

RE: DRAFT HFT Guide Notice 7.17.2019

From: "Stannard, Paula (HHS/IOS)" [REDACTED]
To: "Wolinetz, Carrie (NIH/OD) [E]" [REDACTED], "Giroir, Brett (HHS/OASH)" [REDACTED], "Tabak, Lawrence (NIH/OD) [E]" [REDACTED]
Cc: "Harder, Kristina (HHS/IOS)" [REDACTED], "Charrow, Robert (HHS/OD)" [REDACTED]
Date: Tue, 23 Jul 2019 20:17:32 +0000
Attachments: DRAFT HFT Guide Notice 7.17.2019 BG 7.23.19 ps.docx (49.24 kB)

PRIVILEGED AND CONFIDENTIAL/DELIBERATIVE/PREDECISIONAL

Attached is the version with my suggestions and comments, on top of Admiral Giroir's and Bob Charrow's comments and revisions. Like Admiral Giroir, I think this is a well done guidance.

FYSA, I have shared this version with DPC and WH Counsel's Office, indicating that you need to issue this tomorrow.

Paula

From: Wolinetz, Carrie (NIH/OD) [E] [REDACTED]
Sent: Tuesday, July 23, 2019 3:16 PM
To: Giroir, Brett (HHS/OASH) [REDACTED]; Stannard, Paula (HHS/IOS) [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED]
Cc: Harder, Kristina (HHS/IOS) [REDACTED]
Subject: RE: DRAFT HFT Guide Notice 7.17.2019

Hi Brett,

Thank you!

HHS Redaction

The statute states that the EAB is convened when the Secretary wishes to "withhold funds for research for the research because of the ethical considerations." The Board recommends in support or not in support of withholding funds, thus allowing the Secretary to *not* fund the research, which is not something Council review or agency decision would HHS Redaction countermand. Cheers, Carrie

From: Giroir, Brett (HHS/OASH) [REDACTED]
Sent: Tuesday, July 23, 2019 8:46 AM
To: Stannard, Paula (HHS/IOS) [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED]; Wolinetz, Carrie (NIH/OD) [E] [REDACTED]
Cc: Harder, Kristina (HHS/IOS) [REDACTED]; Giroir, Brett (HHS/OASH) [REDACTED]
Subject: RE: DRAFT HFT Guide Notice 7.17.2019

Well done guidance. I made one minor word change. Responded to a couple of comments.

I asked one question in the comment section that we should discuss:

HHS Redaction

HHS Redaction

Paula: did you review this yet?
Deadline is tomorrow for NIH to appropriately publish/notify

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
Senior Adviser, Immediate Office of the Secretary
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: [REDACTED]

From: Stannard, Paula (HHS/IOS) [REDACTED]
Sent: Monday, July 22, 2019 1:43 PM
To: Harder, Kristina (HHS/IOS) [REDACTED]; Giroir, Brett (HHS/ASH)
[REDACTED]
Subject: Fwd: DRAFT HFT Guide Notice 7.17.2019

As mentioned.

Paula

Sent from my iPhone

Begin forwarded message:

From: "Charrow, Robert (HHS/OGC)" [REDACTED]
Date: July 18, 2019 at 8:35:35 AM EDT
To: "Stannard, Paula (HHS/IOS)" [REDACTED]
Subject: DRAFT HFT Guide Notice 7.17.2019

I've put in some edits. B

Produced to Committee on Oversight and Reform Pursuant to Oversight Request from Dep't of Health and Human Services
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