Attachment 17 – Letter to Provider for Record Abstraction

Multi-site Study
Request – Medical Record Abstraction
Flesch-Kincaid Readability Score – 12.5

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

[ON INVESTIGATOR'S INSTITUTION LETTERHEAD]
[DATE]

[NAME OF PROVIDER]
[ADDRESS]
[CITY, STATE ZIP CODE]

Subject: Medical verification and records review for Multi-site Study

Dear [NAME OF PROVIDER]:

The Agency for Toxic Substances and Disease Registry (ATSDR) and [institution name] are conducting a research study of the health effects from exposure to per- and polyfluoroalkyl substances (PFAS) found in drinking water. ATSDR and its research partners are conducting this research study with oversight from the CDC/ATSDR Institutional Review Board (IRB) under CDC Protocol No. 7207.

Under Section 316 of the 2018 National Defense Authorization Act (Public Law 115-91), Congress authorized ATSDR to study the impact that exposure to PFAS in drinking water might have on the health of affected citizens. This study will see if there is an increase of symptoms or illness related to these chemicals.

We plan to recruit at least 6,000 adults and 2,000 children for the Multi-site Study. Those persons had to reside in areas served by PFAS contaminated drinking water or were exposed in utero or during breastfeeding when their mother consumed the contaminated drinking water. Drinking water exposure must have occurred within 15 years of the start of the study. Persons who were ever employed as a firefighter, ever participated in fire training exercises using AFFF foam, or were ever employed at industrial facilities that used PFAS chemicals in the manufacturing process will be excluded.

[ADULT PARTICIPANT'S NAME or PARENT OR GUARDIAN'S NAME] has given the study investigators authorization to conduct a medical records review. [Institution name] and ATSDR are interested in more information about [ADULT PARTICIPANT'S NAME/CHILD PARTICIPANT'S NAME]'s self-reported health conditions that may be related to chemical exposure. We have included an abstraction form for your office to fill out and return to us in the enclosed return envelope.

If we need additional information, the [institution name] study team may wish to review the medical records in your office. We would appreciate your assistance if this is necessary.

ATSDR is an agency of the U.S. Department of Health and Human Services. ATSDR is performing this activity as a public health authority as defined by the Health Insurance Portability and Accountability Act (HIPAA) [45 CFR §164.501]. The requested information represents the minimum necessary to carry out the public health purposes of this study as described in 45 CFR §164.514(d) of the Privacy Rule. The research is also covered by a Certificate of Confidentiality under Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d))

For questions about this research study, please call the ATSDR study lead, Dr. Marian Pavuk, at [study telephone number] or [institution name] study lead [name]. Please leave a message with your name and a telephone number or address.

Thank you for your assistance.

[Investigator's Name]
[institution name]

Marian Pavuk, MD, PhD and Frank Bove, DSc
ATSDR/CDC

Investigators
Multi-site Study

ATSDR estimates the average public reporting burden for this collection of information as 20 minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0923-xxxx).