November 30, 2006

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NIH GWAS RFI Comments
National Institutes of Health
Office of Extramural Research
6705 Rockledge Drive, Room 350
Bethesda, MD 20892-7963

RE: Request for Information: Proposed Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies

Dear Dr. Rockey:

This letter responds to the *Request for Information (RFI): Proposed Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWA*S), published in the *Federal Register* on August 30, 2006 (71 Fed. Reg. 51629-51631)("RFI"). This response was prepared by the members of the Data Sharing and Intellectual Capital (DSIC) Workspace of the cancer Biomedical Informatics Grid (caBIG™) initiative (www.cabig.nci.nih.gov) with input from the caBIG™ Integrative Cancer Research Workspace's Population Sciences Special Interest Group (SIG).

caBIG™ is a voluntary network or grid connecting individuals and institutions to enable the sharing of data and tools, creating a World Wide Web of cancer research. The goal is to speed the delivery of innovative approaches for the prevention and treatment of cancer. The DSIC Workspace seeks to facilitate data sharing between and among caBIG™ participants by addressing legal, regulatory, and proprietary barriers to data exchange. Among these issues are the privacy and security of data exchanged, ownership and use rights of data contributors and human participants, the nature of agreements among the centers providing or using data, and the requirements for abiding by ethical standards embodied in part in federal law and regulations, such as the Common Rule for Human Subjects Research, the FDA Regulations on Human Subjects, the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules, and state, local, and institutional requirements. DSIC Workspace participants include intellectual property and regulatory attorneys, patient advocates, policy specialists, biomedical researchers, bioethicists, bioinformaticists, experts in technology transfer, and others. More information is available on the DSIC Workspace webpage at https://cabig.nci.nih.gov/working_groups/DSIC_SLWG/index_html. As the DSIC Workspace has been considering some of the same issues that are raised in the RFI for several years, we would like to share our perspective on the proposed policy.

Below we have addressed each question posed in the RFI. First, however, we begin with some general comments that pertain to several of the questions posed.

We are aware that public attitudes regarding both the federal government's holding of personal data and the adequacy of controls over such data are, at best, mixed. Allowing the government to control GWAS data is likely to engender strong reactions on the part of those who fear that access to, and use of, such data may not be sufficiently controlled to ensure their privacy and to avoid events adverse to their personal interests. Members of the public may not generally be aware of the current state of the technology that enables linking their genetic data to them. While the ability to link aggregated de-identified genetic datasets may not yet exist to the degree imagined by some, there is nevertheless a public perception that increasingly more sophisticated capabilities will emerge to enable assembling bits of de-identified information to permit re-identification of individuals. However, it is our collective judgment that such potential future risks could be mitigated in part by a strong program of public education and data access controls that are carefully vetted through broad stakeholder involvement and clearly articulated to the public.

As the questions posed in the RFI appear to seek the comparative advantages between the use of a centralized government database and the traditional one-to-one methods of sharing data between providing and receiving investigators ("traditional methods"), we have focused primarily on this comparison. However, as noted in more detail below in Section 5, the caBIG™ community has considered a number of these issues and has settled upon a distributed approach to data sharing that represents a "third way" compared to either centralized or traditional methods of sharing research data.

Given these perspectives, we provide the following specific responses to the questions presented in the RFI.

1. *What are the potential benefits and risks associated with wide sharing of phenotypic and genotypic data where identifying information has been removed*?

Participants in caBIG™ believe that sharing data, including phenotypic and genotypic data, is essential to furthering the objectives of contemporary biomedical research. Although researchers are capable of producing vast quantities of data by using high throughput technology platforms and tools, analyzing such data can be tremendously labor-intensive and time consuming. Permitting broad access to data repositories can promote the use of common taxonomies and facilitate access that will increase the rate at which such data is mined and analyzed, thus speeding discoveries and the resulting scientific, proprietary, and medical benefits. Given the significant costs associated with conducting genome-wide association studies, widespread data sharing should promote more efficient utilization of federally funded research resources. Another advantage to

broad-based data sharing is the development of larger data sets, which can improve the statistical validity and reliability of findings, or provide an interested researcher a greater likelihood of identifying specific, rare samples or examples. Finally, it is anticipated that the integration of these large and often disparate data sources may enable the testing of novel hypotheses, or even the discovery of new relationships within the data. The patient advocates who participate in the various caBIG™ Workspaces view such data sharing efforts as a critical means of advancing important research and support the efforts to address the risks described below.

Turning to the risks of sharing GWAS data, we note that genetic information may be the most personal, most specifically identifiable data that can exist. A name, address or phone number may be common to many individuals. A fingerprint alone reveals little about an individual aside from his or her uniqueness. Despite the de-identified nature of the data proposed for the GWAS database, it is imaginable, if not yet technically conceivable, that genetic data, either alone or when combined with other identifying information, could point to a specific individual. Further, such data could also provide information about the individual's current and future health risks and conditions, as well as his or her ethnicity and heritage. Moreover, an individual's family members could also be subjected to the risk of losing their privacy or having their information used inappropriately since genetic traits are inherently shared within families. Although beyond the scope of this RFI, it is important to note that many DSIC Workspace participants and patient advocacy groups are concerned by the absence of national protections against the misuse of genetic information or the implications for its use to affect changes in coverage of healthcare. This concern may contribute to negative public perceptions regarding the proposed NIH GWAS data repository.

The risks inherent in widespread sharing of genetic information are potentially more significant when the information collected involves whole-genome data. Repositories that provide only single nucleotide polymorphism (SNP) data on a limited basis pose a relatively low-risk to the individual since identification of the individual from a single SNP is more difficult. Studies generating GWAS data will provide much more information that could be misused. Such genetic data could conceivably be used to make adverse decisions related to an individual's health insurance, employment, fitness for military or other service, or selection for opportunities of various kinds. Such information could also be used to trace and identify individuals in legal matters or civil disputes. Ultimate consequences could be the violation of individual rights, legal liability on the part of institutions or individuals abusing the data, or a loss of public trust and a consequent unwillingness of potential research participants to provide their data voluntarily. For these reasons, the processes for de-identifying data and for access to and use of such data must be tightly controlled and shared within established and agreed upon protocols. The protocols must be carefully considered and must minimize the potential dangers posed by the misuse of this type of data. Our hope is that such guidelines can be developed collaboratively through the facilitation of government stewards who bring

together the appropriate mix of stakeholders in the research, medical, ethics, and patient communities.

Finally, apart from the threat of actual violations of individual or familial privacy rights, there is considerable risk of engendering the public perception that GWAS data is being shared inappropriately in violation of these rights. Therefore, regardless of the data sharing policies and procedures that are actually implemented, public education and allaying of fears and misperceptions regarding "whole genome" research are paramount. A positive public reception of the NIH GWAS Data Repository will depend on involving stakeholders in the development of the detailed protocols and procedures to be used when submitting requests for and obtaining access to GWAS data.

2. *In addition to removing personal identifying information, what protections are needed to minimize risks to research participants whose phenotypic and genotypic data are included in a centralized NIH data repository and shared with qualified investigators for research purposes?*

Given that the GWAS data sharing policy is proposed in the context of a centralized government database, the DSIC WS supports the removal of "protected health information" (PHI), as that term is defined by the Health Insurance Portability and Accountability Act's (HIPAA's) Privacy Rule, prior to submission of the data to the NIH GWAS database. The submitted data will therefore be de-identified, as defined by HIPAA, and the likelihood of a research user of the database associating the data with a specific individual will be minimized. We are also encouraged that the draft policy seeks the submission of coded data as there is much evidence to suggest that de-identification, without the ability to re-link the data and the identifiers, may have an adverse impact on research. However, we also believe that in some instances the use of limited datasets, as defined by HIPAA, and even PHI, may yield a greater contribution to the biomedical research community, provided such data are transmitted under appropriate security procedures and institutional and participant authorizations. Therefore, we would suggest that the centralized database provide a mechanism for expediting contacts between requesting and providing institutions to facilitate the transfer of such data.

In addition to these privacy protections, access to individual de-identified data records that may be contained in the NIH GWAS database requires greater security than access to aggregated de-identified datasets. Adequate security measures with appropriate and strict penalties for misuse must be established and implemented so that the investigators who obtain access to such de-identified data from individuals are authenticated and are held accountable for their actions by the NIH and their institutional employers. The DSIC Workspace suggests that the proposed policy include a list of recommended security controls as best practices for the submitting and receiving institutions, as appropriate. At a minimum, such a list should include:

- Documentation of policies and procedures, especially roles and responsibilities for ensuring adequate security, and for verifying that each control is addressed and is effective
- Education, training, and awareness for all individuals who may access phenotype or genotype data, including training on what to do in the event that a privacy or security breach is suspected, and on what sanctions exist for negligent or willful mishandling or misuse of the data
- Execution of data use agreements (DUAs) that require institutions to maintain technologically appropriate, robust privacy and security controls, including logs and audits of data accesses
- Authentication and authorization structures that ensure that access controls are effective and users held accountable for their actions. Restriction of access to sensitive data to bona fide users, i.e., those who have a need to access the data for research purposes, have been trained in its proper use, have agreed to restrictions on its access and use, and are certified for access by their institutions.
- Restricting access of each individual to only the activity for which he or she was granted access
- Use of a tiered approach to data access, with one tier permitting fairly easy access to aggregated data and a second tier providing more controlled access to data on individual records. The more sensitive the data in a repository, the stronger the privacy and security protections need to be.
- Responsibility for monitoring authentication and authorization of individual users should reside with the institutions employing the investigators or other individuals who will have access to individual subject records, subject to oversight by NIH.

Similar protective security procedures have been used for years by biospecimen repositories, so implementing such processes should not be excessively burdensome. Given the sensitive nature of some of the data to be shared, it seems that these kinds of protections could be extended easily to GWAS data.

3(a). What are the advantages and disadvantages of the proposed NIH centralized data repository?

The draft policy proposes the development of a central GWAS data repository to be housed at NIH's National Center for Biotechnology Information (NCBI), within the National Library of Medicine (NLM). Centralized data repositories seem to offer the obvious advantage of minimizing privacy violations because access can be controlled through a set of uniform procedures at a single location. However, the potentially lower risk of privacy and security breaches may be offset by the magnitude of harm in the event such breaches occur. The extent of such harm will depend on the structure of the database and the manner in which access procedures are implemented.

Potential disadvantages of a centralized government database, in contrast to traditional methods of data sharing, include:

- Reluctance of researchers and their institutions to provide data without clear detailed guidelines (from NIH or other HHS agencies) and assurances that they will not be held liable for its misuse or for compromises of its integrity
- Given that authentication responsibility should reside with institutions of investigators receiving data from the NIH GWAS repository, the burden on such institutions to institute new authentication procedures or controls over and above what they would ordinarily deploy
- Limitation on original consents may inhibit data sharing because some institutions may be unwilling to inform, re-consent, or allow waivers of authorization to permit the broad non–specific uses to which the data may be subjected
- The loss of the collegiality that occurs when researchers share data and results among themselves in a personal relationship
- A broader impact in the event of data corruption or other adverse events
- The greater ability to identify individuals through triangulation of multiple datasets
- Greater risk of neglected attribution to researchers who provide the data
- The increased need for and complexity of provenance and version controls
- Potential use of GWAS data by other parts of the federal government, such as forensic or law enforcement components, to the detriment of the human research subjects (or family members) from whom such data were originally collected
- The risk that the database manager (in this case, NCBI) may not implement properly the institutional conditions on data release, including those imposed by IRBs or HIPAA Privacy Boards

The members of the DSIC Workspace do not think that these potential disadvantages should prevent the sharing of GWAS data as contemplated by the proposed policy. Rather, we think that these challenges bear serious prior consideration so that NIH can productively launch an initiative to advance the rapid and widespread dissemination of research information to benefit the public health. In most instances, members of the DSIC Workspace believe that neither a centralized nor a distributed configuration in and of itself provides a better approach to safeguarding GWAS data. There are numerous and highly complex variables that interact within the design of a data repository or network, such as the choices of access and authorization controls, the adequacy of and adherence to governance procedures, and the day-to-day vigilance required for maintenance of the databases. However, the public perception of the potential for access to the NIH GWAS database by third parties directly or via a FOIA request or by other parts of the federal government without the explicit permission of the original participants could weigh in favor of a distributed data architecture. Thus, paramount to decisions on any configuration are a number of complex design and governance factors that must be explored and balanced with input from the affected research and patient communities.

3(b). What are the advantages and disadvantages of the proposed approach to data submission?

The draft policy expects investigators to submit as rapidly as possible: (i) basic descriptive information, including protocols, to the open access portion of the repository; and (ii) de-identified genetic and clinical information to the controlled access section of the database, with access provisions administered by NIH Data Access Committees (DACs). However, many pharmaceutical sponsors subject protocols and certain data resulting from clinical studies to confidentiality requirements. It may be helpful for NIH to open a dialogue with representatives of the pharmaceutical industry to encourage widespread data sharing and to assure the companies that procedures will be in place to protect against use of the data for commercial purposes other than regulatory filings.

We also note that research subjects may seek to obtain access to their own data. We recognize that the proposed policy states that "research participants should not expect the return of individual research results derived from analyses of submitted data." However, it is conceivable that individuals will seek access to data relating to them for "second opinions," just as many patients now ask for their pathology slides. Therefore, the DSIC Workspace recommends that NIH consider this possibility and determine whether it is necessary to implement procedures under the Privacy Act to deal with such requests.

In addition to the considerations mentioned above, we note that while most researchers participating in large scale research initiatives with structured data sharing requirements want to disseminate information rapidly and broadly, they are concerned about having the financial resources to do so effectively. In particular, investigators are concerned about the costs associated with such requirements as formatting data to comply with interoperability specifications, maintaining good library methods, and obtaining necessary permissions. It should also be noted that many of these guidelines overlap with similar guidelines that focus on the collection, processing, storage and use of biospecimens and their associated data that have been put forward by the National Cancer Institute in its First Generation Guidelines for NCI-supported biorepositories (http://biospecimens.cancer.gov/). NIH should take these factors into consideration when establishing a data sharing policy for a centralized GWAS data repository so that investigators who incorporate data sharing in the initial design of their studies may establish more readily and economically adequate procedures for protecting the identities of participants and share a useful dataset with appropriate documentation.

3(c). What are the advantages and disadvantages of the proposed approach to scientific publication?

The draft policy proposes that investigators who contribute genotype-phenotype datasets to the NIH GWAS data repository be given the exclusive right to publish analyses of

such data (including pre-computed analyses of such data) for a defined period of time (presently nine months) following release of the data. The proposed policy states: "During this period of exclusivity, **the NIH may grant access to other investigators**, who may analyze the data, but are expected not to publish their analyses or conclusions during this period. This period of exclusivity is presently anticipated to be nine months from the date that the GWAS dataset is **made available for access through the GWAS data repository**, although a shorter period of exclusivity may be requested by the NIH funding Institute or Center." *(Emphasis supplied.)* Thus, it appears that qualified researchers will be able to obtain access to and use GWAS data but will not be able to publish for some period of time up to nine months following release of the data.

This approach is being explored by some initiatives with commitments to widespread dissemination of data, e.g., the Genetic Association Information Network (GAIN) as an incentive to researchers to provide data quickly without risk of losing publication priority, but it has not yet been broadly tested. It is expected that this method will facilitate earlier access to research data and thereby avoid some research redundancies and misdirection that could be occurring while the data is being sequestered by the producing researcher prior to publication. However, if the data is provided in some sort of "raw" unedited form, it may be less useful to other researchers. This seems to be a more likely problem with the provision of any data that has not been replicated or authenticated. The expediency of access must be balanced against the quality of the data.

The objectives of this approach are laudable in that early access to other researchers' GWAS data could serve to reduce duplicative or fruitless lines of inquiry. However, the procedures for implementing the publication exclusivity requirement may complicate the management of access to the data by the NIH DACs. First, the proposed policy does not appear to restrict the use of GWAS datasets by recipient institutions to derive patentable findings, if such use is consistent with the approach proposed by the policy, which could be of concern to submitting investigators, their institutions, and industry sponsors. While it might be argued that submitting institutions are just as free as receiving institutions to submit patent applications on submitted data in keeping with the proposed policy, the greater risk is that institutions generating NIH-funded GWAS data that also received some form of industry support may not be willing to submit such data right away, if at all, to the NIH GWAS repository without restrictions on use in patent applications as well as publication.

Second, rejections by NIH DACs of requests for GWAS data could operate to restrict access to such data while the submitting GWAS researchers could nonetheless assert that they have complied with NIH's data sharing policy for the GWAS data repository. Obviously, the timing of availability of GWAS data will depend on how quickly NIH DACs process requests for access. Moreover, we wonder if the apparent short term exclusivity is in fact a sufficient protection in light of the potential for access to the data via either a FOIA request or legitimate requests from the forensic or law enforcement communities before the nine month period ends. Thus, adequately detailed and well

vetted procedures will be needed to allay or at least mitigate fears of misuse. The issues surrounding access are critical to the public's perception and researchers' adoption of the proposed NIH GWAS data repository. As noted previously, access procedures must be developed in greater detail and vetted with the affected communities.

Third, some researchers may worry about the possibility that NIH DAC members or NIH GWAS database managers could have unfair access to GWAS datasets before the data are made publicly available. Presumably, this concern can be allayed by requiring NIH DAC members and NIH GWAS database managers to agree not to use the data except as authorized and to communicate such procedures to researchers.

Finally, the DSIC Workspace notes that many research institutions have policies that prohibit restrictions on publication of research results. These policies may consider a delay of nine months to be excessive and therefore not an acceptable condition of access to the data. Questions about publication of the data itself, attribution to the data producer, and the FOIA status of the data are common to the wider variety of databases currently available to researchers and should be addressed in the terms governing access to the NIH GWAS database.

In view of the foregoing discussion, it may be simpler for the NIH funding institute or center to manage access to GWAS data by specifying the period of exclusivity for a given data set before submission to the NIH GWAS database and then requiring submission of such data without restriction after expiration of the period of exclusivity. Even if this latter approach is not adopted, the DSIC Workspace recommends that NIH articulate more clearly the rationale for establishing a period of publication-related exclusivity for data deposited in a government-hosted database.

3(d). What are the advantages and disadvantages of the proposed approach to intellectual property?

The draft policy expects that datasets made available through the GWAS data repository, and "their obvious implications," will remain freely available, without any licensing requirements, to all researchers in a manner consistent with the NIH's *Best Practices for the Licensing of Genomic Inventions* and the *NIH Research Tools Guidelines*. The DSIC Workspace considers this aspect of the proposed policy to be quite complex and has not yet had a chance to consider its implications fully. However, we would like to make the following preliminary observations.

First, it is unclear whether the policy is intended to be binding as policy or is instead intended to serve as a guideline. Given the complexity of this issue, we would strongly urge that NIH expectations on this topic be proposed as "Best Practices." Such an approach has the added advantage of allowing both the NIH and the research and public communities it serves the opportunity to learn from experience, refine the proposed

practices based on experience and achieve gradual acceptance of such practices, which might thereafter be codified as policy.

Second, the formulation of the draft "policy" is internally contradictory in that it appears to discourage patenting at one point and later seems to permit patenting as long as inventions are made available under terms consistent with the NIH Research Tools Guidelines and Best Practices for Licensing Genomic and Proteomic Inventions. In addition, the NIH should clarify whether the proposed policy is in fact a new policy or a proposed manner of implementing the *NIH Final Statement on Data Sharing*.

Third, it is worth noting that some institutions may claim that this approach erodes their rights, and impairs their ability to comply with their obligations, under the Bayh Dole Act, 35 U.S.C. §§200-212, which requires recipients of federal funding to "ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering research and discovery." 35 U.S.C. §200. In fact, some researchers participating in the DSIC Workspace have expressed great concern that their institutions interpret their statutory obligations under the Bayh Dole Act as standing in opposition to the ability to share data widely though there is no hard evidence to support such a position. This claim, insofar as it applies to associations derived from the databases between genes and diseases, could be mooted by the U.S. Patent and Trademark Office's (USPTO) revision, currently under consideration, of its guidelines to be used by USPTO personnel in their review of patent applications to determine whether the claims in a patent application are directed to patent eligible subject matter. Regardless of any regulatory changes, we think that NIH's approach is practical in that it does not directly impede invention and, in fact, may enable the creation of intellectual property that could be derived from downstream discoveries based on GWAS data.

However, the draft policy is predicated on the assumption that GWAS data is "pre-competitive" information, a term that is not defined in the RFI nor, to our knowledge, is it a term with a generally understood meaning. Therefore, it is not clear whether there is any need to describe further the uses of GWAS data in the course of claiming inventions, e.g., referencing GWAS data in support of patent applications or to establish the basis for derivations of algorithms from analyses of GWAS datasets. A thoughtful dialog among the multiple stakeholders drawn from the research, medical, ethics, and patient communities invested in the outcomes of biomedical research could drive the evolution of more imaginative business models that permit broader access to information derived from databases such as the NIH GWAS data repository.

4. *What specific resources may investigators and institutions need to address policies in these areas?*

Researchers and health care organizations continue to struggle with the complex web of federal and state privacy laws and regulations that persists in our country today. Although

NIH has provided some valuable guidance on HIPAA compliance at http://privacyruleandresearch.nih.gov, consistent interpretation of basic legal requirements within and among institutions remains elusive. NIH could provide invaluable assistance to the research community and promote more rapid adoption and participation by providing explicit and detailed guidance to the research community concerning covered entity and researcher obligations when contributing to or receiving information from the GWAS database. Although the guidance posted on the HIPAA website at http://privacyruleandresearch.nih.gov/research_repositories.asp, together with OHRP's 2004 guidance on coded data and specimens, serves as a good starting point, far more might be accomplished with guidance specific to the particular initiative. Such guidance should be developed through a process that solicits broad stakeholder input, which will increase the likelihood of widespread adoption once issued.

5. Other Considerations

As noted previously, caBIG™ is a voluntary network or grid connecting individuals and institutions to facilitate the sharing of data and tools, creating a World Wide Web for cancer research. caBIG™ enables the sharing of information through a "federated" or distributed approach, which permits data to be retained locally at the site of each participant. Thus, caBIG™ represents a "third way" in comparison to either centralized or traditional methods of sharing research data.

The DSIC Workspace, by virtue of its role within caBIG™ of addressing legal, regulatory, and proprietary barriers to data exchange, has considered a number of the issues discussed above. Pursuant to our mission, we have engaged in outreach and investigation activities with many other research networks, grids, and consortia, which we have found share our concerns. Many, for example, have found a need for role-based access and trust infrastructures. The caBIG™ distributed data architecture permits participants to retain control over data access and to institute security procedures for authentication and authorization that are appropriate for their institutions. The risks of compliance with institutional and governmental requirements thus reside with local institutions rather than a centralized authority. Moreover, data reside on locally controlled servers and as such are not subject to claims for use under FOIA, which may provide greater comfort to research subjects and institutions with proprietary concerns (either their own or those of third party industry collaborators or sponsors. Also minimized are public perceptions of possible unauthorized use of such data for law enforcement or forensic purposes. Our experience indicates that any policies that are developed need to be vetted through a series of use case scenarios, similar to those developed by the caBIG™ community so that proposals can be 'tested' for feasibility before being released. It is especially important that patient advocates who understand the issues involved are included in the development and vetting processes for such policies.

The risks associated with de-centralization of the data are mitigated by the common use of data sharing tools developed by caBIG™ that use standardized vocabularies and

common data elements in order to facilitate data exchange. Under a federated approach, participants who provide data have increased control over the use of and rights in their data, and may be more amenable to data sharing within a more controlled community. In addition, we have observed that large scale initiatives that use standard data formats succeed in facilitating interoperability and assembling large data sets without sacrificing individual control and liability. These models may be of greatest interest to the NIH GWAS database as a method of refining types of data, aggregating like data, connecting researchers with similar interests, enabling more rapid replication and authentication of data, and facilitating the screening of subsets of data users.

Many of the regulatory, proprietary and other issues that caBIG™ has addressed will also need to be addressed in the centralized model proposed for the NIH GWAS database. Some solutions for data sharing that have been identified may be more easily implemented in the caBIG™ distributed data model but the caBIG™ DSIC Workspace welcomes the opportunity to share its experiences with the developers of the NIH GWAS database as you progress.

The DSIC Workspace appreciates your consideration of these comments. We recognize the difficulty in balancing the benefits to biomedical research from widespread sharing data throughout the research community with the issues raised above. We would be very happy to discuss any and all of these issues with you in greater detail. The DSIC Workspace acknowledges the individuals listed below who participated in preparing this response.

/s/

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