

Samuel, Lee (CDC/OID/NCEZID)

From: Yu, Joana (CDC/OID/NCEZID) (CTR)
Sent: Tuesday, August 11, 2015 9:53 AM
To: McMillen, Amy (CDC/OID/NCEZID)
Cc: Roberts, Virginia (CDC/OID/NCEZID)
Subject: FW: IRB approval for new HABs surveillance system
Attachments: Att A_Authorizing_Regulations_T42_section_241 (00000002).doc; SS_A_0920-xxxx Harmful Algal Bloom-related Illness Surveillance System (HABISS)_08Aug2015.doc

Hi Amy,

Here is the supporting statement with changes. Below is the email thread with Laura Youngblood's IRB approval.

Thanks!
Joana

From: Youngblood, Laura (CDC/OID/NCEZID)
Sent: Wednesday, May 27, 2015 11:03 AM
To: Hynes, Ansley (CDC/OID/NCIRD) (CTR); Yu, Patricia A. (CDC/OID/NCEZID)
Cc: Roberts, Virginia (CDC/OID/NCEZID)
Subject: FW: IRB approval for new HABs surveillance system

Thank you for sending the documents, Ansley! Sorry for my earlier confusion! 😊

I agree that these activities are still within the scope of routine non-research public health surveillance.

However, I noted some researchy language in the supporting statements – please see attached versions for my inserted comments and suggestions for rephrasing.

Laura Youngblood, MPH, CIP

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From: Hynes, Ansley (CDC/OID/NCIRD) (CTR)
Sent: Wednesday, May 27, 2015 10:29 AM
To: Yu, Joana (CDC/OID/NCEZID) (CTR); Youngblood, Laura (CDC/OID/NCEZID)
Cc: Roberts, Virginia (CDC/OID/NCEZID)
Subject: RE: IRB approval for new HABs surveillance system

Laura,

Great to talk to you. I have attached the variables for the HAB collection as well as the draft version of supporting statement A and B. Please let me know if you require additional information.

Regards,
Ansley

From: Yu, Joana (CDC/OID/NCEZID) (CTR)
Sent: Tuesday, May 26, 2015 9:05 AM
To: Youngblood, Laura (CDC/OID/NCEZID)
Cc: Hynes, Ansley (CDC/OID/NCIRD) (CTR); Roberts, Virginia (CDC/OID/NCEZID)
Subject: IRB approval for new HABs surveillance system

Hi Laura,

I am working with Ansley to submit OMB approval documents for the harmful algal blooms (HABs) surveillance system, formerly known as HABISS. Our new system will be incorporating the data elements of HABISS but will be operated under NORS. No personally identifiable information will be collected from CDC and will include exposure, symptom, clinical, and laboratory data for single human cases, single animal cases, and environmental events associated with HABs. For human cases, age will be collected (in years) and the state of the exposure will be collected.

I just wanted to double check with you that our system will not require IRB approval and is considered routine surveillance.

Thank you for your help.

All the best,

Joana

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