



## Decision

**Matter of:** U.S. Department of Health and Human Services—Application of Fiscal Law to Other Transactions

**File:** B-333150

**Date:** April 8, 2024

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### DIGEST

The National Heart, Lung, and Blood Institute (NHLBI) within the National Institutes of Health (NIH) violated the recording statute when it recorded obligations for three Other Transaction Agreements (OTAs) at the time it issued the respective Notices of Award for such agreements. The recording statute requires an agency to record the full amount of its obligation against funds available at the time it incurs the obligation. However, as is the case here, award notices do not establish an obligation if another document has already established the agency's legal liability for the project or if the notices condition funding on the agency's approval of the applicant's plan, the execution of a future agreement, or both.

NHLBI also violated the recording statute when it recorded a liability for one of the agreements in an amount that included funds that were not available to the awardee until NHLBI approved their release in the future. An agency may not generally record an obligation if the government's liability is subject to a precondition, and the satisfaction of the condition is in the government's control.

NHLBI did not violate the *bona fide* needs statute when it entered into the three OTAs with fiscal year appropriations, even though the agreements covered activities that would be conducted over multiple years, because the purposes of the agreements were to provide federal assistance to facilitate medical research. When the principal purpose of the transaction is to provide federal assistance, then the agency's need is fulfilled when it awards funds from the currently available appropriation, regardless of when the recipient will expend the awarded funds.

NHLBI complied with the *bona fide* needs statute when it modified one of the agreements but did not alter the agreement's scope or purpose. A modification is a *bona fide* need of the year in which the agreement was originally executed when there is a continuing need for the work contemplated in the agreement and the purpose and scope of the agreement remain unchanged.

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## DECISION

This responds to a request from the U.S. Department of Health and Human Services, Office of Inspector General (HHS OIG), on whether and how fiscal law, including the recording statute and the *bona fide* needs statute, applies to three specific National Heart, Lung, and Blood Institute (NHLBI) Other Transaction Agreements (OTAs).<sup>1</sup> The request stemmed from a 2021 HHS OIG audit of NHLBI's compliance with federal requirements for Other Transactions.<sup>2</sup> As explained below, we conclude that NHLBI did not comply with the recording statute with respect to when NHLBI recorded amounts for the three agreements and with respect to the amount that NHLBI recorded for one of the agreements. We further conclude that NHLBI complied with the *bona fide* needs statute with respect to the three agreements and the obligations NHLBI actually incurred, as well as when it modified one of the agreements.

In accordance with our regular practice, we contacted HHS to seek factual information and its legal views on this matter.<sup>3</sup> HHS responded with its explanation of the pertinent facts and legal analysis.<sup>4</sup> We also requested<sup>5</sup> and received additional information from HHS OIG.<sup>6</sup>

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<sup>1</sup> Letter from Acting Chief Counsel to the Inspector General, HHS OIG, to General Counsel, GAO (Apr. 8, 2022) (Request Letter).

<sup>2</sup> Request Letter; HHS OIG, *The National Heart, Lung, and Blood Institute Did Not Fully Comply with Federal Requirements for Other Transactions*, A-04-20-04078 (Apr. 2021) (HHS OIG Audit), available at <https://oig.hhs.gov/oas/reports/region4/42004078.asp> (last visited Apr. 1, 2024).

<sup>3</sup> GAO, *GAO's Protocols for Legal Decisions and Opinions*, GAO-24-107329 (Washington, D.C.: Feb. 2024), available at <https://www.gao.gov/products/gao-24-107329>. Letter from Assistant General Counsel for Appropriations Law, GAO, to Associate General Counsel, General Law Division, HHS (June 6, 2022); Letter from Managing Associate General Counsel, GAO, to Associate General Counsel, General Law Division, HHS (Aug. 8, 2022) (Follow-Up Development Letter).

<sup>4</sup> Letter from Associate General Counsel, General Law Division, HHS, to Managing Associate General Counsel, GAO (Mar. 6, 2023) (HHS OGC Response).

<sup>5</sup> Email from Senior Attorney, GAO, to Senior Counsel, HHS OIG (July 5, 2022); Email from Senior Attorney, GAO, to Senior Counsel, HHS OIG (July 21, 2022).

<sup>6</sup> Emails from Senior Counsel, HHS OIG, to Senior Attorney, GAO (July 11, 2022) (with attachments); Email from Senior Counsel, HHS OIG, to Senior Attorney, GAO (Aug. 3, 2022) (with attachments).

## BACKGROUND

### NHLBI

NHLBI is one of the Institutes, Centers, and Offices of the National Institutes of Health (NIH).<sup>7</sup> NHLBI's mission is to provide global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood disorders and enhance the health of all individuals so that they can live longer and more fulfilling lives.<sup>8</sup> This includes carrying out the National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (NHLBI Program). See 42 U.S.C. § 285b-3. NHLBI receives annual appropriations to carry out its activities.<sup>9</sup>

### Statutory Authority for Other Transaction Agreements (OTAs)

NHLBI has statutory authority to enter into OTAs<sup>10</sup> under section 285b-3 of title 42. The law states:

In carrying out the [NHLBI] Program, the Director of the Institute, under policies established by the Director of NIH[,] . . . subject to section 284(b)(2) of this title<sup>[11]</sup> and without regard to section 3324 of title 31 and section 6101 of title 41, may enter into such contracts, leases, cooperative agreements, *or other transactions*, as may be necessary in

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<sup>7</sup> HHS OIG Audit, at 2.

<sup>8</sup> NHLBI, *About the NHLBI*, available at <https://www.nhlbi.nih.gov/about> (last visited Apr. 1, 2024); see 42 U.S.C. §§ 285b, 285b-3(a).

<sup>9</sup> See, e.g., Consolidated Appropriations Act, 2017, Pub. L. No. 115-31, div. H, title II, 131 Stat. 135, 524 (May 5, 2017); Consolidated Appropriations Act, 2018, Pub. L. No. 115-141, div. H, title II, 132 Stat. 348, 720 (Mar. 23, 2018); Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, div. B, title II, 132 Stat. 2981, 3074 (Sept. 28, 2018); see also HHS OGC Response, at 4, 6–7.

<sup>10</sup> Congress has not defined OTAs or Other Transactions, but the term is understood to refer to a government transaction other than a procurement contract, grant, or cooperative agreement. See, e.g., GAO, *Federal Acquisitions: Use of "Other Transaction" Agreements Limited and Mostly for Research and Development Activities*, GAO-16-209 (Washington, D.C.: Jan. 2016), at 1; B-412711, May 16, 2016, at 6 (citing GAO, *Defense Acquisitions: DOD Has Implemented Section 845 Recommendations but Reporting Can Be Enhanced*, GAO-03-150 (Washington, D.C.: Oct. 2002), at 1).

<sup>11</sup> Section 284(b)(2) includes requirements for entering into contracts, grants, and cooperative agreements, but does not mention OTAs or purport to apply to them.

the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions.

42 U.S.C. § 285b-3(b)(3) (emphasis added).<sup>12</sup>

### NHLBI OTA Process

NHLBI entered into all three OTAs submitted with the request under section 285b-3.<sup>13</sup> NHLBI stated that they generally began the OTA process after NHLBI identified a gap in the prevailing science or problem to be solved and issued announcements soliciting applications for funding.<sup>14</sup> Following the awardee's submission of an initial proposal and, in some cases, negotiations between NHLBI and the awardee, NHLBI issued a Notice of Award (NOA), and NHLBI and the awardee executed an OTA.<sup>15</sup> NHLBI treated the NOAs as providing the documentary basis for obligating funds,<sup>16</sup> and the entire amount listed in each NOA was obligated from the annual NHLBI appropriation available when the NOA was issued.<sup>17</sup> The NOAs and OTAs for each of the three transactions at issue were finalized toward the end of a fiscal year with a period of performance that extended

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<sup>12</sup> In addition to the instruments described in section 285b-3(b)(3), NHLBI is also authorized to provide grants for certain purposes. 42 U.S.C. § 285b-3(b)(2)(B), (4).

<sup>13</sup> Other Transaction Agreement Concerning the Integration of Trans-omics for Precision Medicine (TOPMED) and Other Heart, Lung, Blood, and Sleep (HLBS) Data Sets With the NIH Data Commons, Agreement No. 1OT3HL142478-01 (Sept. 28, 2017) (Dataset Integration OTA), at 5; Other Transaction Agreement Concerning NHLBI Data STAGE Coordinating Center, Agreement No. 1OT3HL147154-01 (Aug. 10, 2018) (Data STAGE Coordinating Center OTA), at 5; Other Transaction Agreement Concerning Cure Sickle Cell Initiative Manufacturing Resource Platform, Agreement No. 1OT3HL152932 (Sept. 26, 2019) (CureSCi Manufacturing Resource Platform OTA), at 5.

<sup>14</sup> See NHLBI General Responses to HHS OIG Questions on Pricing, Funding, and Other Award Execution Matters (Aug. 28, 2020) (NHLBI General Responses), at 3.

<sup>15</sup> See HHS OIG Audit, at 2–3, 9; NHLBI General Responses, at 7 (discussing the negotiation process); NHLBI Specific Responses to HHS OIG Questions on Pricing, Funding, and Other Award Execution Matters (Aug. 28, 2020) (NHLBI Specific Responses), at 1 (chart created by HHS OIG showing information on various OTAs, including the three at issue here). The NOA issuance date was not always the same as the OTA execution date. See NHLBI Specific Responses, at 1–2.

<sup>16</sup> See HHS OIG Audit, at 3; see also NIH, *Other Transactions Policy Guide for NIH Staff* (May 5, 2021) (2021 NIH OT Policy), at 104 (issued after the three OTAs were executed and stating that the NOA serves as the documentary evidence for recording an OT obligation).

<sup>17</sup> See Request Letter; HHS OGC Response.

into future fiscal years.<sup>18</sup> NHLBI subsequently made modifications to all three OTAs, sometimes issuing new NOAs and obligating additional funds. In line with HHS OIG's request, we limit our analysis to the three original OTAs and one particular modification.<sup>19</sup>

#### First OTA: Dataset Integration OTA

On June 16, 2017, NIH issued a funding announcement soliciting applications for the pilot phase of the NIH Data Commons, an initiative intended to accelerate new biomedical discoveries by providing a cloud-based platform where investigators could store, share, and access biomedical research.<sup>20</sup> On September 26, 2017, NHLBI issued an NOA in the amount of \$2.85 million and recorded an obligation for that amount.<sup>21</sup> NHLBI signed the OTA on September 27, 2017.<sup>22</sup> The purpose of the agreement was to integrate certain heart, lung, blood, and sleep datasets within the broader NIH Data Commons initiative.<sup>23</sup> The initial term of the OTA was three years, though the Statement of Budgetary Projections (Budget Statement) provided for only an initial one-year period of performance.<sup>24</sup> NHLBI restricted the amount of obligated funds available to the awardee, authorizing the awardee to expend up to one-fourth of the \$2.85 million each quarter of the first year of the agreement.<sup>25</sup> NHLBI and the awardee made modifications to the OTA on July 6, 2018.<sup>26</sup>

#### Second OTA: Data STAGE Coordinating Center OTA

In 2018, NHLBI solicited applications for a coordinating center for its Data STAGE consortium, a group of academic institutions developing a cloud-based platform for heart, lung, blood, and sleep research investigators to find, access, share, store, and compute on large scale data sets in order to facilitate the development of novel

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<sup>18</sup> See NHLBI Specific Responses, at 1; Dataset Integration OTA, at 1, 5; Data STAGE Coordinating Center OTA, at 1, 6; CureSCi Manufacturing Resource Platform OTA, at 1, 5.

<sup>19</sup> See Request Letter.

<sup>20</sup> NIH, *NIH Data Commons Pilot Phase*, Funding Announcement (FA) Number RM-17-026 (June 16, 2017), at 5, available at [https://commonfund.nih.gov/sites/default/files/RM-17-026\\_CommonsPilotPhase.pdf](https://commonfund.nih.gov/sites/default/files/RM-17-026_CommonsPilotPhase.pdf) (last visited Apr. 1, 2024).

<sup>21</sup> NHLBI Specific Responses, at 1–2.

<sup>22</sup> Dataset Integration OTA, at 1.

<sup>23</sup> *Id.* at 4–5.

<sup>24</sup> *Id.* at 5, Attachment 2.

<sup>25</sup> *Id.* at Attachment 2.

<sup>26</sup> Dataset Integration OTA, Modification 1 (July 6, 2018).

diagnostic tools, therapeutic options, and prevention strategies for heart, lung, blood, and sleep disorders.<sup>27</sup> On August 10, 2018, NHLBI and the awardee signed an OTA.<sup>28</sup> NHLBI issued an NOA on August 13, 2018, listing \$5,798,287 for the OTA and recorded an obligation for that amount.<sup>29</sup> Both the term of the agreement and period of performance were five years.<sup>30</sup> The OTA did not include any restrictions on the amount of funds available to the awardee other than the \$5,798,287 ceiling.<sup>31</sup>

### Third OTA: CureSCi Manufacturing Resource Platform OTA

In 2018, NHLBI launched the Cure Sickle Cell Initiative (CureSCi) to support technologies and treatments related to curing sickle cell disease.<sup>32</sup> As part of that initiative, on September 26, 2019, NHLBI and the awardee signed an OTA to establish a resource platform consisting of a consortium of manufacturers and facilities to support genetic therapies for sickle cell disease.<sup>33</sup> NHLBI issued an NOA on September 27, 2019, listing \$5,641,200 for the OTA and recorded an obligation for that amount.<sup>34</sup> Both the term of the agreement and period of performance were four years.<sup>35</sup>

NHLBI restricted the amount of funds initially available to the awardee. Only \$501,361 was available for the performance of certain milestones; the remaining funds were restricted until certain conditions had been met and NHLBI approved a request from the awardee to lift the funding restriction.<sup>36</sup> Specifically, the remaining

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<sup>27</sup> Memorandum from Chief, Heart Development and Structural Diseases Branch, to Director, NHLBI, *To obtain approval to enter into an Other Transaction Agreement to establish a Coordinating Center for the NHLBI Data STAGE* (Mar. 7, 2018); Data STAGE Coordinating Center OTA, at 3, 5, Attachment 1.

<sup>28</sup> Data STAGE Coordinating Center OTA, at 1.

<sup>29</sup> *Id.*; NHLBI, *Notice of Award*, Award No. 1OT3HL147154-01 (Aug. 13, 2018) (Data STAGE Coordinating Center NOA); Follow-Up Development Letter, at 4 (summarizing obligations); HHS OGC Response, at 6 (confirming obligations).

<sup>30</sup> Data STAGE Coordinating Center OTA, at 6, Attachment 2.

<sup>31</sup> *Id.*

<sup>32</sup> CureSCi Manufacturing Resource Platform OTA, at 3.

<sup>33</sup> *Id.* at 4, Attachment 1.

<sup>34</sup> NHLBI, *Notice of Award*, Award No. 1OT3HL152932-01 (Sept. 27, 2019) (CureSCi Manufacturing Resource Platform NOA); Follow-Up Development Letter, at 5 (summarizing obligations); HHS OGC Response, at 7 (confirming obligations).

<sup>35</sup> CureSCi Manufacturing Resource Platform OTA, at 5, Attachment 2.

<sup>36</sup> *Id.* at Attachment 2.

funds would be restricted until NHLBI approved manufacturing facilities for funding.<sup>37</sup> In addition, NHLBI would review the awardee's progress and financial reports before determining whether to approve the awardee's request to lift the restriction.<sup>38</sup>

## DISCUSSION

At issue here is how fiscal law, including the recording statute and the *bona fide* needs statute, applies to the three specific OTAs that are the subject of HHS OIG's request. In particular, the primary issues presented here are: (1) when did NHLBI incur obligations for the OTAs; (2) what amount should be recorded for those obligations; and (3) whether those obligations satisfy the *bona fide* needs statute.

### Recording Statute

#### (1) Obligating Event

The recording statute, 31 U.S.C. § 1501, requires that an agency record an obligation when there is sufficient documentary evidence of the government's liability and record the amount of the obligation based on such evidence. See, e.g., B-329712, Oct. 15, 2020. It also specifies the type of documentary evidence necessary to record an obligation for different types of transactions, including procurement contracts, grants, and cooperative agreements. See 31 U.S.C. § 1501(a)(1), (5); B-226782, Oct. 20, 1987 (procurement contracts); B-316372, Oct. 21, 2008 (grants); B-321297, Aug. 2, 2011 (cooperative agreements). And when no specific provision applies, the recording statute includes a catch-all provision requiring agencies to record an obligation when there is documentary evidence of a "legal liability of the [g]overnment against an available appropriation or fund." See 31 U.S.C. § 1501(a)(9); B-329712, Oct. 15, 2020; B-332205, Aug. 9, 2023.

OTAs are considered something other than procurement contracts, grants, or cooperative agreements and are not covered by the specific categories listed in the recording statute. See GAO-16-209; 31 U.S.C. § 1501(a). Accordingly, liabilities for these types of agreements should be recorded as an obligation pursuant to section 1501(a)(9) when there is documentary evidence of the government's legal liability.

Unless constrained by limitations or restrictions in the relevant OTA authority, agencies have discretion in determining the form of their OTAs. See GAO-16-209, at 4–5. To determine what type of documentary evidence is sufficient to record an obligation for an OTA, it is helpful to consider whether the transaction resembles one of the instruments expressly described in the recording statute, like a contract or grant, and, if so, to look to the documentary requirements for that instrument.

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<sup>37</sup> *Id.* at Attachments 1–2.

<sup>38</sup> *Id.* at Attachment 2.

NHLBI's organic statute authorizes the NHLBI Director to enter into OTAs as may be necessary to carry out the NHLBI Program, which consists of a broad array of activities to support research, training, health information, and dissemination, and the establishment of programs to promote the diagnosis, treatment, and prevention of heart, lung, and blood disorders. See 42 U.S.C. § 285b-3. In addition to OTAs, NHLBI may enter into both traditional procurement instruments (contracts and leases) and federal assistance instruments (cooperative agreements) with any public agency, person, firm, association, corporation, or educational institution to carry out the NHLBI Program. 42 U.S.C. § 285b-3(b)(3). Therefore, we must consider the characteristics of the specific OTAs at issue to determine which type of traditional instrument they most closely resemble.

The Federal Grant and Cooperative Agreement Act of 1977 (FGCAA) establishes criteria to differentiate among grants, cooperative agreements, and contracts. 31 U.S.C. §§ 6301–6308; B-328615, May 9, 2017. The differences between contracts, on one hand, and grants and cooperative agreements, on the other, hinge on the purpose of the transaction.<sup>39</sup> If the principal purpose of the transaction is to acquire goods or services for the direct benefit or use of the government, the agency should use a procurement contract. 31 U.S.C. § 6303. On the other hand, if the purpose is to provide federal assistance by transferring something of value (like money, property, or services) to the recipient to carry out an authorized public purpose of support or stimulation, the agency should use a grant or cooperative agreement. 31 U.S.C. §§ 6304–6305.

All three OTAs at issue here are focused on facilitating medical research of various diseases and disorders. NHLBI considers its OTAs to be akin to federal assistance instruments and stated that their purpose is to transfer something of value to the recipient to carry out an authorized public purpose.<sup>40</sup> In particular, NHLBI asserted that its OTAs are used to solve problems faced by the general scientific community, like finding a genetic cure for sickle cell disease, or to facilitate rapidly changing science.<sup>41</sup>

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<sup>39</sup> The FGCAA also distinguishes between grants and cooperative agreements based on the degree of the government's involvement. 31 U.S.C. §§ 6304–6305. Both instruments are subject to the same part of the recording statute, section 1501(a)(5). See B-316372, Oct. 21, 2008; B-321297, Aug. 2, 2011.

<sup>40</sup> NHLBI General Responses, at 4.

<sup>41</sup> NHLBI General Responses, at 4. We further note that NIH also uses grants and cooperative agreements, traditional federal assistance instruments, for similar projects. See NIH, *Common Fund Data Ecosystem, Funding Opportunities*, available at <https://commonfund.nih.gov/dataecosystem/FundingOpportunities> (last visited Apr. 1, 2024) (listing grant, cooperative agreement, and OTA funding opportunities to integrate and make accessible various datasets); NIH, *NIH Grants*

(continued...)



With respect to the three OTAs at issue here, we agree with NHLBI. The activities covered by the three OTAs are within the broad scope of the NHLBI Program and appear intended to promote national interests such as making medical data accessible to researchers and providing resources to support the development of medical treatments, rather than to satisfy a specific governmental need for a supply or service. In addition, the awardees fall within the wide-ranging universe of entities with which NHLBI may enter into federal assistance agreements under section 285b-3.

Given the purposes of the three OTAs, we look to the documentary requirements for traditional federal assistance instruments (grants and cooperative agreements) for guidance in determining when to record an obligation for these three transactions.

Section 1501(a)(5) requires an agency to record an obligation for a traditional federal assistance instrument based on evidence of an agreement or approved plans authorized by law.<sup>42</sup> This generally occurs at the time of a grant award, see B-316372, Oct. 21, 2008, B-289801, Dec. 30, 2002, or when an authorized government official signs a cooperative agreement. See B-321297, Aug. 2, 2011.

In previous decisions, we have identified the types of terms and conditions that must be included in a federal assistance award notice for it to establish an obligation. Specifically, award notices establish an obligation if the notice reflects the acceptance of an awardee's application, specifies the project approved and the amount of funding, and imposes a deadline for acceptance by the awardee. B-316372, Oct. 21, 2008; B-126652, Aug. 30, 1977. The notices addressed in those decisions also expressly stated that the award constituted an obligation, see B-316372, Oct. 21, 2008, B-126652, Aug. 30, 1977, and included the relevant terms and conditions. B-126652, Aug. 30, 1977. In contrast, we have determined that award notices do not establish an obligation if the notices condition funding on the agency's approval of the applicant's plan, the execution of a future agreement, or both. B-197274, Feb. 16, 1982 (involving "reservation and notification" letters sent by the Department of Housing and Urban Development (HUD) to federal assistance applicants).

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*Policy Statement* § 15.1 (Dec. 2022), available at [https://grants.nih.gov/grants/policy/nihgps/HTML5/section\\_15/15.1\\_general.htm](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_15/15.1_general.htm) (last visited Apr. 1, 2024) (Consortium Agreements-General).

<sup>42</sup> Section 1501(a)(5) also requires agencies to record an obligation for grants or subsidies payable from appropriations that are "required to be paid in specific amounts fixed by law or under formulas prescribed by law." 31 U.S.C. § 1501(a)(5)(A); B-316915, Sept. 25, 2008.

Here, each OTA involved two primary events: (1) NHLBI's issuance of an NOA<sup>43</sup>; and (2) the execution of an OTA between NHLBI and the awardee. For each OTA, these two events occurred in the same fiscal year but not on the same day. For two of the OTAs, NHLBI issued the NOA after the OTA was executed<sup>44</sup>; for the other OTA, NHLBI issued the NOA before the OTA was executed.<sup>45</sup> In each instance, NHLBI treated issuance of the NOA as the point of obligation for the award.<sup>46</sup>

In analyzing when an obligation arises, we consider the specific language of the relevant documents. See B-316372, Oct. 21, 2008. Each NOA lists the project title, award calculation, the awardee, as well as other information, and states that NIH "hereby awards an other transactions award in the amount of [\$X]" to the awardee in support of the referenced project.<sup>47</sup> The NOAs state that "[a]cceptance of this award including the 'Terms and Conditions' is acknowledged by the award recipient when funds are drawn down or otherwise obtained from the Payment Management System."<sup>48</sup> However, the NOAs further state that they are issued pursuant to the authorities in the special terms and conditions sections of the documents and are subject to those requirements as well as other referenced, incorporated, or attached terms and conditions.<sup>49</sup> The special terms and conditions section of each NOA, in turn, states that the NOA is "for funding reservation only" and is not the official OTA, which "is in the award file."<sup>50</sup>

Each OTA provides detailed information on the scope, term, and administration of the project.<sup>51</sup> Each OTA also includes a "Statement of Milestones and Objectives" that describes the scope of the arrangement and the awardee's responsibilities.<sup>52</sup> In terms of funding, each OTA includes a Budget Statement that states that the awardee "is authorized to expend funds up to the amounts reflected in the 'Funds

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<sup>43</sup> We only received copies of the initial Data STAGE Coordinating Center and CureSCi Manufacturing Resource Platform NOAs. Given the similarities between those NOAs, we assume, for purposes of this decision, that the initial Dataset Integration NOA contained similar terms.

<sup>44</sup> See Data STAGE Coordinating Center NOA; CureSCi Manufacturing Resource Platform NOA.

<sup>45</sup> See NHLBI Specific Responses, at 1.

<sup>46</sup> HHS OIG Audit, at 3. We note that this practice is consistent with the 2021 NIH OT Policy. See 2021 NIH OT Policy, at 104.

<sup>47</sup> See, e.g., Data STAGE Coordinating Center NOA.

<sup>48</sup> See, e.g., *id.*

<sup>49</sup> See, e.g., *id.*

<sup>50</sup> See, e.g., *id.* at § IV.

<sup>51</sup> See, e.g., Data STAGE Coordinating Center OTA.

<sup>52</sup> *E.g., id.* Attachment 1.

Authorized” section of the Budget Statement.<sup>53</sup> The OTAs further provide that NIH/NHLBI’s “liability to make payments to the [awardee] is limited to only those funds obligated under the [OTA] or by modification to the [OTA],” subject to the availability of funds.<sup>54</sup>

Examining both the OTAs and NOAs for each transaction, we conclude that NHLBI incurred an obligation when it signed the OTAs, as that was the point at which the government incurred a legal liability to provide funds to the awardees. The OTAs, not the NOAs, represent the agreement between NHLBI and the awardees.<sup>55</sup> The OTAs also contain the terms and conditions we have determined must be included in federal assistance award notices to establish an obligation. See B-316372, Oct. 21, 2008; B-126652, Aug. 30, 1977. In particular, the OTAs specify the terms of the arrangements, reflect the acceptance of the awardees’ applications, and specify the projects approved and the amounts of funding.<sup>56</sup> The OTAs also expressly authorize the awardees to expend funds for which NHLBI is liable and do not reference or condition funds on the issuance of an NOA, which, for two of the transactions, was issued after the OTA was signed.<sup>57</sup>

In contrast, the NOAs specifically reference the OTAs in their special terms and conditions sections as separate and distinct from the NOAs and clarify that the NOAs are “for funding reservation only.”<sup>58</sup> This language indicates that each NOA contemplates the existence of a separate OTA for the relevant project, and the NOAs merely represent the administrative reservation of funds for the project rather than a legally enforceable commitment to expend funds. In other words, in the

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<sup>53</sup> *E.g.*, *id.* Attachment 2.

<sup>54</sup> *E.g.*, *id.* at Art. V.A.

<sup>55</sup> *E.g.*, Data STAGE Coordinating Center OTA, Art. XIII (stating that the OTA “constitutes the entire agreement of the [p]arties and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions among the [p]arties”).

<sup>56</sup> See, *e.g.*, Data STAGE Coordinating Center OTA. Previous decisions involving open-ended award notices also emphasized that the relevant notices imposed a deadline for awardee acceptance. B-316372, Oct. 21, 2008; B-126652, Aug. 30, 1977. Because the OTAs are signed agreements between the parties rather than open-ended notices, we conclude that the absence of such a deadline in the OTAs is not material to our analysis. *Cf.* B-321297, Aug. 2, 2011 (concluding that an agency should record an obligation for a cooperative agreement when an authorized government official signs the agreement, without any mention of the need for a deadline for awardee acceptance).

<sup>57</sup> See Data STAGE Coordinating Center NOA (issued three days after execution of the OTA); CureSCi Manufacturing Resource Platform NOA (issued the day after execution of the OTA).

<sup>58</sup> See, *e.g.*, Data STAGE Coordinating Center NOA.

absence of an OTA, it does not appear that the NOAs independently authorized awardees to incur costs for which NHLBI would be liable. When issued before the OTA, the NOA was akin to a “reservation and notification” letter, which we (and courts) have found to be insufficient to establish an obligation because liability was conditioned on additional agency action. See B-197274, Feb. 16, 1982; *Champaign County, Illinois v. U.S. Law Enforcement Assistance Administration*, 611 F.2d 1200, 1205 (7th Cir. 1979) (“A reservation of funds does not amount to a formal award especially when . . . the agency has indicated further correspondence is needed.”); cf. B-316372; B-126652, Aug. 30, 1977 (involving notices that expressly stated that the award constituted an obligation). And when issued after the OTA, the NOA merely represented the administrative implementation of the agreement, which had already established NHLBI’s legal liability.

Because the OTAs, not the NOAs, established NHLBI’s legal liability to expend funds for the transactions, NHLBI incurred obligations when an authorized NHLBI official signed the OTA for each of the three transactions.<sup>59</sup> As such, in each instance NHLBI violated the recording statute.

## (2) Amount of Obligation

Having determined that NHLBI incurred an obligation for each of the three transactions when the OTAs were executed, we now examine the liability that NHLBI should have recorded for each OTA. A major purpose of the recording statute is to provide Congress a reasonably precise picture of an agency’s financial requirements so it can more accurately assess the agency’s future appropriation needs. See 64 Comp. Gen. 410 (1985). The recording statute thus requires an agency to record the full amount of its obligation against funds available at the time it incurs the obligation. See, e.g., B-327242, Feb. 4, 2016. This includes amounts for which the government’s liability depends on future events that are outside its control. See B-300480, Apr. 9, 2003. The recording statute likewise prohibits an agency from overrecording the obligation amount. See 64 Comp. Gen. 410. In particular, an agency may not record an obligation if the government’s liability is subject to a precondition and the satisfaction of the condition is in the government’s control. See *id.* This rule “results in a more accurate picture of an agency’s needs being presented to the Congress because unless and until the agency acts to satisfy the condition, it really has no need for funds.” *Id.* at 414.

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<sup>59</sup> Because all three OTAs contemplate that NHLBI would “have continuous involvement with the” awardee, see, e.g., Data STAGE Coordinating Center OTA, at 5, they are more akin to cooperative agreements than grants. See 31 U.S.C. §§ 6304–6305. Agencies must record obligations for cooperative agreements when an authorized government official signs the agreement. See B-321297, Aug. 2, 2011. Accordingly, we view the agency’s signing of the agreement as the obligating event for each of the OTAs.

For example, HUD violated the recording statute when it recorded obligations for “reservation and notification letters” sent to financial assistance applicants, even though the letters conditioned funding on HUD’s approval of the applicant’s plan/final proposal, the execution of a future agreement, or both. B-197274, Feb. 16, 1982. We noted in the decision that final approval of the applicant’s plan required more than perfunctory action by HUD; it required HUD to exercise discretion and judgment to determine whether the applicant met all legal and administrative requirements, and HUD retained sole control over whether a final contract would be entered into with the applicant. *Id.* Because funding was conditioned on HUD’s future approval, the applicant’s actions in response to the letters, such as submitting additional items to HUD, could not, on their own, result in future liability for HUD. *Id.* Accordingly, these letters did not result in an obligation. *Id.*

In contrast, preconditions that are solely within the awardee’s control do not affect when the agency incurs an obligation. See B-300480, Apr. 9, 2003; B-325526, July 16, 2014. In that situation, “the government should obligate funds to cover the maximum amount of the liability,” and then deobligate funds if the government’s liability is subsequently reduced because the preconditions are not met. B-300480, Apr. 9, 2003. For example, a statutory grant program administered by the Election Assistance Commission (EAC) directed EAC to make payments to states under a prescribed formula, provided that the state certified that it met certain statutory preconditions. B-316915, Sept. 25, 2008. We concluded that EAC incurred an obligation for the grant payments by operation of law regardless of when or if a particular state submitted a certification because the states had the ability to fulfill the preconditions without any action on the part of the agency. *Id.*

Looking at the obligations recorded for the three OTAs at issue, NHLBI recorded an obligation of \$2.85 million for the Dataset Integration OTA when the associated NOA was issued on September 26, 2017.<sup>60</sup> The OTA, signed on September 27, 2017, lists the “Funds Authorized” as \$2.85 million as well as four “Quarterly Authorizations” of \$712,500 for the first year of the agreement, and the OTA states that the awardee “is authorized to expend funds up to the amounts reflected in” those sections.<sup>61</sup>

As discussed above, NHLBI should have recorded an obligation for this OTA when the OTA was signed on September 27, 2017, rather than when NHLBI issued the NOA on September 26, 2017. Although NHLBI violated the recording statute by recording the obligation too early, we conclude that NHLBI properly recorded the amount of the obligation for the OTA as \$2.85 million. An obligation occurs when an agency incurs a legal liability for payment, or a legal duty that could mature into a legal liability for payment by virtue of actions beyond the control of the agency. B-300480, Apr. 9, 2003. Although, at the time the OTA was executed, the awardee

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<sup>60</sup> Request Letter, at 3; NHLBI Specific Responses, at 1–2.

<sup>61</sup> Dataset Integration OTA, Attachment 2.

was only authorized to expend funds up to the quarterly authorization of \$712,500 rather than the full \$2.85 million award, the awardee's ability to expend the remaining funds was conditioned only on the passage of time, which was outside NHLBI's control. See B-300480, Apr. 9, 2003; B-325526, July 16, 2014. Instead, this provision merely delayed the awardee's expenditure of the funds and did not affect the total amount awarded or NHLBI's liability for that total amount when it executed the OTA. See B-300480, Apr. 9, 2003. NHLBI therefore properly recorded the obligation amount as \$2.85 million, the maximum amount of its potential liability when the OTA was executed.

NHLBI recorded an obligation of \$5,798,287 for the Data STAGE Coordinating Center OTA on August 13, 2018.<sup>62</sup> The OTA lists the "Funds Authorized" as this amount and states that the awardee "is authorized to expend funds up to" that amount.<sup>63</sup> The OTA also provides that the awardee "is authorized to allocate and expend funds as needed in support of all Milestones and Objectives in the [OTA]."<sup>64</sup> The OTA does not otherwise restrict the amount of funds the awardee is authorized to expend. Although NHLBI violated the recording statute by recording the obligation when NHLBI issued the NOA on August 13, 2018, instead of when NHLBI signed the OTA on August 10, 2018, NHLBI properly recorded the amount of the obligation for the OTA as \$5,798,287.

NHLBI recorded an obligation of \$5,641,200 for the CureSCi Manufacturing Resource Platform OTA on September 27, 2019.<sup>65</sup> Like the other two agreements, this OTA provides that the awardee "is authorized to expend funds up to" the amounts reflected in the "Funds Authorized" column.<sup>66</sup> The amount listed under "Federal Funds Authorized" is \$5,641,200, but a separate column titled "Authorization Description/Notes" states:

**\$501,361 are available** for performance of Operational Milestone 1 and Operational Milestone 2. The remaining awarded funds of **\$5,139,839 are restricted** until facilities for manufacturing are approved for funding and remain subject to the programmatic requirements of the NHLBI. *Awardee should submit request to [Agreements Officer (AO)] & [Scientific Program Director (SPD)] to lift funding restrictions. Upon recommendation from SPD and based on satisfactory review of*

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<sup>62</sup> Request Letter, at 4.

<sup>63</sup> Data STAGE Coordinating Center OTA, Attachment 2.

<sup>64</sup> *Id.*

<sup>65</sup> Request Letter, at 4–5.

<sup>66</sup> CureSCi Manufacturing Resource Platform OTA, Attachment 2.

*progress and financial reports, AO will lift restrictions and notify Awardee.*<sup>67</sup>

The OTA thus only authorized the awardee to expend up to \$501,361 on two of the four milestones described in the Statement of Milestones and Objectives.<sup>68</sup> The remaining amount referenced in the OTA was not available without a request from the awardee and NHLBI approval based on its review of the awardee's progress and financial reports, as well as approval of manufacturing facilities for funding.<sup>69</sup>

The initial OTA therefore only constituted a definite commitment to pay the awardee up to \$501,361. NHLBI's liability for additional amounts was subject to a precondition, and NHLBI's actions, not the awardee's, controlled whether that precondition would be satisfied. With respect to the restricted funds, the OTA was similar to HUD's reservation and notification letters in B-197274. See B-197274, Feb. 16, 1982. The OTA did not commit NHLBI to provide those restricted amounts to the awardee; such amounts would only be made available after NHLBI approved the awardee's request, and that determination required more than perfunctory action on NHLBI's part. Specifically, NHLBI was required to exercise its discretion and judgment in reviewing the awardee's financial and progress reports and deciding whether to approve manufacturing facilities for funding.<sup>70</sup> NHLBI retained control over whether to modify the OTA to unrestrict additional funds and was free to disapprove the awardee's request, thereby leaving the funds restricted and unavailable to the awardee.<sup>71</sup>

As discussed above, NHLBI should have recorded the obligation for the OTA when NHLBI signed the OTA on September 26, 2019, not when NHLBI issued the NOA on September 27, 2019. In addition, NHLBI should have recorded an obligation only in the amount of \$501,361 when the OTA was signed, as NHLBI's potential liability for further amounts was subject to a precondition, satisfaction of which was in NHLBI's control. See 64 Comp. Gen. 410.

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<sup>67</sup> *Id.* Both the AO and SPD were government employees. See *id.* at 3–4 (defining the positions), 7–8 (identifying the AO and SPD as “NIH Points of Contact”).

<sup>68</sup> See *id.* at Attachment 1.

<sup>69</sup> See *id.* at Attachment 2; Attachment 1 (describing the process for NHLBI approval of proposed consortium members and NHLBI approval of consortium members for specific manufacturing projects); see also NHLBI, *Standard Operating Procedure (SOP): Guidance for Other Transactions Authority*, § 4.3.5.2 (June 25, 2019) (describing “restricted funds” as “not available for reimbursement or payment”).

<sup>70</sup> See CureSCi Manufacturing Resource Platform OTA, Attachment 2.

<sup>71</sup> *Id.* at 6–7 (describing the process for modifying the OTA).

### Bona Fide Needs Statute

The *bona fide* needs statute provides that a time-limited appropriation is available only to fulfill a genuine or “*bona fide*” need that arises during the period of availability of the appropriation. 31 U.S.C. § 1502(a); B-289801, Dec. 30, 2002. This means that an agency may not obligate current, annual appropriations for the *bona fide* needs of future fiscal years without statutory authority. See B-322455, Aug. 16, 2013. We have long held that the *bona fide* needs statute applies to all federal government activities carried out with appropriations, regardless of the funding mechanism used. See, e.g., B-289801, Dec. 30, 2002; B-229873, Nov. 29, 1988. The statute therefore applies to activities carried out with OTAs.<sup>72</sup>

Compliance with the *bona fide* needs statute is measured at the time the agency incurs an obligation and depends on the purpose of the transaction and the nature of the obligation. B-289801, Dec. 30, 2002 (citing 61 Comp. Gen. 184, 186 (1981)). Here, NHLBI obligated funds for awardee activities that would begin or continue in a future fiscal year. The *bona fide* needs analysis therefore depends on both the purpose and nature of the contemplated activities.

As discussed above, the principal goal of the three OTAs was to provide funds to the awardee to carry out a public purpose of support or stimulation authorized by law, namely facilitating medical research, either through making medical data accessible or providing resources to support the development of medical treatments.

When the principal purpose of a transaction is to provide federal assistance, in other words, to transfer something of value to the recipient to carry out an authorized public purpose of support or stimulation, the agency’s need is fulfilled when it awards funds from a currently available appropriation, regardless of when the recipient will expend the awarded funds. B-229873, Nov. 29, 1988; B-289801, Dec. 30, 2002. Accordingly, we evaluate whether the award was made during the period of availability of the appropriation charged and furthers the authorized purposes of the program. B-289801, Dec. 30, 2002. In addition, when multiple-year instruments are used, we examine whether instruments of that duration are in accordance with the agency’s statutory authority. See *id.*

In this instance, all three OTAs were executed near the end of the fiscal year, and NHLBI charged the annual appropriation current at the time.<sup>73</sup> As noted above, NHLBI violated the recording statute by recording obligations when it issued the

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<sup>72</sup> HHS shares this view. See Email from Associate General Counsel, General Law Division, HHS, to HHS OIG (Dec. 22, 2020); 2021 NIH OT Policy, at Appendix H; NHLBI, *Standard Operating Procedure (SOP): Guidance for Other Transactions Authority*, § 5.3.4.3 (Mar. 22, 2022) (2022 NHLBI OT Policy); see also HHS OGC Response (discussing how to apply the *bona fide* needs statute to the three OTAs).

<sup>73</sup> See Follow-Up Development Letter; HHS OGC Response.



NOAs for the transactions instead of when it signed the OTAs. However, this error did not affect the agency's compliance with the *bona fide* needs statute because, for each transaction, NHLBI's issuance of the NOA and signing of the OTA both occurred in the same fiscal year.

All three OTAs were entered into under NHLBI's organic statute, which allows the agency to use OTAs to carry out the NHLBI Program, subject to policies established by the Director of NIH. 42 U.S.C. § 285b-3. This includes providing for research and establishing programs related to heart, lung, and blood disorders. *Id.* The purpose of the three OTAs was to facilitate research related to these disorders as part of the NHLBI Program.

In addition, we have not identified any provisions in the statute, the appropriations acts for the relevant years, or the NIH policies in effect when the OTAs were executed that limit the duration of NHLBI OTAs.<sup>74</sup> NHLBI therefore had broad discretion in establishing the duration of its OTAs. See B-289801, Dec. 30, 2002 (concluding that because the statute governing a grant program did not establish any requirements beyond the basic objective, the agency had broad discretion and awarding 2-year grants fell within that discretion).

The three OTAs had terms between three and five years. Given that the relevant statutory authority affords NHLBI broad discretion in using OTAs to carry out the NHLBI Program, we conclude that entering into these multiyear OTAs was within that discretion.

As discussed above, NHLBI recorded an obligation for the CureSCi Manufacturing Resource Platform OTA in an amount that included both unrestricted and restricted funds, and the recording statute dictates that NHLBI should have only recorded an obligation for the unrestricted funds. Compliance with the *bona fide* needs statute is measured at the time the agency incurs an obligation. B-289801, Dec. 30, 2002. Notwithstanding NHLBI's actions, NHLBI only incurred an obligation for the unrestricted amount, and that obligation was consistent with the *bona fide* needs statute because it was charged to the NHLBI annual appropriation available when the agreement was signed and furthered the authorized purposes of the NHLBI Program. Compliance with the *bona fide* needs statute with respect to the restricted amount, on the other hand, would be assessed when the relevant preconditions were satisfied and NHLBI incurred an obligation for those funds.<sup>75</sup>

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<sup>74</sup> *Cf.* 2022 NHLBI OT Policy, § 5.3.4.3 (issued after the three OTAs were signed and stating that the budget period for OTAs "may be for one year or multiple years depending on the strategic and programmatic goals of the initiative").

<sup>75</sup> Because our decision focuses on NHLBI's compliance with the *bona fide* needs statute with respect to the original CureSCi Manufacturing Resource Platform OTA, we make no determination as to whether NHLBI complied with the *bona fide* needs statute with respect to modifications made to the agreement in subsequent fiscal

(continued...)

Based on the foregoing, NHLBI complied with the *bona fide* needs statute with respect to the three original OTAs and the obligations NHLBI actually incurred.

#### Dataset Integration OTA Modification

The requester also asked how the *bona fide* needs statute applies to the first modification of the Dataset Integration OTA.<sup>76</sup> Specifically, NHLBI and the awardee made modifications to the OTA, including revisions to the Statement of Milestones and Objectives, on July 6, 2018.<sup>77</sup> NHLBI did not modify the funding for the agreement or record a new obligation associated with the modification.<sup>78</sup>

NHLBI obligated fiscal year (FY) 2017 funds for the Dataset Integration OTA and modified the agreement in FY 2018, raising the question of whether the modified agreement constitutes a *bona fide* need of FY 2017 or FY 2018.

In determining whether a modification to an agreement providing federal assistance represents a *bona fide* need of the year in which the agreement was originally executed rather than the year the modification was made, there are three conditions that must be satisfied: (1) the *bona fide* need for the project continues; (2) the purpose of the agreement remains the same; and (3) the revised agreement has the same scope as the original agreement. 58 Comp. Gen. 676 (1979) (applying this analysis to a grant); see B-322628, Aug. 3, 2012. We have noted that the agreement's purposes help identify those aspects that make up substantial and material features of the agreement and establish its scope. See 58 Comp. Gen. 676.

If these conditions are met, then the modification is a *bona fide* need of the year in which the agreement was originally executed. 58 Comp. Gen. 676. If the conditions are not met, then the modification creates a new obligation chargeable to appropriations available at the time of the modification. *Id.*; see 57 Comp. Gen. 459 (1978).

The modification added a definition for "Science Officers" and revised the points of contact.<sup>79</sup> The modification also revised the introductory section of the Statement of

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years to unrestrict previously restricted amounts. If such modifications created new obligations chargeable to the annual appropriations available at the time of the modifications, NHLBI would violate the *bona fide* needs statute if it instead charged the obligations for the newly unrestricted amounts to its FY 2019 appropriation.

<sup>76</sup> Request letter, at 4.

<sup>77</sup> Dataset Integration OTA, Modification 1.

<sup>78</sup> *Id.*

<sup>79</sup> Dataset Integration OTA, Modification 1.

Milestones and Objectives. The original statement provided that the OTA's purpose was to collaborate on the integration of heart, lung, blood, and sleep datasets with the NIH Data Commons Pilot Phase Consortium and that this involved harmonizing and making accessible the datasets to those entities developing the NIH Data Commons.<sup>80</sup> The modified statement provides that the purpose of the OTA is to effectively develop an NHLBI Data STAGE for research investigators who need to access and use large scale heart, lung, blood, and sleep datasets and indicates that the NHLBI Data STAGE would be a cloud-based platform providing tools and applications to enable these capabilities and would be integrated within the NIH Data Commons ecosystem.<sup>81</sup> Regarding the listed milestones, the modification deleted two deliverables from Milestone 3 that were set to take place within a few months after the original agreement was signed.<sup>82</sup> The modification also added a new Milestone 4, "Work Activities," which includes specific objectives aimed at: (1) enhancing the usability of the datasets and tools for a variety of users; (2) facilitating the combination and reuse of datasets; (3) integrating datasets into a scalable, secure, and collaborative multi-cloud infrastructure; and (4) working with other OT awardees and the larger community to incorporate common systems to facilitate data use and to provide training and support.<sup>83</sup> Finally, the modification increased the initial period of performance in the Budget Statement from one year to 18 months (the total 36-month term of the agreement remained unchanged).<sup>84</sup>

We have previously determined that modifications substituting a new project with different objectives in place of the original project establish a new obligation chargeable to the appropriation currently available when the modification is made. 57 Comp. Gen. 459. In contrast, we have determined that changes to nonmaterial aspects of the project (those that would not have affected the government's initial decision to provide funding) do not create a new obligation. See 58 Comp. Gen. 676.

Looking at the original OTA and the modification, we conclude that the overarching purpose of the OTA remained the same and there was a continuing need to provide assistance for the project when the modification was made. The modification did not amend the Goals/Objectives of the OTA, and the purpose of the modified OTA remained unchanged: to integrate certain heart, lung, blood, and sleep datasets within a broader NIH initiative.

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<sup>80</sup> Dataset Integration OTA, Attachment 1.

<sup>81</sup> Dataset Integration OTA, Modification 1, Attachment 1.

<sup>82</sup> See Dataset Integration OTA, Attachment 1; Dataset Integration OTA, Modification 1, Attachment 1.

<sup>83</sup> Dataset Integration OTA, Modification 1, Attachment 1.

<sup>84</sup> Dataset Integration OTA, Modification 1, Attachment 2.

The modification did not create a new or separate undertaking or enlarge the scope of the project. The changes to the Statement of Milestones and Objectives merely clarified and refined what the end result of the integration would be (creation of the NHLBI Data STAGE platform) and specific activities the awardee would undertake as part of that integration (Milestone 4). The modification did not alter any substantial or material aspects of the project and therefore did not alter the scope of the OTA. Accordingly, the modification was a *bona fide* need of the year, FY 2017, in which the agreement was originally executed and did not create a new obligation at the time it was made in FY 2018. NHLBI therefore complied with the *bona fide* needs statute with respect to this modification.

## CONCLUSION

NHLBI did not comply with the recording statute with respect to the obligating event for the three OTAs at issue; the OTA, not the NOA, established NHLBI's liability for payment to the awardee. NHLBI also did not comply with the recording statute with respect to the obligation amount recorded for one of the OTAs because NHLBI included an amount for which its liability was subject to a precondition within the agency's control. However, NHLBI complied with the *bona fide* needs statute with respect to the agreements and the obligations NHLBI actually incurred, as well as when it modified one of the OTAs.



Edda Emmanuelli Perez  
General Counsel