



# INSTRUCTIONS FOR THE PARKINSON'S DISEASE INTERVIEW (11/09/2015) (PDI, VERSION 1, 11/09/2015)

## I. General Instructions

This form is administered during a separate telephone interview from the annual or semi-annual follow-up contact OR following the annual or semi-annual follow-up interview. This form should be completed for participants who have provided information to the ARIC Study between Visit 1 and the last completed Follow-up interview indicating they may have Parkinson's disease (PD). This form is designed to be administered to the participant or a knowledgeable proxy/informant, such as a spouse, other family member or close friend. When speaking with the proxy/informant, it is permissible to refer to the participant as "your mother" or "your father" etc., rather than including the participant's full name for the interview.

We prefer to complete the PDI by telephone interview; however, mailed versions of the PDI are available in the instance where a participant or proxy could not be reached by telephone or prefer to be contacted by mail. There are two versions of the mailed PDI, one for living participants (Version A) and the other for proxy/informant when the participant is deceased (Version D). When the completed questionnaire is returned, the field centers are expected to enter the answers starting from question 3 on the returned questionnaire into the corresponding questions in CDART. The numbering of the questions that need to be keyed into CDART is mostly consistently with what's in the CDART form with the following few exceptions:

1. Question Q0a (form completion date) in CDART form is numbered as Q3 (Complete today's date) on the mail versions.
2. Questions 9a1 through 9k in CDART form are numbered as Q9.1a through 9.1k on the mail versions.
3. Questions 20a1 through 20i3 in CDART form are numbered as Q 20.1a through 20.3i on the mail versions.

As indicated on the first page of the mailed versions of PDI, several questions have been omitted on purpose. When a field that's expected to be answered is left empty on the returned mailed questionnaire, please click on the arrows to the right of the missing field, select 'No response' as the reason for the missing data in the drop down menu and then click on the save button to save the selected reason. If the response 'Don't know' is not listed as an option in the CDART form but is recorded as an answer on the mail versions, please follow the same above instruction but select 'Don't know' as the reason for the missing data.

## II. Detailed Instructions for each Item.

When the interviewer makes contact with someone on the telephone (may or may not be the participant), read the following script.

**Script: "Hello, this is [your name] from the ARIC Study. May I please speak with [name of contact]?"**

Determine the availability of the participant or follow-up proxy and vital status of the participant. The [name of contact] in this case could be the study participant or his/her proxy in case that the participant deceased.

If the interviewer is notified that the participant for whom we need to confirm the PD diagnosis is recently deceased, offer condolences, and ask for permission to continue the interview with a knowledgeable proxy. The contact may a) agree to schedule another call during the given time frame, b) agree to complete the interview, or c) refuse the interview. As needed, inform the respondent of the possible need to contact a family member later on, and ask when would be the best time to call.

If the participant or follow-up proxy ("respondent") is available, greet them with the following script.

**Script: "Hello [name of respondent]. My name is [your name] and I am from the ARIC Study. Our records indicate that you [name] may have reported a possible diagnosis of Parkinson's disease or may have used medications for Parkinson's disease or a related disorder. May I ask you a few questions about this, which will take less than 10 minutes? It will be very important for us to confirm with you whether or not you have [name has] the disease. The information you provide will be kept strictly confidential to the extent possible by the law and will only be used for research. "**

For participants who are reluctant to participate, the interviewer should make an attempt to determine the reason, clarify any misunderstandings, and try to answer any questions. Please refer to Appendix I for refusal scripts that could be used.

We identify possible PD patients from multiple ARIC data sources (e.g. medication use, self-report, hospitalization and death records). Further, we cover a long time period from visit 1 until the last Follow-up Interview. The individual status of the study participants may vary; please be sensitive to the following situations:

1. Some participants may not have PD and they may be anxious when we ask them questions about PD. For these participants, please ease their anxiety and tell them that we will correct our record and will only need to ask a few questions.
2. Some participants are deceased; some may even have died a long time ago. The proxy may be reluctant to answer questions regarding the participant. Please keep this in mind and use refusal conversions when needed. For most participants, we should be able to determine their survival status before the call. In the case that you call a proxy of a participant who died a long time ago, please adjust the introductory language accordingly.
3. Many of the participants may have physical and mental difficulties, hearing, and speaking or memory problems. In this case, we may collect the data with help from an informant or entirely from a knowledgeable informant. In our last round of confirmation, most interviews were completed by proxies.

PDI questions:

- 0a. Enter the date of contact or the date the status determination was made. For mailed responses, enter the date recorded in question 3 of the mailed questionnaire.
- 0b. Enter the staff ID for the telephone interviewer, the staff ID that made last contact attempt, or the staff ID for the person entering the data from the mailed questionnaire.

Additional information for specific items:

## **A. CONTACT AND BACKGROUND**

1. Result of contact for the interview. Enter the contact status code that describes whether or not the interview was completed and the person interviewed.

- A. **Participant contacted, agreed to be interviewed**
- B. **Participant contacted, agreed to respond by mail**
- C. **Proxy/Informant contacted, agreed to be interviewed**
- D. **Proxy/Informant contacted, agreed to respond by mail**
- E. **Contacted and refused**
- F. **Contact pending; continue to attempt to contact**
- G. **Contact not possible**

A. Participant contacted, agreed to be interviewed: Contact was made with the participant and he/she agreed to be interviewed. The interview was done with the participant or someone who assisted the participant in answering the questions, i.e., not a proxy.

**Action:** Begin interview at question 4.

If the interview is interrupted or the participant requests the interview be done at another time, record question 27 as 'b. Partially complete; contact again'. The interviewer will continue to attempt to contact at a later date.

B. Participant contacted, agreed to respond by mail: If possible, the interview is done with the participant or proxy/informant over the phone (preferred). However, if the participant is still reluctant to participate after exhausting all refusal conversion strategies OR after at least 3 attempts are made to conduct the interview over the phone, the interviewer may offer the possibility to respond by mail. If the participant agreed to respond by mail, then record question 1 as 'B', record question 1a as 'D' and record question 27 as 'B'.

**Action:** Follow the study protocol about mailing the questionnaire along with other required materials to the participant. When the completed questionnaire is received from the participant, enter the data into CDART. If all the expected forms have been returned, update question 1a and question 27. If no forms have been returned after repeated attempts, record question 1a as 'D' and record question 27 as 'C'.

C. Proxy/Informant contacted, agreed to be interviewed: Contact was made with follow-up proxy or other informant who is knowledgeable and able to answer the interview questions on behalf of the participant (e.g., relative, spouse).

**Action:** Begin interview at question 3. If the respondent is unable to provide reliable information about the participant, or is unable to answer the questions, try to identify another contact person who might be able to provide this information. Record Q3 as 'N' and Q27 as 'b. Partially complete; contact again' and get contact information for the person. Ensure the information is provided to ARIC Follow-up staff so that it may be entered into the CIU.

D. Proxy/informant contacted, agreed to respond by mail: If possible, the interview is done with the participant or proxy/informant over the phone (preferred). However, if the proxy/informant is still reluctant to participate after exhausting all refusal conversion strategies OR after at least 3 attempts to conduct the interview over the phone are made, the interviewer could offer the possibility to respond by mail. If the proxy/informant agreed to respond by mail, then record question 1 as 'D', record question 1a as 'D' and

record question 27 as 'B'.

**Action:** Follow the study protocol about mailing the questionnaire along with other required materials to the participant. When the completed questionnaire is received from the proxy/informant, enter the data into CDART. If all the expected forms have been returned, update question 1a and question 27. If no forms have been returned after repeated attempts, record question 1a as 'D' and record question 27 as 'C'.

- E. **Contacted and refused:** Contact was made with the participant or proxy/informant, but he/she refused to be interviewed or respond by mail despite exhausting all refusal conversion attempts. A cohort member is considered to have refused following at least 3 conversion contacts, or if they otherwise firmly refuse.

**Action:** Only record this code for "hard" refusal. Complete question 2/2a, then code question 27 as 'a. Complete'.

- F. **Contact pending; continue to attempt to contact:** Contact pending.

**Action:** No action necessary; save and close form. Further attempts will be made to complete the interview.

- G. **Contact not possible:** Neither the participant, the proxy, nor another person was able to be contacted after repeated attempts.

**Action:** No action necessary; save and close form.

- 1a. Record what packet materials (PDI Parkinson's Disease Interview and/or consent form for medical records release) were returned to the field center. If the question is recorded as 'Consent only', the form skips to question 24. If the question is recorded as 'PDI only' or 'Consent and PDI', the form skips to question 4. If the question is recorded as 'None', save and close form.

- 2-2a. Record the reason for refusal. If 'B' or 'D' are selected, open a notelog to record interviewer's certainty about whether or not the participant has PD. Then code question 27 as 'a. Complete', then save and close form. If 'Other' is selected, specify the reason in Q2a, code question 27 as 'a. Complete', then save and close form.

3. Determine whether the respondent is able to answer health questions pertaining to the participant. If the respondent is unable to answer these questions, try to identify another contact person who might be able to provide this information. If another contact person is identified, record question 27 as 'Partially complete; contact again' and get contact information for the person. If another contact person is unable to be identified, record question 27 as 'Partially complete; unable to complete questionnaire'.
4. This question asks the respondent to recall a diagnosis of Parkinson's disease. If the question is recorded as "No" or "Don't know, the form skips to question 9a1.

Parkinson's disease is often diagnosed by a neurologist or movement disorder specialist, but also can be diagnosed by internist, general physician, family practitioner etc. If the participant has the disease, they should know and be able to tell you. If the participant has been evaluated for a Parkinson diagnosis, but the diagnosis is uncertain but suspected, record question 4 as "maybe". In the case that a participant has never heard of Parkinson's disease, it probably means that he/she does not have the disease. Few people, if anyone, should be in the category of "don't know," which is reserved for individuals who are really not sure whether they have Parkinson's disease or not.

5. Record the age of the participant when he/she was first diagnosed with Parkinson's disease. If age is recorded, the form skips to question 8. If age is unknown, probe for year or best estimate of year diagnosed in the following questions.
6. Record in what year the participant was first diagnosed with Parkinson's disease. If year is recorded, the form skips to question 8.
7. Indicate how long ago the participant was first diagnosed with Parkinson's disease.

The PDI has several questions where the prompt will be different depending on the vital status of the participant. Instructions will be provided before these questions to remind the interviewer to recall if the participant is alive or not and then select the corresponding prompt.

*[For the interviewer – select one of the following 2 prompts based on the vital status of the participant.]*

8. Indicate whether the participant still has the diagnosis of Parkinson's disease, or had the diagnosis when she/he passed away. Parkinson's disease is not curable, if someone has Parkinson's disease; he/she will have the disease for the rest of his/her life. However, the disease "diagnosis" is based on clinical symptoms, and in a small number of cases, the "diagnosis" may change in the first couple of years, depending on reactions to dopaminergic therapies and other clinical parameters. If the question is recorded as "Yes" or "Don't know", the form skips to question 10.

## **B. NEUROLOGIC DISORDERS**

### **Script: "Did you [name] ever have any of the following neurological diagnoses?"**

*Please refer to Appendix III for the meaning of medical terms and definitions as needed. These questions are asked only if the participants do not have PD or their initial diagnosis of PD is a misdiagnosis.*

- 9a1. Indicate whether the participant ever had diagnosis of *Essential tremor*. If the question is recorded as "No" or "Don't know", the form skips to question 9b1.
- 9a2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9b1. Indicate whether the participant ever had diagnosis of *Restless leg syndrome or RLS*. If the question is recorded as "No" or "Don't know", the form skips to question 9c1.
- 9b2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9c1. Indicate whether the participant ever had diagnosis of Alzheimer's disease or AD. If the question is recorded as "No" or "Don't know", the form skips to question 9d1.
- 9c2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9d1. Indicate whether the participant ever had diagnosis of *Dementia with Lewy bodies or DLB*. If the question is recorded as "No" or "Don't know", the form skips to question 9e1.
- 9d2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9e1. Indicate whether the participant ever had diagnosis of other types of dementia. If the question is recorded as "No" or "Don't know", the form skips to question 9f1.

- 9e2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9f1. Indicate whether the participant ever had diagnosis of *Progressive supranuclear palsy or PSP*. If the question is recorded as “No” or “Don’t know”, the form skips to question 9g1.
- 9f2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9g1. Indicate whether the participant ever had diagnosis of *Multiple system atrophy or MSA*. If the question is recorded as “No” or “Don’t know”, the form skips to question 9h1.
- 9g2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9h1. Indicate whether the participant ever had diagnosis of *Shy Drager syndrome*. If the question is recorded as “No” or “Don’t know”, the form skips to question 9i1.
- 9h2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9i1. Indicate whether the participant ever had diagnosis of *Nigrostriatal degeneration*. If the question is recorded as “No” or “Don’t know”, the form skips to question 9j1.
- 9i2. Indicate whether the diagnosis was made by neurologist or other doctor.
- 9j1-9k. Indicate whether the participant ever had other neurologic disease in question 9j1. If the question is recorded as “Yes”, indicate whether the diagnosis was made by neurologist or other doctor in question 9j2 and specify other neurologic disease in question 9k.

[When 9a1 through 9k are completed, GO TO QUESTION 27.]

### C. PARKINSON’S DIAGNOSIS

10. Indicate whether the participant’s Parkinson’s diagnosis was made by a movement disorder specialist? If the question is recorded as “Yes”, the form skips to question 13. If participant asks “What is a Movement Disorder Specialist?”, the interviewers can respond “A **movement disorder specialist** is a neurologist with special training to treat Parkinson’s disease and related movement disorders.”  
Movement disorders basically are a group of diseases that the patient have problems with body movement, for example, you cannot move part of your body or it shakes when you do not want it to shake. The differential diagnosis of PD from other Parkinson-like diseases often requires a movement disorder specialist or neurologist.
11. Indicate whether the participant’s Parkinson’s diagnosis was made by a neurologist. If the question is recorded as “Yes”, the form skips to question 13.
12. Specify the type of doctor who made the Parkinson’s diagnosis.
13. Record the age of the participant when he/she first noticed the symptoms of Parkinson’s disease. If age is recorded, the form skips to question 16a.

14. Record in what year the participant first noticed the symptoms of Parkinson's disease. If year is recorded, the form skips to question 16a.
15. Indicate how long ago the participant first noticed the symptoms of Parkinson's disease.

**Script:** "Did you [name] have any of the following symptoms around the time of diagnosis:"

Indicate "Yes" or "No" to questions about symptoms for questions 16a-16e.

16a. Trembling or shaking in any part of your [name's] body?

16b. Slowness in moving, such as walking or performing a task?

16c. Smaller handwriting than it was once?

16d. Dragging a foot, shuffling feet, or taking smaller steps while walking compared to the past?

16e. Difficulty getting up from a chair or sofa or getting out of a car?

16f-17c. Indicate if the participant experienced any other symptoms besides those listed in questions 16a-16e. If the question is recorded as "Yes", list up to 3 other symptoms in questions 17a, 17b and 17c. Examples of most reported "other" symptoms include loss of the sense of smell, drooling, sleep problems, voice becoming softer, masked face, depression, fatigue or pain. Some may also report memory problems and falls, although these symptoms are typically more pronounced after diagnosis.

Questions 18 and 19 are asked only if any of items Q16a through Q16f are recorded as "Yes".

18. Indicate if any of the symptoms that the participant had around the time of diagnosis started on only one side of his/her body (either side). If the question is recorded as "Yes", the form skips to question 20a1

19. Indicate whether any of the symptoms that the participant reported was ever more severe on one side of his/her body (either side).

#### **D. MEDICATION**

**Script:** "Now I will read the names of some common medications used for treating Parkinson's disease. Please tell me if you have ([name] has/had) ever taken any of these medications for more than a month."

20a1-20i3. Indicate whether the participant has/had ever taken the listed medications for more than a month. If the response is "Yes", indicate whether the medication ever helped and if the participant still takes the medication or if the participant took the medication during the last year of his/her life in respective questions. ***Please note that the wordings of 20a3-20i3 depend on whether the participant is still alive.***

These drugs help to control or alleviate Parkinson's motor symptoms, particularly in the first several years of the treatment. If they take the drug for many years, then it should be considered helpful; alternatively, if their symptoms worsened after skipping doses of the drugs, then it should

be considered helpful. For some drugs, after many years of treatment, patients may develop side-effects and adjust their medication accordingly.

The following questions 21, 21a and 21b are asked only if all Q20a1, Q20b1, Q20c1, Q20d1, Q20e1, Q20f1, Q20g1, Q20h1, and Q20i1 are recorded as “No” or “Don’t know”. It is unlikely that a Parkinson’s patient does not take any of the medication listed in the question. However, the proxy may not be familiar with the specific names of these medications.

21-21b. Indicate whether the participant has/had ever taken ANY prescribed medication for Parkinson’s disease for more than a month in question 21. If the response is recorded as “No” or “Don’t know”, the form skips to question 22. If the response is recorded as ‘Yes’, indicate whether the medication ever helped in controlling the symptoms in question 21a and whether the participant still uses the medication now or was using the medication during the last year of his/her life in question 21b.

## **E. FAMILY AND PHYSICIAN INFORMATION**

22. Indicate if anyone else in the participant’s family has Parkinson’s disease that was diagnosed by a doctor. This would include biological (natural) parents, biological brothers or sisters, or biological children. If the question is recorded as “No” or “Don’t know”, the form skips to question 24.

23a-23f. Read the following script: **“Which other family members have had Parkinson’s disease diagnosed by doctor? Is it your [name’s]...”** and then read the relatives listed in questions 23a through 23f one by one and record the responses for each of these questions.

**Script:** **“Thank you for answering my questions. It would also be helpful if I could contact your [name’s] health care providers and ask them to tell us more information about your [name’s] health status. If you agree to do this, I will send you a form that tells your [name’s] health care providers that you authorize the ARIC study to collect this information from them. After you sign that form and mail it back to me, I will contact your health care providers. Again the information will only be used for research purpose and will be kept confidential.”**

24. The medical release form is sent to a physician only after the participant/proxy/informant provides consent to release medical information to ARIC.

This question requests permission to send the release form to the participant. If the response is “No”, do not send the release form. If the participant/proxy/informant does not want to sign a release, use the refusal conversion scripts in Appendix I (see reason#3) to gain permission.

If participant/proxy/informant agreed to respond by mail and returned consent only to the field center, record question 24 as ‘Yes’ and continue with the rest of the form.

25. Ask the participant/proxy/informant to recall whether the participant saw a movement disorder specialist or neurologist for Parkinson’s disease in the past 5 years? If the question is recorded as ‘N’, the form skips to question 26.

**Script:** **“What is the contact information for the movement disorder specialist or neurologist?”**

25a.-25f. If question 25 is recorded as ‘Yes’, record the contact information for the movement disorder specialist or neurologist including doctor name, clinic or institution name, address and phone number in respective questions.



26. Ask the participant/proxy/informant to recall whether the participant sees another type of physician who regularly takes care of him/her for Parkinson's disease, or if the participant saw another type of doctor who regularly took care of him/her for Parkinson's disease while he/she was alive. This could be the participant's family doctor or general doctor. If the question is recorded as 'No', the form skips to question 27.

**Script: "What is the contact information for the other doctor?"**

26a.-26f. If question 26 is recorded as 'Yes', record the contact information for the other doctor including doctor name, clinic or institution name, address and phone number in respective questions.

27. Parkinson's disease interview questions completion status. Enter the code that describes whether or not the Parkinson's disease interview questions were completed.

- a. **Complete**: Direct contact was made or a completed questionnaire was returned by mail. The contact either refused the interview or the contact provided all the questionnaire information they could offer by telephone interview or mailed responses. The contact is not required to answer every question to be able to call the interview complete.
- b. **Partially complete, contact again**: Direct contact was made, but the questionnaire could not be fully administered due to an interruption – not because of a refusal. This status is not a final status, as the interviewer will be attempting another contact to continue the interview. The final status must be a. Complete, or c. Partially complete; unable to complete questionnaire (done).
- c. **Partially complete, unable to complete questionnaire (done)**: Direct contact was made, but the questionnaire could not be fully administered.

**CLOSURE SCRIPT:**

*[For the interviewer – select a closure script based on the answer to Q27.]*

If Q1 is recorded as 'A' or 'C', and Q27 is recorded as 'A' or 'C', read the closure script and continue with Q27.

**"Thank you for agreeing to answer these questions."**

If Q27 is recorded as 'B', read the closure script, save the form and resume when the participant/proxy is able to finish the interview.

**"May I contact you again to finish the interview? When would be a good time?"**

**F. INTERVIEW EVALUATION**

*[For the interviewer – Q28-Q29e are only completed when Q1 is recorded as 'A' or 'C', and Q27 is recorded as 'A' or 'C'.]*

28. Evaluate your confidence in the informant's answers.

29a-29e. Indicate whether the informant had any difficulties in the interview. If question 29d is recorded as “Yes”, please specify other difficulties the informant encountered during the interview in question 29e.

*[For the interviewer – Q30-Q33 are only completed when Q1 is recorded as ‘A’, ‘B’, ‘C’ or ‘D’, and Q27 is recorded as ‘A’ or ‘C’.]*

30. Indicate who responded to the questions regarding the participant. For **mailed responses** (question 1 recorded as ‘B’ or ‘D’): enter the response if the version returned is A (living participant) OR enter ‘C’ if the version returned is D (deceased participant).

31. Indicate helper or proxy’s relationship to the participant.

32-33. If there are any other comments about the interview, record question 32 as “Yes” and specify the comments in question 33. If no comments, record question 32 as “No” and save and close form. For **mailed responses** (question 1 recorded as ‘B’ or ‘D’): enter ‘Y’ in Q32 if there are any comments recorded in Q33 and then record the comments in Q33. If Q33 is blank on the mailed responses then enter ‘N’ in Q32.

## Appendix I

### Refusal Conversion Scripts for Participants

ARIC did not conduct Parkinson's disease case confirmation until recent years. Therefore some of the participants might have died over the years become incapacitated. Some others may be taken care of by family members on a daily basis or live in nursing homes. We should take all these into consideration and try to understand to whom we're talking.

Ideally, we want to minimize refusals where possible. For participants who are reluctant to participate, the interviewer should make an attempt to determine the reason, clarify any misunderstandings, and try to answer any questions. For those who refuse to answer the questionnaire, the interviewer should try to ascertain whether the patient has Parkinson's or not. Below are common reasons for refusals and possible responses.

#### **Reason #1**

No time for phone call - clarify the brief length of the call. "I understand your time is very valuable. This call will take less than 10 minutes. Your help is extremely important in understanding the causes of Parkinson's disease."

If No – determine if there is a better time to call back.

#### **Reason #2**

Misunderstanding about the scope of the study - explain that we would only need to do the following:

- 1) Find out over the phone whether or not they have PD. The questions are easily understandable and patients and their caregivers should be able to answer without much difficulty.
- 2) Request permission to contact their doctor for information related to their Parkinson diagnosis.

This is not a clinical trial and will not affect the participant's life or health in any way.

#### **Reason #3**

Does not want to sign a release – the interviewer may need to clarify that the purpose of contacting their doctor is only to gather further information about the diagnosis of Parkinson's disease. We are looking for information such as the signs and symptoms of Parkinson's disease. The doctor could provide more complete clinical information. All personal information, including what was previously provided, will be kept confidential to the full extent permitted by state and federal laws. The data will be stored indefinitely at secure and locked areas. No individual data will be reported and only group data will be analyzed collectively for medical research purposes.

#### **Reason #4**

I am too ill to participate – explain that we can speak to a knowledgeable relative or person who knows his/her disease well (caregiver). "I am very sorry to hear that. The study allows a relative to assist in completing the forms. Would it be okay to have your <insert relative here> assist you in completing the forms?"

#### **Reason #5**

Subject just not interested in participating – Explain the importance of their participation and the participation is easy. "Your participation is very important. This study may help to identify the causes and will potentially lead to better strategies to prevent or treat Parkinson's. Your help is instrumental in this effort."

**Reason #6**

I have a hard time writing / hearing / speaking / dementia – Ask if having the questions sent in the mail would be better. Or ask to speak with a caregiver.

**Reason #7**

Concerns about cost – clarify that there is no cost associated with the data collected in this study.

If the participant still refuses to participate in the telephone interview after at least three refusal conversion attempts, ask “My I send you a short form for you to fill out that asks questions about the diagnosis and treatment history of Parkinson’s disease? It will take only a few minutes to complete the form. I’ll include a prepaid self-addressed envelope for you to mail it back.”

**Refusal Scripts for Proxy/Informant:**

Ideally, we want to minimize refusals where possible. For those who are reluctant to participate, the interviewer should make an attempt to determine the reason, clarify any misunderstandings, and try to answer any questions. The questions are brief and easily understandable, and patients or their caregivers should be able to answer without much difficulty. Below are common reasons for refusals and possible responses.

**Reason #1**

**No time for phone call** - clarify the brief length of the call. “I understand that your time is very valuable. This call will take less than 10 minutes. Your help is extremely important in understanding the causes of Parkinson’s disease.”

If No – determine if there is a better time to call back.

**Reason #2**

**Misunderstanding about the scope of the study:** explain that we would only need to do the following:

- 1) Find out over the phone whether or not the participant had Parkinson’s disease.
- 2) Request permission to contact the participant’s doctor for information related to their Parkinson diagnosis.

**Reason #3**

**Does not want to sign a release** – the interviewer may need to clarify that the purpose of contacting the doctor is only to gather further information about the diagnosis of Parkinson’s disease. We are looking for information such as the signs and symptoms of Parkinson’s disease. The doctor could provide more complete clinical information. All personal information, including what was previously provided, will be kept confidential to the full extent permitted by state and federal laws. The data will be stored indefinitely at secure and locked areas. No individual data will be reported and only group data will be analyzed collectively for medical research purposes.

**Reason #4**

**I am too ill to participate** – explain that we can speak to a knowledgeable person who knows the participant’s disease well. “I am very sorry to hear that. The study allows another person to assist in completing the forms. Would you give us the name and telephone number of another person who could assist us in completing the forms?”

**Reason #5**

**NOK/Proxy just not interested in participating** – Explain the importance of their participation and the participation is easy. “Your participation is very important. Parkinson’s disease is common among elderly

Americans and the causes are largely unknown. This study may help to identify the causes and will potentially lead to better strategies to prevent or treat Parkinson's. Your help is instrumental in this effort. May we first send you the study materials, and then let you decide whether or not you want to participate?"

**Reason #6**

**I have a hard time writing / hearing / speaking / dementia** –Ask for the name and phone number of another knowledgeable person.

**Reason #7**

**Concerns about cost** – clarify that there is no cost associated with the data collected in this study.

If the proxy/informant still refuses to participate in the telephone interview after at least three refusal conversion attempts, ask "May I send you a short form for you to fill out that asks questions about [name's] health? I'll include a prepaid self-addressed envelope for you to mail it back."

**Reason #8**

**Participant died a long time ago** – explain to the informant that we still need their help. This will allow us to use the valuable data that the study participant provided to the ARIC study over the many years to investigate the causes of Parkinson's disease. This probably will be quite common.

## Appendix II

### Frequently Asked Questions

#### Confirmation of PD Patients in the ARIC Study

##### **FAQ1. What is Parkinson's disease?**

Parkinson's disease is a brain disease that affects more than 1 million elderly Americans. It is one of a group of conditions called movement disorders. The disease is caused by the progressive loss of dopamine-producing brain cells. Its typical symptoms include tremor or trembling, stiffness of the limbs and trunk, slowness of movement and impaired body balance and coordination. Early symptoms of Parkinson's disease are subtle and develop gradually, but as the disease progresses the symptoms may become severe and interfere with daily activities.

##### **FAQ2. What is the purpose of this study?**

The purpose of this project is to confirm the diagnoses of possible Parkinson's disease. By doing so, we may be able to identify the disease early on and to learn more about the environment and genes responsible for Parkinson's disease. This may result in better ways of treating and preventing it.

##### **FAQ3. How did you get my name?**

The ARIC Study Investigators are contacting all ARIC participants who previously told us they have Parkinson's disease, or reported the use of medications to treat Parkinson's disease or similar conditions. In addition, we are contacting individuals whose hospitalization records indicated a Parkinson's disease diagnosis.

##### **FAQ4. How do I participate?**

If you agree to participate, you will be asked a few short questions over the telephone about your experience with Parkinson's disease. In addition, we will ask you to sign a Medical Release Form which will allow us to contact your doctor to gather further information about your Parkinson's disease diagnosis.

##### **FAQ5. How are the results of this study going to be used?**

The information will be used to search for causes of Parkinson's disease and ways to prevent it

##### **FAQ6. Will my information be kept confidential?**

Our staff treats your medical data confidentially, according to strict rules and the information will only be used for medical statistical purposes. Statistical results may be published in a scientific journal, but individual information and identity will not be released.

##### **FAQ7. What are the Costs of Participation?**

There are no monetary costs to participate in this study other than your time.

##### **FAQ8. Do I have to participate?**

Taking part in this research study is voluntary. You may decide not to take part at any time. There is no penalty or loss of benefits to which you may otherwise be entitled.

**FAQ9. How long will this take?**

The questions about your experience with Parkinson's disease should only take about 10-20 minutes.

**FAQ10. Are there any risks?**

There are no known risks associated with participation in this study. We take every measure to protect your confidentiality.

**FAQ11. Is there a deadline for returning the study materials?**

We ask that you complete the Medical Release form and return it to us within 2 weeks.

**FAQ12. What happens to the information I give you?**

All personal information will be kept confidential to the full extent permitted by state and federal laws. The data will be stored indefinitely at secure and locked areas.

**FAQ13. Will you send me the results of the study?**

No individual data will be reported and only group data will be analyzed collectively for medical research purposes.

**FAQ14. Will anyone else have access to my information?**

Your data collected may be shared with researchers from other institutions. Any request for use of your information will first be reviewed by appropriate procedures to ensure that the proposed research is of the highest quality and that your rights have been safeguarded. Your name will not be shared with other researchers.

**FAQ15. Who do I contact if I have additional questions?**

You can contact the ARIC study office anytime at ###-###-####. (*Provide contact number*).

**FAQ16. I have a friend who also has Parkinson's disease, can he/she participate?**

At this time we are only inviting ARIC participants to participate in this study. If this person is a participant of the ARIC study and has Parkinson's disease, they are eligible to participate. Please contact \_\_\_\_\_ . (*Provide contact*).

**FAQ17. I am not able to sign my name; am I allowed to have my caregiver sign for me?**

Yes, you are allowed to have a caregiver sign for you as your personal representative. Please let your caregiver know to add their name and contact information to the form and make a note of this.

**FAQ18. I am the subject's caregiver; am I allowed to sign for the participant?**

Yes, you are allowed to sign for the participant as the participant's personal representative. Please add your name and contact information to the form and make a note of this.

### Appendix III

**Why do we ask question 9:** In the ARIC Parkinson confirmation study, we aim to confirm the diagnosis of Parkinson’s disease for cohort participants who might have the disease. These potential Parkinson’s patients are identified by self-report, use of medications that are typically for Parkinson’s disease, or have a code for Parkinson’s disease from hospitalization/death surveillance. We do expect some reporting errors, misdiagnosis, and coding errors. Some diseases have symptoms that mimic Parkinson’s disease; examples include essential tremor, progressive supranuclear palsy, multiple system atrophy, or dementia with Lewy body. They could be misdiagnosed as Parkinson’s disease, particularly at early stages. Some common, yet benign condition may need the same type of medications that are typically used to treat Parkinson’s disease, example includes restless leg syndrome. Therefore, some patients could be identified as potential Parkinson’s patients but will deny the diagnosis when we contact them for disease confirmation.

The purpose of question 9 is to find out why some participants are wrongly identified as PD patients in ARIC. For example, do they have a disease that is similar to Parkinson’s disease or do they use Parkinson’s medication for another disease.

Most of the information below is from Wikipedia with modifications from Drs. Honglei Chen and Xuemei Huang. Of the disease below, common ones are essential tremor, restless leg syndrome, and Alzheimer’s disease. Other diseases, particularly Parkinsonism such as progressive supranuclear palsy, multiple system atrophy, Shy Drager syndrome, and Nigrostriatal degeneration are relatively rare.

Medical terms	Explanation
Parkinson’s disease or PD	PD most occurs among older adults; clinically as rest tremor (e.g. in hands and legs), slow movement, shuffling gate, muscle rigidity and difficult in balance. In addition to these symptoms, PD patients may have some other symptoms such as loss of the sense of smell, sleep problems (such as act out of dreams, daytime sleepiness), constipation, depression, mild cognitive impairment in early stage, they may develop several mental (e.g. dementia, hallucination) or physical disabilities in later stage.
Essential tremor or ET	ET typically involves a tremor of the arms, hands or fingers but sometimes involving the other body parts during voluntary movements such as eating and writing. It is distinct from PD—and often misdiagnosed as such—although some individuals have both conditions. ET is commonly described as an action tremor (it intensifies when one tries to use the affected muscles) or postural tremor (present with sustained muscle tone) rather than a resting tremor, such as is seen in PD.
Restless leg syndrome or RLS	RLS is a neurological disorder characterized by an irresistible urge to move one's body to stop uncomfortable or odd sensations. It most commonly affects the legs, but can affect the arms, torso, head, and even phantom limbs. Symptoms occur primarily at night when a person is relaxing or wants to rest and can increase in severity during the night. Moving the affected body part modulates the sensations, providing temporary relief. At a low-dosage, some Parkinson drugs such as a dopamine agonist such as pramipexole, ropinirole, and ritigotine are often used in RLS.
Alzheimer’s disease or AD	This is a major type of dementia (60-70%). It starts slowly and gets worse over time; the most common early symptom is difficulty in remembering recent events



	(short-term memory loss); as the disease advances, symptoms can include problems with language, disorientation (including easily getting lost), mood swings, loss of motivation, not managing self-care, and behavioral issues.
Dementia with Lewy bodies or DLB	Its primary feature is cognitive decline, which can lead to hallucinations, as well as varied attention and alertness when compared to a person's baseline function. It can cause motor symptoms similar to PD, such as tremor, stiffness and slowness. Persons with LBD display an inability to plan or a loss of analytical or abstract thinking and show markedly fluctuating cognition. Wakefulness varies from day to day, and alertness and short-term memory rise and fall. Persistent or recurring visual hallucinations with vivid and detailed pictures are often an early diagnostic symptom. There are overlaps between LBD and AD or PD, sometime misdiagnosis in early stages occurs. LBD is diagnosed when cognitive symptoms begin at the same time or within a year of Parkinson symptoms.
Other types of dementia	The main other type of dementia is vascular dementia which is caused by problems in the supply of blood to the brain, typically by a series of minor strokes. Patients often present with cognitive impairment, acutely or sub-acutely as in mild cognitive impairment, after one or many cerebrovascular events. The symptoms of dementia may progress gradually or step-wise after each small stroke.
Progressive supranuclear palsy or PSP	Another neurodegenerative disease that often is misdiagnosed as PD. The initial symptoms in two-thirds of cases are loss of balance, lunging forward when mobilizing, fast walking, bumping into objects or people, and falls. Other common early symptoms are changes in personality, general slowing of movement, and visual symptoms. Later symptoms and signs are dementia, slurring of speech, difficulty swallowing, and difficulty moving the eyes, particularly in the vertical direction. The latter accounts for some of the falls experienced by these patients as they are unable to look up or down. The eye movement problem (called vertical gaze palsy) is of particular importance in the diagnosis of this disorder. Patients typically complain of difficulty reading due to the inability to look down well. PSP patients can be treated with Parkinson's drugs, but the response is not as good as PD patients.
Multiple system atrophy or MSA	This is another Parkinson mimics: often present as autonomic dysfunction (constipation, urinary problems, erectile dysfunction, oversweating), parkinsonism (muscle rigidity +/- tremor and slow movement) and/or ataxia (Poor coordination / unsteady walking). MSA patients can be treated with Parkinson's drugs, but the response is not as good as PD patients.
Shy Drager syndrome	It is a bit outdated word, current refer as one type of MSA that is dominated by autonomic dysfunction.
Nigrostriatal degeneration	This is another outdated word, currently refer as one type of MSA that is dominated by Parkinsonism.
Movement disorder specialist	Movement disorder specialists are a group of neurologists with special training to treat Parkinson's disease and related movement disorders. Movement disorders basically are a group of diseases that the patient have problems with body movement, for example, you cannot move part of your body or your hand shake when you do not want them to. The differential diagnosis of PD from other Parkinson like diseases often requires movement disorder specialist or neurologist.