

Vice, Rudith (CDC/DDID/NCEZID/OD)

From: Youngblood, Laura (CDC/DDID/NCEZID/OD)
Sent: Friday, August 4, 2023 3:51 PM
To: Vice, Rudith (CDC/DDID/NCEZID/OD); Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR); Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD)
Cc: Albrecht, Valerie S. (CDC/DDID/NCEZID/OD)
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Thanks, Rudith.

I confirm that ELIMS is not a research activity. It is a long-standing IT platform designed to manage specimen data. Because it is not a systematic investigation designed to develop or contribute to generalizable knowledge, it does not meet the regulatory definition of research at 45 CFR 46.102(l), and it is not subject to IRB review or oversight.

Laura

Laura Youngblood, MPH, CIP

Human Subjects Advisor | NCEZID Information Collections & Human Studies Team | lyoungblood@cdc.gov | Office: (404) 639-6394 | Mobile: (404) 510-0093

From: Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>
Sent: Friday, August 4, 2023 2:58 PM
To: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>; Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <qkh7@cdc.gov>
Cc: Youngblood, Laura (CDC/DDID/NCEZID/OD) <zfk9@cdc.gov>; Albrecht, Valerie S. (CDC/DDID/NCEZID/OD) <gpy8@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Hi Brian,

Thanks for following up on this.

Laura, would you mind responding to confirm? I can include this email as an attachment in the package in place of a formal determination. Brian, you can include what you mentioned below in Section 11 (Institutional Review Board (IRB) and Justification for Sensitive Questions) in the Supporting Statement A and I think that should suffice.

Thanks,
Rudith

From: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>
Sent: Friday, August 4, 2023 2:20 PM
To: Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>; Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <qkh7@cdc.gov>
Cc: Youngblood, Laura (CDC/DDID/NCEZID/OD) <zfk9@cdc.gov>; Albrecht, Valerie S. (CDC/DDID/NCEZID/OD) <gpy8@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Hello Chip and Rudith,

Laura, Val, and I just had a call to discuss whether a STARS entry would be required for OMB's review of the Revision Request (including a 3-year extension) for ELIMS' 50.34 Form and Global File Accessioning Template Information collections.

Based on conversation on the history of these ICs and their supportive role to ELIMS, Laura indicated that ELIMS is not a research program, and therefore, a formal STARS entry, review, and determination are not required for inclusion in the 30-day FRN document package.

Please confirm your agreement with this assessment or if you would like to have a call to discuss further.

Regards,

Brian

Brian Behrens | Independent Contractor to Booz Allen Hamilton | ELIMS Project Manager | cpu2@cdc.gov | 678-357-0613
Centers for Disease Control and Prevention | NCEZID | Office of the Director



From: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR)
Sent: Tuesday, July 18, 2023 4:11 PM
To: Youngblood, Laura (CDC/DDID/NCEZID/OD) <zfk9@cdc.gov>
Cc: Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>; Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Thanks Laura. I'll get a meeting scheduled for us, likely Thursday or Friday. Please let me know if you have a date/time preference.

Regards,

Brian

Brian Behrens | Independent Contractor to Booz Allen Hamilton | ELIMS Project Manager | cpu2@cdc.gov | 678-357-0613
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From: Youngblood, Laura (CDC/DDID/NCEZID/OD) <zfk9@cdc.gov>
Sent: Tuesday, July 18, 2023 3:33 PM
To: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>
Cc: Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>; Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Good afternoon, Brian!

I think it is probably a good idea to go ahead and document this in STARS this time around. Have you used STARS before? If not, let's set up a meeting this week and I can walk you through it. Something this basic will not need a separate protocol, so I am just attaching our STARS cheat sheet so you know what information to put in the STARS fields.

Laura

Laura Youngblood, MPH, CIP

Human Subjects Advisor | NCEZID Information Collections & Human Studies Team | lyoungblood@cdc.gov | Office: (404) 639-6394 | Mobile: (404) 510-0093

From: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>
Sent: Tuesday, July 18, 2023 3:25 PM
To: Youngblood, Laura (CDC/DDID/NCEZID/OD) <zfk9@cdc.gov>
Cc: Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>; Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>
Subject: FW: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Hello Laura,

Rudith pointed me to you for assistance on a Human Subjects Determination for ELIMS which has two collection instruments that are going through the OMB PRA renewal process. I located an email conversation we had regarding this topic back in 2020 when I was working on the initial OMB approval (see attached email).

As of today, ELIMS is still not a research program nor is the information collected by it used for research purposes. I want to re-confirm that ELIMS is not required to complete a Human Subjects determination for the OMB renewal.

Thank you.

Regards,

Brian

Brian Behrens | Independent Contractor to Booz Allen Hamilton | ELIMS Project Manager | cpu2@cdc.gov | 678-357-0613
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From: Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>
Sent: Thursday, July 13, 2023 3:19 PM
To: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>; Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Apologies, email was sent while I was still typing!

For the Human Subjects determination, was this project ever submitted in STARS? I did a quick search and didn't see one. If not, I recommend reaching out to Laura Youngblood and James Peterson to see about how to get a copy of that form since that's something they would've filled out.

Let us know if you have any questions.

Thanks,
Rudith

From: Vice, Rudith (CDC/DDID/NCEZID/OD)
Sent: Thursday, July 13, 2023 3:16 PM
To: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>; Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Hi Brian,

Responding since Chip is on leave this week. I've attached the two requested documents.

From: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>
Sent: Thursday, July 13, 2023 2:51 PM
To: Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>
Cc: Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Hello Chip,

Will you please provide me with the following templates for completing the 30-Day package. Thank you!

- Supporting Statement A
- Supporting Statement B
- Human subjects determination (I am not sure I am supposed to complete this document)

Regards,

Brian

Brian Behrens | Independent Contractor to Booz Allen Hamilton | ELIMS Project Manager | cpu2@cdc.gov | 678-357-0613
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From: Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>
Sent: Thursday, May 11, 2023 1:35 PM
To: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>
Cc: McMillen, Amy (CDC/DDID/NCEZID/OD) <auh1@cdc.gov>; Vice, Rudith (CDC/DDID/NCEZID/OD) <nhr9@cdc.gov>
Subject: RE: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Thanks for the handoff, Amy!

Hi Brian,

Thanks for reaching out. Since the last time we spoke, Amy has stepped off the PRA team and Rudith has stepped on.

To get your data collection approved by OMB for another 3 years, we will need to submit a Revision/Extension Information Collection Request (ICR). If you'd like to make changes to your form, now would be a good time to do so (Revision). Otherwise, we can submit largely the same documents submitted last time (Extension).

The first step in the OMB clearance process for your ICR is to publish a 60-day notice in the Federal Register. To do that, the following elements must be submitted:

1. 60d FRN combined Request Form (attached)
2. 60d FRN (attached)
3. Draft version of information collection instrument(s)

After the 60-day FRN publishes (and we've incorporated/replied to comments from the public), the following pieces will be submitted to OMB:

1. Supporting Statement A
2. Supporting Statement B
3. Published 60-day FRN
4. Authorizing legislation
5. FRN publication request worksheet (attached)
6. 30-day FRN (example and template attached)
7. Information collection instrument(s)
8. Part I Worksheet (one for entire package, attached)
9. Part II Worksheet (one for each instrument, attached)
10. Human subjects determination/IRB approval
11. Completed/signed Privacy Impact Assessment

Feel free to utilize the documents from our previous submission here: [View Information Collection Request \(ICR\) Package \(reginfo.gov\)](#) under the "View Supporting Statement and Other Documents" link near the top.

As far as timeline goes, you will maintain continuity of clearance as long as the 30-day published before the current expiration of 11/30 (though I wouldn't recommend pushing it).

Please feel free to reach out to Rudith or myself if you have any questions when you're putting these packages together.

Best,
Chip

From: McMillen, Amy (CDC/DDID/NCEZID/OD) <auh1@cdc.gov>

Sent: Thursday, May 11, 2023 12:05 PM

To: Daymude, Thomas (Chip) (CDC/DDID/NCEZID/OD) <gkh7@cdc.gov>

Subject: FW: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

For you 😊

Amy McMillen, MPH
Deputy Associate Director for Policy
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Auh1@cdc.gov
404-639-1045
404-272-5022 cell

From: Behrens, Brian (CDC/DDID/NCEZID/OD) (CTR) <cpu2@cdc.gov>

Sent: Thursday, May 11, 2023 10:55 AM

To: McMillen, Amy (CDC/DDID/NCEZID/OD) <auh1@cdc.gov>

Subject: Upcoming OMB Form Expiration of CDC Specimen Submission Form 50.34.

Hello Amy,

I worked with you and Chip Daymude back in 2020 on the initial PRA and OMB approval of the “CDC Specimen Submission Form 50.34”. The form was approved by OMB with Control Number 0920-1309 and an Expiration Date of 11/30/2023. I am contacting you to request information about what actions are required to have the 50.34 Form approved for use for another 3-year period taking its new Expiration Date to 11/30/2026.

I’ve attached a copy of the form populated with TEST DATA for re-familiarization purposes.

Regards,

Brian

Brian Behrens | Independent Contractor to Booz Allen Hamilton | ELIMS Project Manager | cpu2@cdc.gov | 678-357-0613

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