

INSTRUCTIONS FOR BASELINE MEDICAL HISTORY FORM BMH, VERSION 1.0 (QxQ)

I. GENERAL INSTRUCTIONS

The Baseline Medical History Form is filled out by the study coordinator at the baseline visit.

Header Information: The header information consists of key fields which uniquely identify each recorded instance of a form.

FORM DATE: Record date this is being completed. Select the date from the pop up calendar or type in the date in the space provided. Dates should be entered in the mm/dd/yyyy format.

INITIALS: Record the staff code of the person entering the data on this form. This code is assigned to each person at each site by the GIC. If you do not have a staff code and are collecting SPIROMICS data please contact the GIC in order to receive your own individual staff code.

II. DETAILED INSTRUCTIONS FOR EACH ITEM

Please answer every question on this form. The Baseline Medical History From collects important information that will better help to understand how various other medical conditions relate to COPD.

- Item 1. Select 'Yes' or 'No' to answer whether the participant has been hospitalized in the previous 12 months. If the participant has been hospitalized in the past year use items 1a through 1h to enter information regarding each hospitalization. If the participant has NOT been hospitalized in the past year go to item 2.
 - Items 1a-1h. For each hospitalization in the past 12 months give a brief description and enter the date of hospital admittance. If the actual date is not known enter the month and year.
- Item 2. Select 'Yes' or 'No' to answer whether the participant has visited an emergency department or urgent care center in the previous 12 months. If the participant has been an ED or urgent care center in the past year use items 2a through 2j to enter information regarding each visit. If the participant has NOT been an ED or urgent care center in the past year go to item 3.
 - Items 2a-2j. For each emergency department visit or urgent care center visit in the past 12 months give a brief description and enter the date of the visit. If the actual date is not known enter the month and year.
- Item 3. Select 'Yes' or 'No' to answer whether the participant has any surgeries in their lifetime. If the participant has ever had any surgeries use items 3a through 3j to enter information regarding each surgery. If the participant has NOT ever had any surgeries go to item 4.
 - Items 3a-3j. For each surgery visit in the past 12 months give a brief description and enter the date of the surgery. If the actual date is not known enter the month and year.
- Item 4. Select the participant's response to whether or not s/he gets an influenza vaccination every year. If the participant has ever gotten a flu shot enter date in item 4a. If the participant has never had a flu shot go to item 5.

- Items 4a. Enter the month and year of the last flu shot the participant received.
- Item 5. Select when the participant last had a pneumonia vaccination.
- Item 6. Select 'Yes', 'No' or 'Don't know' to describe if the participant has ever been diagnosed with alpha-1 anti-trypsin deficiency.
- Item 7. This item asks about specific problems with the eyes, ears, nose, and throat that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a condition involving the eyes, ears, nose or throat that is NOT listed in items 7a-7e describe the condition in item 7f.
- Item 8. This item asks about specific cardiovascular problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a cardiovascular condition that is NOT listed in items 8a-8j, describe the condition in item 8k.
- Item 9. This item asks about specific gastrointestinal problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a gastrointestinal condition that is NOT listed in items 9a-9h, describe the condition in item 9i.
- Item 10. This item asks about specific pulmonary and vascular problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a pulmonary or vascular condition that is NOT listed in items 10a-10f, describe the condition in item 10g.
- Item 11. This item asks about specific oncology and hematology problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for an oncology or hematology condition that is NOT listed in items 11a-11b, describe the condition in item 11c.
- Item 12. This item asks about specific genitourinary and reproductive problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a genitourinary or reproductive condition that is NOT listed in items 12a-12c describe the condition in item 12d.
- Item 13. This item asks about specific endocrine problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for an endocrine condition that is NOT listed in items 13a-13b, describe the condition in item 13c.
- Item 14. This item asks about specific neurological problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why

- medical care was sought. If the participant has seen a medical provider for a neurological condition that is NOT listed in items 14a-14c, describe the condition in item 14d.
- Item 15. This item asks about specific muscular/skeletal problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a muscular or skeletal condition that is NOT listed in items 15a-15f, describe the condition in item 15g.
- Item 16. This item asks about specific dermatological problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a dermatology condition that is NOT listed in items 16a-16c, describe the condition in item 16d.
- Item 17. This item asks about specific infectious diseases that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the diseases listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for an infectious disease that is NOT listed in items 17a-17b, describe the condition in item 17c.
- Item 18. This item asks about specific psychiatric problems that the participant may have seen a physician or other medical provider about over his/her life time. If the participant has ever seen a medical provider for any of the problems listed select 'Yes' and then briefly explain why medical care was sought. If the participant has seen a medical provider for a psychiatric condition that is NOT listed in items 18a-18b, describe the condition in item 18c.
- Item 19. This item allows for any other medical conditions that the participant has ever visited a physician or other medical provider about over his/her life time to be listed. If any condition has not been described above for which medical care was sought select 'Yes' and use items 19a-19e to describe any other conditions.
- Item 20. This item asks about illnesses or problems that have occurred in the past TWO WEEKS. Carefully read each item on 20a-20g and select 'Yes' if this describes an occurrence from the past two weeks. If any other illness has occurred in the past two weeks that is described in items 20a-20g select 'Yes' on item 20h and give a brief description in item 20i.
- Item 21. List ANY allergies and describe the reaction that occurs upon exposure or consumption of these substances.
- Item 22. This item asks for an estimate of how many alcohol containing beverages have been consumed, on average, over the previous 12 months. If the participant has not consumed any beverages containing alcohol in the previous 12 months select 'No alcohol in the past 12 months' and skip to item 29.
- Item 23. This item asks for an estimate of alcohol containing beverages consumed in one sitting. Ask the participant to carefully consider how many alcoholic beverages are consumed at one time on average, and select then answer that best fits his/her description.
- Item 24. This item asks about specific types of alcoholic beverages that are consumed. Check every description that is applicable to the participant's consumption of beverages containing alcohol.
- Item 25. If the participant ever had more than EIGHT drinks on one occasion select how often this occurs. If this never occurs, select 'Never'.

- Item 26. If the participant has not been able to remember the events of the previous night when alcohol was involved in the past year select how many times this has happened. If this has not happened in the past year select 'Never'.
- Item 27. If the participant has ever failed to complete a task or do what is normally expected of him/her as a result of drinking alcohol in the past year, select how often this has happened. If this has never happened select 'Never'.
- Item 28. This item asks if the participant has ever been told they should reduce the amount of alcoholic beverages he or she consumes. If he or she has never been told they should cut down select 'Never'; if he or she has been told to cut down select whether or not this has happened in the past year.
 - Items 29 through 43 ask questions that pertain only to females ONLY. If the participant is marked as 'Male' on the Eligibility form these questions will be automatically skipped.
- Item 29. Ask the participant at what age she began having monthly menstruation, and record the age in the space provided.
- Item 30. If the participant has not yet reached menopause or is unsure if she has reached menopause then select 'No' or 'I don't know' and go to item 32. If she has reached menopause select 'Yes' and enter the age menopause was reached in item 31.
- Item 31. Record the age at which menopause started for the participant.
- Item 32. If the participant has never used oral birth control medication or is unsure if she ever has oral contraceptives then select 'No' or 'I don't know' and go to item 34. If she has used oral birth control medication select 'Yes' and enter the number of years oral contraceptives were taken or have been taken in item 33.
- Item 33. Record how many years she used oral contraceptives.
- Item 34. If the participant has never used hormone replacement therapy or is unsure if she has ever used hormone replacement therapy then select 'No' or 'I don't know' and go to item 36. If she has used hormone replacement therapy select 'Yes', and enter how many years hormone replacement therapy was or has been used in item 35.
- Item 35. Record how many years she used or has used hormone replacement therapy.
- Item 36. If the participant has EVER been pregnant, including any miscarriages or abortions, select 'Yes' and answer questions regarding specific information about her pregnancies in items 27-40. If she has never been pregnant select 'No' and go to item 41.
- Item 37. Record the age she was at the time of her FIRST pregnancy. This includes any pregnancy that may have been a miscarriage or an abortion.
- Item 38. Record how many times she has been pregnant, including all miscarriages and abortions.
- Item 39. If she never breastfed select 'No' and go to item 41. If she did breastfeed select 'Yes' and record the total amount of time in item 40.
- Item 40. Record the total number of months the participant breastfed for ALL pregnancies. For example if she gave birth twice and breastfed for 9 months for the first child and 7 months for the second child '16' should be recorded as the total months breastfed.

- Item 41. If the participant has ever had an ovary removed select 'Yes' and answer whether it was just one or whether it was both ovaries that were removed in item 42. If she has never had an ovary removed select 'No' and the last 2 items will skip. Save and close the form.
- Item 42. Select 'One' or 'Both' to describe the ovary or ovaries that were removed.
- Item 43. Record how old the participant was when she had her ovary/ovaries removed. Then save and close the form.