

Attachment Ra-i – Recruitment and Follow-up Communications

Attachment Ra - Introductory Letter



<Date>

<Title.> <FirstName> <LastName>

<Address1>

<City>, <State> <Zip Code>

Dear <Title.> <LastName>:

We are writing to tell you about a study on muscular dystrophy. The study is a survey of adults with many types of muscular dystrophy. The goal of the study is to learn about experiences with COVID-19 disease and vaccinations, chronic pain and fatigue related to muscular dystrophy, and family planning of adults with muscular dystrophy. Adults with muscular dystrophy in seven states (north central Florida, Iowa, central North Carolina, western New York, Utah, South Carolina, and Virginia) are being asked to complete the survey, called the MD STARnet Living with Muscular Dystrophy Survey. We are asking you to fill out the survey because the <site> MD STARnet identified you as having muscular dystrophy.

The <grantee institution(s)> is working on a project to identify and track the health of people with muscular dystrophy who live in <site>. This project is called the <site> Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet) and is funded by the Centers for Disease Control and Prevention. Please visit <https://www.cdc.gov/ncbddd/muscular dystrophy/ survey-on-adults-living-with-muscular-dystrophy.html> to learn more about the survey and MD STARnet.

In about two weeks, we will send you a study letter with a link to the online survey. We will also include a form that you may use to let us know how you prefer to take the survey (online, paper, or over the phone) or if you do not want to be part of the study. We will send you a \$25 <token of appreciation> if you complete the survey.

Thank you for thinking about taking part in this study. It is your choice to be in this study. If you have any questions about the study or do not wish to be in the study, please contact our study coordinator, <StudyCoordinator>, toll free at <StudyPhoneNumber>. With your help, we hope that knowledge gained from this study will lead to improved health care and support systems in the future.

Sincerely,

Name of PI
Principal Investigator
Affiliation

Attachment Rb - Enclosure Form

Name of Study Coordinator
Study Coordinator
Affiliation



<<Date>>

MD STARnet Living with Muscular Dystrophy Survey

I do not wish to participate in this study. (Please write your name so we can take you off our list: _____)

Please email me the link to the survey at: _____.

OR

Please mail me a paper copy of the survey

OR

Please contact me to complete the telephone survey. My contact information and best times to call is below.

Please complete the following section, making any necessary corrections, and return the completed form in the postage-paid envelope:

<<FirstName LastName>> Name _____

<<Street Address>> Address _____

<<City, State, Zipcode>> Address _____

<<Telephone number>> Phone number _____

Alternate Phone Number _____

Best day(s) / time(s) you can be reached at the above number(s):

(Signature)

(Date)

(Printed Name)



<Date>

<FirstName> <LastName>
<Address1>
<City>, <State> <Zip Code>

Dear <Title.> <LastName>,

We are writing to invite you to take part in a muscular dystrophy research study. The study is a survey of adults with many types of muscular dystrophy. The goal of the study is to learn about experiences with COVID-19 disease and vaccinations, chronic pain and fatigue related to your muscular dystrophy, and family planning of adults with muscular dystrophy. We are asking you to fill out the survey because the <site> MD STARnet identified you as having muscular dystrophy.

The Muscular Dystrophy Surveillance Tracking and Research Network (MD STARnet) is the group conducting the study. The Centers for Disease Control and Prevention (CDC) is funding MD STARnet. <Site> is one of the seven states that is currently part of MD STARnet. Please visit <https://www.cdc.gov/ncbddd/musculardystrophy/survey-on-adults-living-with-muscular-dystrophy.html> to learn more about the survey and MD STARnet.

If you would like to be in the study, please complete the MD STARnet Living with Muscular Dystrophy Survey. This survey takes about <<15 minutes (male) or 20 minutes (female)>> to complete. The survey can be completed online at <https://redcapcdc.rti.org/mdstarnet/surveys/> by entering the following code <<access code>> or by accessing the enclosed QR code. We can also email you the link to the online survey. If you would like an email with the link, please write down your e-mail address on the enclosed form and return it in the postage-paid envelope. We will then e-mail you the link to the survey. The online survey is being administered in a program called REDCap.

<<First sending>> If you prefer to complete a paper copy of the survey, please check the box on the enclosed form and return it in the postage-paid envelope. We will then mail you a paper copy of the survey with a postage-paid envelope. **OR** <<Second sending>> If you prefer to complete a paper copy of the survey, please complete the enclosed survey and return it in the postage-paid envelope.

If you would like to complete the survey by phone, please fill out the enclosed form with your contact information and return it in the postage-paid return envelope. A study coordinator will then contact you to schedule a convenient time to complete the survey.

If you decide to fill out the survey, you may skip any questions that you do not wish to answer. If you choose not to be in this study, or if you decide to stop being in the study, it will not affect the health care or services you or your family members receive.

The survey will not ask you for personal information such as your name. Instead, a unique survey ID number will be used to link your responses to your name and health information already in MD STARnet. Only certain staff within the <site> MD STARnet site have access to personal information such as your name and address. The study staff will keep this information private. Your name or information that can be linked to you will not be used in any report or publication about this study.

There is very little risk to being in the study. One risk is that some questions could make you feel upset. You may choose to skip questions or choose to stop taking the survey at any time. If you fill out the survey, but decide you no longer want to be in the study, call <Study Coordinator>, toll free at <Study phone number> and your answers will be deleted. You personally may not benefit from being in this study. However, we hope that others may benefit in the future from what we learn from this study.

If you have questions about your rights in this research study, please contact <grantee institution office of research>. Leave a message with your name, phone number, and refer to protocol <site protocol number>, and someone will call you back.

We will contact you by phone and/or letter in two weeks to remind you to fill out the survey. If you do not wish to be contacted about the study, please let us know by sending back the enclosed form in the postage-paid envelope or call our study coordinator, <Study Coordinator>, toll free at <Study phone number>.

Thank you for thinking about taking part in this study. If you have any questions about the study, please call our study coordinator, <Study Coordinator>. With your help, we hope that knowledge gained from this study will lead to improved health care and support systems in the future.

Sincerely,

Name of PI
Principal Investigator
Affiliation

Name of Study Coordinator
Study Coordinator
Affiliation

Enclosure

Attachment Rd - Preferred mode letter



Dear <Title.> <LastName>,

Thank you for agreeing to complete the MD STARnet Living with Muscular Dystrophy Survey. <<**Email content and reminder letters:** The survey can be completed online at <<unique web-survey link>>.>> <<**Paper preference:** <<**Paper Cover letter:** Please fill out and send back the paper survey in the postage-paid envelope.>> OR <<**Paper Reminder letter:** Please complete the paper survey we mailed to you. You may call us at <Study Coordinator>, toll free at <Study phone number>, if you need another copy of the survey. <<**Phone preference reminder letters:** We have been trying to reach you to schedule the survey.>>

This survey should take about <<**15 minutes to complete (for males) OR 20 minutes (for females)**>> but may take longer depending on your personal experiences. You may skip any questions you do not wish to answer. You may also choose to stop the survey at any time or choose to stop and continue at a later time. If you complete the survey, but decide you no longer want to be in the study, call <Study Coordinator>, toll free at <Study phone number> and your answers will be deleted.

We will ask about your experience with COVID-19, flu, and vaccination; chronic pain and fatigue related to your muscular dystrophy; and your experiences with family planning. All of your answers will be kept private. We will not publish any information that can be linked to you. If you have any questions about the survey, please contact the study coordinator.

Sincerely,

Name of PI
Principal Investigator
Affiliation

Name of Study Coordinator
Study Coordinator
Affiliation

Attachment Re - Reminder Letter 1 and 2: No Preference



<Date>

<FirstName> <LastName>
<Address1>
<City>, <State> <Zip Code>

Dear <Title.> <LastName>:

We recently sent you an invitation for you to fill out the MD STARnet Living with Muscular Dystrophy Survey. The goal of the study is to learn about experiences with COVID-19 disease and vaccinations, chronic pain and fatigue related to your muscular dystrophy, and family planning of adults with muscular dystrophy. We hope that knowledge gained from this study will lead to improved support systems and health care in the future.

We have not yet received your completed survey. If you have already filled out the survey, please accept our thanks for taking part in the study. If you would like to take part in the study, please use this link, <https://redcapedc.rti.org/mdstarnet/surveys/> and enter the following code <<access code>> or use the QR code to access the online survey. If you prefer to fill out a paper survey or complete it over the phone, please fill out the enclosed form and mail it back in the postage-paid envelope.

<<*Leave out paragraph if there has been phone contact with participants.*>> <<No preference received with known telephone number: We have been unable to reach you by telephone to discuss any questions that you may have about the study. The current telephone number we have for you is <Phone>. If this is not correct, please contact our study coordinator, <Study Coordinator>, toll free at <Study Phone Number>.>> OR <<No preference received with unknown telephone number: We do not have a current telephone number listed for you. Please contact our study coordinator, <Study Coordinator>, toll free at <Study Phone Number> to give us a current telephone number or complete the enclosed form and send it back to us in the postage-paid envelope.>>

Sincerely,

Name of PI
Principal Investigator
Affiliation

Name of Study Coordinator
Study Coordinator
Affiliation

Enclosure

Attachment Rf - Survey Reminder Calls Script

**MD STARnet MUSCULAR DYSTROPHY SURVEY
TELEPHONE SCRIPT
Survey Reminder Calls 1, 2**

Reminder Calls 1, 2 – No Mode Preference

If answered electronically:

This message is for <**Person with MD**>. This is <**Recruiter**> calling from <**Site**>. We had sent you a letter about the MD STARnet Living With Muscular Dystrophy Survey, and we wanted to see if you would be willing to complete it or not. You can mail us the contact form in the postage paid envelope that was included with the letter we sent you, or call us at <**Study Phone Number**>. Thank you.

If a person answers:

Hello, this is <**Recruiter**> from <**Site**>. Is <**Person with MD**> available?

NO, not available

I'm calling regarding a survey we sent to him/her. Is there a better time for me to call to reach him/her? [Try to leave a message]: We have a toll free number that he/she can call with any questions. It is <**Study Phone Number**>.

YES, is available

My name is <**Recruiter**> and I am calling regarding the MD STARnet Living with Muscular Dystrophy Survey for adults with muscular dystrophy. Recently we mailed you a letter with information about our web-based survey asking you to participate in our study. Did you receive this information?

YES, received materials

Do you have any questions or concerns regarding the survey? [answer questions] Do you plan to complete the survey or would you like any assistance?

NO

Is there a reason or reasons that you're not interested in participating in the study? [Record reasons] Thank you for your time.

YES

Thank you for your time and participation.

NO, did not receive materials

We are contacting adults with muscular dystrophy, hoping to learn more about their experiences with COVID-19 and flu, pain and fatigue, and pregnancy and infertility. We are interested in your participation in the study but would like to send you some materials describing the study first. The current address we have for you is <Address>. May I send you the materials?

NO

Is there a reason or reasons that you're not interested in participating in the study? [Record reasons] Thank you for your time.

YES

[Record address] Thank you.

| |
|---|
| Reminder Calls 1, 2 – Mode Preferred |
|---|

If a mode has been chosen by the subject, then a best time to call may have been provided and should be adhered to as closely as possible when the recruiter is making reminder calls.

If answered electronically; choose the script for the highlighted mode that the subject selected:

1. This message is for <participant>. This is <recruiter> from <site>, and I'm calling about a research study we're conducting. We received your contact form that said you're willing to complete a **phone** survey for the MD STARnet project. Please call <site phone number>, so we can get that scheduled. Thank you!
2. This message is for <participant>. This is <recruiter> from <site>, and I'm calling about a research study we're conducting. We received your contact form that said you're willing to complete a **paper** survey for the MD STARnet project, and we mailed that out to you last week. Please call <site

phone number> if you have any questions, or you can mail it back to us when you have it completed. Thank you!

3. This message is for <**participant**>. This is <**recruiter**> from <**site**>, and I'm calling about a research study we're conducting. We received your contact form that said you're willing to complete an **online** survey for the MD STARnet project, and we emailed the link to you last week. Please call <site phone number> if you have any questions or visit the link in the email we sent you and complete the survey at your earliest convenience. Thank you!

If a person answers: May I speak to <participant>?

NO, <participant> not available: This is <recruiter> calling from <site>. I'm calling about a survey we sent to him/her. Is there a better time for me to call to reach him/her? [record and end call]

YES, <participant> is available; when <participant> is on the phone, choose the script for the highlighted mode that the subject selected:

1. This is <recruiter> from <site>, and I'm calling about a research study we're conducting. We received your contact form that said you're willing to complete a **phone** survey for the MD STARnet project. Is now a good time to get that started? [Be prepared to go to page 3 of the paper survey].
2. This is <recruiter> from <site>, and I'm calling about a research study we're conducting. We received your contact form that said you're willing to complete a **paper** survey for the MD STARnet project, and we mailed that out to you last week. Did you receive it, or do you have any questions? [Pause for response from participant]. Please call <site phone number> if you have any questions, or you can mail it back to us when you have it completed. Thank you!
3. This is <recruiter> from <site>, and I'm calling about a research study we're conducting. We received your contact form that said you're willing to complete an **online** survey for the MD STARnet project, and we emailed the link to you last week. Did you receive it, or do you have any questions? [Pause for response from participant]. Please call <site phone number> if you have any questions, or if you need us to resend the link. Thank you!

Attachment Rg - Final Letter



<Date>

<FirstName> <LastName>
<Address1>
<City>, <State> <Zip Code>

Dear <Title.> <LastName>,

We recently mailed you an invitation to fill out the MD STARnet Living with Muscular Dystrophy Survey. This research study is funded by the Centers for Disease Control and Prevention and conducted by the Muscular Dystrophy Surveillance Tracking and Research Network (MD STARnet).

The goal of the study is to learn about experiences with COVID-19 disease and vaccinations, chronic pain and fatigue related to muscular dystrophy, and family planning of adults with muscular dystrophy. We hope that knowledge gained from this study will lead to improved support systems and health care in the future.

We have not yet received your completed MD STARnet Living with Muscular Dystrophy Survey. If you have already filled out the survey, please accept our thanks for taking part in the study. If you would like to take part in the study, please complete the survey as soon as you can. This survey takes about <<15 minutes (male) or 20 minutes (female)>> to complete. The survey can be completed online at <https://redcapcdc.rti.org/mdstarnet/surveys/> by entering the following code <<access code>> or by accessing the enclosed QR code. If you prefer to complete a paper copy of the survey, please complete the enclosed paper copy of the survey and return it in the postage-paid envelope.

We can also email you the link to the online survey. If you would like an email with the link, please write down your e-mail address on the enclosed form and return it in the postage-paid envelope. We will then e-mail you the link to the survey. If you would like to complete the survey by phone, please fill out the enclosed form with your contact information and return it in the postage-paid return envelope. A study coordinator will then contact you to schedule a convenient time to complete the survey.

It is your choice to fill out the survey. You may skip any questions that you do not wish to answer and you may stop participating at any time.

If you have any questions about the study, please call our study coordinator, <Study Coordinator>, toll-free at <Study phone number>. If you do not wish to be contacted about

the study, please let us know by sending back the enclosed form in the postage-paid envelope.

Sincerely,

Name of PI
Principal Investigator
Affiliation

Name of Study Coordinator
Study Coordinator
Affiliation

Enclosure

Attachment Rh – Follow-Up for Missing/Confusing Information Call Script

**MD STARnet LIVING WITH MUSCULAR DYSTROPHY SURVEY
TELEPHONE SCRIPT**

Survey Follow-up for Missing/Confusing Information

Survey Follow-up for Missing Information

[If answered electronically, skip to Leave Message]

Hello, this is <Recruiter> from <Site>. May I speak with <Person with MD>?

NO [If subject is not available, skip to Leave Message with person]

YES [If subject is available, skip to Follow-up]

Leave Message

This is <Recruiter> from <Site>. I am calling <Person with MD> about a research study we're conducting, and I would like to talk with him/her about it. <Name>, please call us, toll-free, at <Study Phone Number>. We are here Monday through Friday from 9 a.m. to 5 p.m. At any other time, you can leave a message on our voice mail. Thank you.

Leave Message with person

This is <Interviewer> calling from <site>. Can you please leave a message for <Name> to call us, toll-free, at <Study Phone Number> at his/her earliest convenience? Thank you.

Follow-up

My name is <Recruiter> and I am calling regarding the MD STARnet Living with Muscular Dystrophy Survey. Recently we received the survey you completed, and we would like to thank you for your participation. It is important that our information is as accurate as possible, so we wanted to clarify [an item OR a few items with you. Do you have a few minutes to talk with me?

YES [continue to clarification scripts]

NO Is there a better time when I can call you back?

Yes [schedule call back]

No [Thank you for your time. We appreciate the responses you provided.]

Clarification Scripts - choose each as needed, especially consider the Barriers option for subjects who may have cooperation barriers, communication barriers, time commitment barriers, etc.:

Missing answer(s): There was one/were a few item(s) that weren't filled out, and we're not sure if you meant to skip those questions or not. We're sorry if the questions or directions were unclear. I'm going to read the question(s) to you. Would you please tell me if you want to skip the question, or if it was previously unclear to you? If it was unclear, I'll explain as best I can now. Question <number> asks, [read question and response choices if listed, then pause for subject response; if subject does not respond, repeat the "Would you please tell me if you want to skip the question, or if it was previously unclear to you" question].

Confusing answer(s): There [was one OR were a few] item(s) where we didn't understand your answer. We're sorry if the questions or directions were unclear. I'm going to read the question(s) to you. Question <number> asks, [read question] For your answer, you marked/wrote [read subject's response/explain our confusion]. Can you explain what you meant? [give subject the opportunity to clarify without pressure]

Barriers: Can we send you a new survey with a few item(s) highlighted? We would ask you to fill out just the highlighted question(s), then return the survey to

us in a prepaid envelope that we send you. Of course, it would still be your choice to skip any questions you do not wish to answer.

Conclusion

Thank you for helping us with this study.

Optional: If you have any concerns about the study or how it is conducted, you may contact our Study Coordinator, <**Study Coordinator**>, toll free at <**Study Phone Number**>.

Attachment Ri - Thank You Letter



<<Date>>

<<FirstName Lastname>>

<<StreetAddress>>

<<City, State, Zipcode>>

Dear <Title.> <LastName>:

We would like to thank you for filling out the MD STARnet Living with Muscular Dystrophy Survey.

By taking part in this study, you will help us learn about experiences with COVID-19 disease and vaccinations, chronic pain and fatigue related to muscular dystrophy, and family planning of adults with muscular dystrophy.

We know your time is valuable and we thank you for participating. Please accept this \$25 token of appreciation for completing the survey.

Sincerely,

Name of PI
Principal Investigator
Affiliation

Attachment Rj – How did you get my name? script

How did you get my name or know I had muscular dystrophy?

Email

Thank you for sharing your concerns about our knowing that you are someone living with muscular dystrophy. We understand it might have been upsetting to receive the invitation to complete the Living with Muscular Dystrophy Survey. We obtained your information through a public health surveillance project called the Muscular Dystrophy Surveillance, Tracking and Research Network or MD STARnet that is led by the Centers for Disease Control and Prevention. Public health surveillance is authorized by state or federal law. The laws allow health departments to collect data needed for public health without getting an individual's consent. *Site-specific information about applicable laws.* We protect the privacy of this data by using secure computer networks to collect and store the data. We also require confidentiality training and agreements from staff who have access to the data.

We hope this information allays your concerns. It is your choice to complete the survey. By completing the survey, we can better understand the challenges you face living with muscular dystrophy.

[Signature: PI]

Phone Script

Thank you for sharing your concerns about our knowing that you are someone living with muscular dystrophy and the recent invitation to complete our survey. We understand it was upsetting to receive the invitation. We obtained your information through a public health surveillance project called the Muscular Dystrophy Surveillance, Tracking and Research Network or MD STARnet that is led by the Centers for Disease Control and Prevention. Public health surveillance is authorized by state or federal law. The laws allow health departments to collect data needed for public health without getting an individual's consent. *Site-specific information about applicable laws.* We protect the data by using secure computer networks to collect and store the data. We also require confidentiality training and agreements from staff who have access to the data.

Do you have any further questions or concerns? It is your choice to complete the survey but hope you will complete it so we can better understand the challenges you face living with muscular dystrophy.

No Further Contact Request

Actions

- Mark as hard refusal in survey tracking database.
- If they indicate they never want to be contacted again for any reason, provide name, Indexcase ID to Study Coordinator.

- Study Coordinator enters into comment field of abstraction database to prevent future contacts.

Email or Phone Response

Thank you for contacting us. We will record this in our system so we do not contact you again.

Please Remove My Data Request

Thank you for contacting us. If you have already completed the survey, we will remove your survey response.

MD STARnet is public health surveillance and authorized by law. We must retain information on every identified case of muscular dystrophy. Although we cannot remove your surveillance information, if you wish, we can note that you do not want to be contacted for future surveys.

Attachment Rk– Distressed Participant Scripts and Resources

Response to mail or letter

Dear [],

Thank you for sharing your concerns regarding the Living with Muscular Dystrophy survey. We are very sorry that the questions on [topic] upset you. It was important to collect information on [topic] because people with muscular dystrophy may be more likely to experience [topic], but we understand the questions can be sensitive. We have included a list of resources that may be helpful to you. Some resources on the list have experienced counselors who will listen and talk to you about how you are feeling. The other resources may provide access to other services or resources that may be helpful.

Thank you again for reaching out to us. We welcome any suggestions on how to make the questions less upsetting.

Phone script for eligible participant calling in

Hello. May I help you?

[caller statements]

Thank you for sharing your concerns. I am very sorry that you were upset by the survey questions on [topic]. We know this topic can be sensitive for some people. I would like to send you a list of services that may be helpful. Some of the resources have experienced counselors who will listen and talk to you about how you are feeling. The other resources provide access to other services or resources that may be helpful. May I send the list to [email address]? [Or if we do not have an email address] Is there an address or email address where I can send the list of resources?

We welcome any suggestions on how to make the questions less upsetting. Is there anything else I can help you with today?

Thank you again for contacting us.

Phone script during phone survey or call back to clarify survey answers

“I know that this topic can be stressful. Would you like to continue or would it be better for me to call back or schedule another interview later?”

“These questions seem to be stressful for you. Would you like to continue the survey or would it be better for me to call back or schedule another interview later?” If you would like to talk with someone about your distress, the [Service – select appropriate resource from list] has experienced counselors who will listen and talk to you about how you are feeling. Their number is [insert resource phone number]. We can also send you a list of resources that might be helpful.

Resources & Hotlines

National Maternal Mental Health Hotline

<https://mchb.hrsa.gov/national-maternal-mental-health-hotline>

Call or text: 1-833-TLC-MAMA (1-833-852-6262)

Health Resources and Services
Administration

English and Spanish Service

Available 24/7

For pregnant and new moms experiencing perinatal depression or anxiety.

Star Legacy Foundation National

Telephone Grief Support Line

<https://starlegacyfoundation.org/>

1-952-715-7731, ext. 1

English and Spanish Service

For those who have experienced stillbirth or neonatal loss. Support line is staffed by professionals who have personal experience with pregnancy and infant loss.

RESOLVE Helpline

<https://resolve.org>

1-866-NOT-ALONE (1-866-668-2566)

For those experiencing infertility. The Helpline is a voicemail system where a message can be left on any topic related to infertility and family building options. Calls are returned within 1-3 days.

988 Suicide & Crisis Lifeline

<https://988lifeline.org/>

Live chat services available via website.

Mobile phone: call or text 988

Spanish: call 988 and press 2 or text AYUDA to 988

English and Spanish Service

Available 24/7

For individuals who are depressed, going through a hard time, need to talk, or contemplating suicide.

SAMSHA National Helpline

<https://www.samhsa.gov/find-help/national-helpline>

1-800-662-HELP (4357)

English and Spanish Service

Available 24/7

For individuals and family members facing mental and/or substance use disorders.

RAINN (Rape, Abuse and Incest National Network)

www.rainn.org

1-800-656-HOPE (4673)

Live chat services available via website.

Spanish and English Service

Available 24/7

For those who have experienced sexual assault.