

ICR Non-Substantive CHANGE REQUEST MEMO

ICR Title: The MD STARnet Living with Muscular Dystrophy Survey

OMB NO. 0920-1405

Expiration Date 06/30/2025

Summary:

1. Letters and scripts have been added or language modified to account for participants who indicate a preferred method of taking the survey. Additionally, the enclosure form that participants can send back to indicate a preferred mode of taking the survey no longer accompanies the introductory letter (but still accompanies other recruitment letters). During initial recruitment, when participants had indicated a mode of preference, some of the language in the study letter and subsequent recruitment letters included information about the other modes and was confusing to participants. For example, if a participant indicated he/she wanted to be sent a paper survey, the study letter accompanying the paper survey would include information on how to take the web, paper, and phone versions. Changes were made to make language clearer and more specific to the participants preferred mode of taking the survey.
2. Since the enclosure form is no longer being sent with the introductory letter and this was the primary way of determining whether potential participants preferred to communicate in English or Spanish, the MD STARnet surveillance data will be used to identify Spanish-speaking participants.
3. The phone survey will not be conducted in Spanish due to low number of Spanish speakers being recruited (fewer than 30 individuals across 7 sites for whom surveillance data indicate primary language). Web and paper will continue to be available in Spanish.
4. The missing Information phone script changed to better clarify whether a participant who completed the survey meant to skip questions or whether questions were unclear. If questions were meant to be skipped, staff caller would not press for answers. The reason for this change is because, during initial recruitment, when staff called about missing information, it became clear that some participants had meant to skip questions or even became distressed when pressed for an answer.
5. A script has been added for when participants ask how MD STARnet got their name and knew they had muscular dystrophy. During initial recruitment, one potential participant had asked these questions. We anticipate others will have similar questions. The new script will enable recruiters to have standard language describing MD STARnet that also includes site-specific information on their legal authority to collect information about individuals with MD.
6. A new script and resources for participants who become distressed when taking the survey is being added. While completing the phone survey during initial recruitment, one participant become mildly distressed when answering some of the pregnancy questions. The new script is being added to provide recruitment staff with standard language if they encounter a distressed participant and to be able to offer appropriate resources.

Attachments:

List them with their corresponding numbers

- Attachment Q – Flowchart
- Attachment Ra-k

Background & Justification:

Brief explanation for the change requested, including the reason (purpose or benefit) for the requested change

The changes described above are being implemented to refine the recruitment process after recruitment had occurred for the first 30 potential participants in each site. These changes are meant to make it easier for the

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participant to understand how to participate and to anticipate how to handle certain questions or situations with participants if they arise.

Effect of Proposed Changes on Current Approved Instruments:

- There have been no changes to the approved surveys, only the recruitment materials.

Form	Current/Question Item	Requested Change

Effect on Burden Estimate:

Discuss and include a table comparing to previously approved burden

- There is no change in estimated burden.

Form	Approved Burden	Requested Burden
Total		