ if test not performed, why?
- ☐ Form is correctly filled out
- ☐ Reviews form for completeness

Appendix 1 Flu Substudy Illness Cutoff Date and Target Window Log (page 1)

Date Flu Substudy Eligibility Asssessment Form completed (during Annual or Semi-Annual Contact)		Target Window to schedule first flu substudy visit if eligibility assessment is done as part of the Semi-Annual Telephone Contact		
01/02/01	10/14/00	01/02/01	to	01/16/01
01/03/01	10/15/00	01/03/01	to	01/17/01
01/04/01	10/16/00	01/04/01	to	01/18/01
01/05/01	10/17/00	01/05/01	to	01/19/01
01/06/01	10/18/00	01/06/01	to	01/20/01
01/07/01	10/19/00	01/07/01	to	01/21/01
01/08/01	10/20/00	01/08/01	to	01/22/01
01/09/01	10/21/00	01/09/01	to	01/23/01
01/10/01	10/22/00	01/10/01	to	01/24/01
01/11/01	10/23/00	01/11/01	to	01/25/01
01/12/01	10/24/00	01/12/01	to	01/26/01
01/13/01	10/25/00	01/13/01	to	01/27/01
01/14/01	10/26/00	01/14/01	to	01/28/01
01/15/01	10/27/00	01/15/01	to	01/29/01
01/16/01	10/28/00	01/16/01	to	01/30/01
01/17/01	10/29/00	01/17/01	to	01/31/01
01/18/01	10/30/00	01/18/01	to	02/01/01
01/19/01	10/31/00	01/19/01	to	02/02/01
01/20/01	11/01/00	01/20/01	to	02/03/01
01/21/01	11/02/00	01/21/01	to	02/04/01
01/22/01	11/03/00	01/22/01	to	02/05/01
01/23/01	11/04/00	01/23/01	to	02/06/01
01/24/01	11/05/00	01/24/01	to	02/07/01
01/25/01	11/06/00	01/25/01	to	02/08/01
01/26/01	11/07/00	01/26/01	to	02/09/01
01/27/01	11/08/00	01/27/01	to	02/10/01
01/28/01	11/09/00	01/28/01	to	02/11/01
01/29/01	11/10/00	01/29/01	to	02/12/01
01/30/01	11/11/00	01/30/01	to	02/13/01
01/31/01	11/12/00	01/31/01	to	02/14/01
02/01/01	11/13/00	02/01/01	to	02/15/01
02/02/01	11/14/00	02/02/01	to	02/16/01