

Attachment 3
Revisions to Data Collection

Revision or New	Change	Rationale
Revision to Registration	Attachment 5 - Add question to confirm email address during registration	Many email addresses are invalid and have obvious typographical errors. This would decrease the number of errors.
Revision to Registration	Attachment 5 - Add zip code	There are some clinics that specialize in care for persons with ALS. To better evaluate the access to these clinics, we need to be able to better locate the patients.
Revision to Registration	Attachment 5 - Allow a participant to designate another person to receive copies of emails sent to him	Persons with ALS may not check emails regularly especially as their disease progresses. Some ALS patients have recommended we make it optional for a registrant to allow emails to go to a designee of their choice.
Revision to Registration	Attachment 5 - Add question to collect where the person heard about the Registry	To assess the impact of and to better focus outreach activities it would be helpful to know how the person learned about the Registry.
New	Attachment 5 - Add question to assess interest in the biorepository.	Our experience with emails has been mixed because of errors in addresses as well as decreased use of email by our population. This will allow individuals to express an interest in receiving more information about the biorepository.
New	Attachment 5 - Add question to collect mailing address and phone number for those interested in the biorepository.	This will allow the program to mail an information package to the Registrants who want to receive more information and to follow-up with them to determine if they would like to take part in the biorepository.
New	Attachment 5 - Add question to assess interest in having a GUID assigned to his/her record.	NIH is advocating the use of a Global Unique Identifier (GUID). A GUID is assigned to each patient's data. The GUID enables tracking and following of patients over time and across diseases, registries, studies and countries.
New	Attachment 5 - Add questions to collect information necessary to calculate the GUID.	Eight variables are required to calculate the GUID and only 2 of them are currently collected by the Registry. We would ask the participant provide all eight variables at this time so that they know what information is used and so all of the needed information is in one location. After the GUID is calculated and verified, the information will be deleted.
New	Attachment 12 - Specimen processing form	This information is needed by the researchers using the specimens and will be provided to approved researchers along with the specimens
New	Attachment 11A - Researcher application for the use of biorepository samples or epidemiological data.	ATSDR collects specimens from ALS patients enrolled in the Registry with the intent of making them available to outside researchers. Researchers must apply for the use of specimens and be approved by a review group that includes both internal and external experts. The application, along with supporting documentation, e.g., letter of IRB approval, will be used by the review group.
New	Attachment 11B - Researcher annual update.	Researchers receiving specimens from the biorepository and/or epidemiological data from the Registry must provide ATSDR with an annual update of research using the specimens. Researchers will also be asked to provide feedback on specimen quality and future specimen needs.
New	Attachments 13A and 13B - ALS service organization,	ALS service organizations such as the ALS Association and the Muscular Dystrophy Association (ALS Division) conduct

	chapter and parent organization reports.	outreach to their constituents to inform them about the Registry. On a monthly basis, the chapters report activities including activities held and the number of people told about the Registry to the parent organization. The parent organization complies these reports and sends a monthly update to ATSDR.
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