January 20, 2017

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD, 20852

RE: Docket No. FDA-2010-N-0548: Good Laboratory Practice for Nonclinical Laboratory Studies; Proposed Rule

Dear Sir/Madam

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to offer comments to Food and Drug Administration (FDA)'s "Good Laboratory Practice for Nonclinical Laboratory Studies." In our comments to FDA's 2011 advanced notice of proposed rulemaking (ANPRM)[1], we applauded FDA's initiative to revise the Good Laboratory Practice (GLP) regulations to more completely address how nonclinical studies are currently conducted. These efforts are particularly critical in light of the fact that the regulations have not been substantially revised since the late 1970s. BIO continues to support a quality systems approach to GLP to ensure continual improvement and high quality lab studies, which is embodied in the current GLP regulation.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

General Comments

Retention of single point of control

In previous comments, BIO indicated that additional specific responsibilities of Sponsors of nonclinical laboratory studies will not improve the quality and integrity of nonclinical laboratory study conduct. The current GLP regulations require the Sponsor to approve nonclinical laboratory protocols prior to study initiation (section 58.120(a)). Once the study is initiated, the Study Director is the single point of control.

In the proposed rule, we note that single points of control and oversight appear to be spread across several management individuals, the sponsor, contributing scientists, principle investigators, and quality assurance units simultaneously. These proposed changes introduce overlapping, duplicative, and conflicting responsibilities. We are very concerned that the proposed rule will likely cause confusion in the determination of the person who is ultimately accountable in any given situation. We again believe that the Study Director point of control, when complemented by test facility management responsibilities (section

[1] https://www.bio.org/sites/default/files/files/20110222.pdf

58.31) and other requirements outlined in the current GLPs, should be sufficient to ensure the quality and integrity of nonclinical study conduct.

Clarifying the proposed rule's scope

BIO notes the proposed rule, section 58.1, "prescribes good laboratory practices (GLPs) for conducting nonclinical laboratory studies of safety or toxicity or both that support or are intended to support an application or submission for products regulated by the Food and Drug Administration (FDA)…" The use of "intended to support" could be interpreted to include a broad scope of preclinical work that would be required to be conducted under GLP. This interpretation would effectively preclude the ability of preclinical biotech companies and academic institutions in conduct studies to develop new, live saving products.

We do not believe this is FDA's intent and also note in the proposed rule that "basic exploratory studies carried out to determine whether a test article has any potential utility or basic exploratory studies to determine the physical or chemical characteristics of a test article…" are excluded from the definition of nonclinical laboratory study. However to remove uncertainty, BIO strongly recommends the Agency clarify, whether in the preamble or section 58.1, the types of nonclinical laboratory studies that would not be subject to GLP requirements.

Harmonization of GLP regulations

We applaud the efforts by FDA to improve its level of harmonization of the GLP rules by reviewing and considering documents from the working group on GLP of the Organisation for Economic Co-operation and Development (OECD), including the general principles of GLP and consensus and advisory documents. BIO believes that this alignment in the proposed rule will aid in international consistency and not unnecessarily introduce another layer of oversight beyond that required by the OECD GLPs, particularly regarding the Principal Investigator concept and responsibilities as stated in those documents.

Animal Welfare

BIO supports the goal of ensuring the welfare of research animals and using animals for research only when no scientifically valid alternative to animal use exists. We reaffirm that the current GLP regulations, coupled with FDA's *Bioresearch Monitoring Good Laboratory Practice Compliance Program Guidance Manual 7348.808* (Section7) already directs investigators to review, observe, and inspect animal care activities. We agree with FDA's conclusion that there are limitations in the application of GLP regulations to Animal Rule studies and again ask the agency remove animal welfare from the proposed rule and consider separate rulemaking actions to address this.

Archiving of data and specimens

We are concerned regarding the interchangeable use of the terms "Storage" and "Retain" and "Archive". The archive terminology is generally accepted in the GLP sense to be the final location and retention of records after a study report is finalized. We request the use of Storage to be reviewed (§ 58.19) and restricted to use of the in-life period of a study.

Conclusion

BIO appreciates the opportunity to provide comments regarding proposed changes to the regulations governing "Good Laboratory Practice for Nonclinical Laboratory Studies." We support the Agency's efforts to improve consistency with other regulations, including the Environmental Protection Agency (EPA) GLPs, 21 CFR Part 11, the USDA Animal Welfare Act, and OECD GLPs. We provide additional specific, detailed comments to improve the clarity of the Proposed Rule in the following chart. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely

/S/

Gregory Frank, PhD
Director, Infectious Diseases Policy
Biotechnology Innovation Organization

Specific Comments

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Subpart A – General Provisions		
58367 / § 58.3 Definitions: Omitted Definition	The FDA's meaning of "deviation" is somewhat unclear. Given the requirement for reporting and timely corrective actions it would be helpful to have a specific definition for this word.	BIO asks FDA to add a definition for "deviation".
58368 / § 58.3 Definitions: Attending Veterinarian	The Proposed Rule defines "attending veterinarian." This definition is unclear whether the appointment or delegation of the attending veterinarian should be performed by management with executive authority.	BIO suggests editing the text to read: "*Attending veterinarian* means a veterinarian who has training or experience or both in the care and management of the species being attended and who has direct or delegated authority by management with executive authority for activities involving animals."
58368 / § 58.3 Definitions: Batch	The Proposed Rule defines "batch." As defined, it is unclear that this is specific to the batch used in study conduct or if it extends to lead lot analysis.	BIO suggests editing the text to read: "Batch means a specific quantity or lot of test, control, or reference article used in the conduct of a non-clinical study that has been characterized according to 58.105 and handled according to 58.107. Appropriate characterization of applicable lead lots may be acceptable if characterized according to 58.105 and handled according to 58.107 and a confirmation that follow on lots are characterized when appropriate."
58369 / § 58.3 Definitions: Management with executive responsibility	The Proposed Rule's intent is for a single point of control for testing facility or test site management. We believe a single management representative should be accountable for GLP compliance and roles	BIO suggests editing the text to read: "*Management with executive responsibility* means person(s) with authority and responsibility for organization and functioning of the GLP aspects of the test facility. ~~those senior employees of a testing facility or test site who have the authority to~~

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	and responsibilities, per the GLP preambles and the accountability cannot be delegated to others.	~~establish or make changes to the quality policy and GLP Quality System at the testing *facility and test site, respectively.*~~ Related tasks may be delegated to other senior level employees, however the accountability and responsibilities cannot be transferred."
58369 / § 58.3 Definitions: Short Term Studies	The current definition of "short-term studies" uses the term "in-life period", which appears to exclude *in vitro* or *ex vivo* studies.	BIO suggests editing the text to read: "Short-term study means a short duration study for which ~~the in-life period~~ test or control articles are applied and observations recorded ~~is completed~~ within ~~several days or a~~ two weeks at most. ~~The in-life period of a study is that period during which data are collected~~."
58369 / § 58.3 Definitions: Validation	The current definition of validation implies applicability to a scope beyond computer systems validation, which we believe was not its intent.	BIO suggests editing the text to read: "Validation means confirmation by examination and provision of objective evidence that the particular requirements for ~~a specific~~ electronic system intended use can be consistently fulfilled."
58370 / § 58.5 Sponsor Responsibilities (a)	The Proposed Rule requires a Sponsor to "ensure the nonclinical laboratory study protocol (the study protocol) meets the requirements in §58.120. In our ANPRM comments, BIO previously cautioned against requirements such as this, which dilute the responsibility of the Study Director as single point of control and compliance for the study. Also, by adding the requirement for the Sponsor to sign the protocol, it already implies that the Sponsor has ensured the protocol meets the GLP requirements.	We recommend eliminating this requirement.

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58370 / § 58.5 Sponsor Responsibilities (d) 221	The Proposed Rule requires the Sponsor to contract with persons accredited as following appropriate animal welfare procedures. BIO notes that accreditation is usually available for institutional or organizational "persons" but not for individuals who may also serve as a "contracted person" contributing to a nonclinical laboratory study. One example would be an independent consulting veterinary ophthalmologist or cardiologist.	BIO believes that "qualified" individuals serving as a "contracted person" need not hold "accredited" status, per se. As such, we recommend editing the text to read: "Contract with persons accredited as following appropriate animal welfare procedures or individuals qualified by education, training, and experience for phases of a nonclinical laboratory study that include the use of animals."
58370 / § 58.5 Sponsor Responsibilities (e) 226	The Proposed Rule requires a Sponsor document that any contracted person conducting a laboratory study is qualified. Test Facility mangers with executive responsibility typically maintain documenting qualifications. We believe that the sponsor should ensure the test facility has systems to meet this requirement.	BIO suggests editing the text to read: e) "Ensure that the qualifications of ~~Document that~~ any contracted person conducting a phase of a nonclinical laboratory study are documented ~~is qualified according to the provisions in this part~~."
58370 / § 58.5 Sponsor Responsibilities (f) 228–9	The Proposed Rule discusses documentation of all study-related communications. BIO does not believe that *all* communications warrant documentation. In the definition of *Raw Data* (See section 58.3), correspondence defined as part of the "raw data" is more narrowly defined as that which is "necessary for the reconstruction and evaluation of the report of that study."	BIO recommends improving consistency across the Proposed Rule by using the wording: "f) Ensure that appropriate lines of communication are established among all persons conducting a phase of the nonclinical laboratory study and document ~~all~~ study-related communications that involve the sponsor, which are necessary for the reconstruction and evaluation of the report of that study."

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58370 / § 58.5 Sponsor Responsibilities (f)	The proposal for the Sponsor to ensure that adequate communication lines are established among study personnel appears redundant with the responsibilities of the Study Director as the single point of control as described in section 58.33 (b)(12).	We suggest clarifying whether the Study Director has ultimate responsibility for this requirement.
58370 / § 58.5 Sponsor Responsibilities (i)	The Proposed Rule discusses the need to review, approve, sign, and date each proposed amendment before implementation. However, decisions about animal welfare (in particular, pain and distress) are elsewhere deferred to the attending veterinarian (see 58.33 (a) (6) and 58.37 (a) (3) (ii)).	BIO believes it is impractical to require the Sponsor to sign all amendments prior to implementation. This requirement may prevent scientifically necessary changes to study protocols in a timely manner and could negatively impact animal welfare. As such, BIO recommends removing this section.
58370 / § 58.5 Sponsor Responsibilities (k)	The term "summary report" is used in this part only in reference to studies that have been discontinued (or halted) before study completion.	BIO proposes language for a 120 day window, as permitted by FDA guidance when "audited draft reports" are used to support an IND: (k) "Include, in any application or submission to FDA that includes the results of a nonclinical laboratory study, the final or unedited draft study reports, and all amendments. If a summary ~~report~~ of the nonclinical laboratory study is included in such applications or submissions, a copy of the final study report, as described in §58.185, must be appended or provided elsewhere within the application or submission, or made available within 120 days."
58370 / § 58.15 Inspection of any person conducting	The Proposed Rule discusses the inspection of any person conducting a phase of a nonclinical laboratory study.	Opening of these records would likely result in a documented lack of findings and problems reported; thereby weakening the strength of current quality systems in place at testing

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a phase of a nonclinical laboratory study (a)	BIO is very concerned that this proposal as written would allow the Agency access to QAU records or copying QAU records of findings or problems or to actions recommended and taken.	facilities and test sites. The impact of this proposal and agency view has been previously documented in the 1978 preambles. As such, BIO suggests editing the text to read: (a) "Any person conducting a phase of a nonclinical laboratory study must permit, at reasonable times and in a reasonable manner, an authorized employee of FDA to inspect and comply all records and inspect all specimens required to be maintained for nonclinical laboratory studies within the scope of this part, and where applicable, to collect reserve samples for such studies. The records inspection and copying requirements ~~do not routinely apply to QAU records of findings and problems~~ shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken. ~~However, FDA retains the authority to inspect all QAU records when necessary to ensure compliance with this part."~~
Subpart B – Organization and Personnel		
58371 / § 58.31 Testing facility management with executive responsibility (q) 367-369	The Proposed Rule discusses the establishment of procedures to ensure QAU review of SOPs and study protocols.	BIO believes that requiring the QA to implement and review all SOPs could cause a significant burden, especially in cases of multiple studies being run concurrently at test facilities. Moreover requiring testing management to be responsible for establishing QAU procedures conflicts with QUA independence and may adverse impact study integrity. BIO suggests removing this requirement.

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58371 / § 58.31 Testing facility management with executive responsibility (a)	The Proposed Rule discusses the requirement to have a testing facility management with executive responsibility. The GLPs already incorporate a quality system approach and do not require additional specificity or GMP/ISO principles for nonclinical studies. Additional specificity currently proposed, applicable to GMP/ISO, are intended to produce a quality product in a consistent, controlled and customer-facing manufacturing environment. The GLP product is the non-clinical study report and collection of study data and specimens.	As previously recommended in our ANPRM comments, BIO believes there are sufficient controls in place in the current GLP regulations for the production of consistently reproducible and reliable data and accurate study reports. As such, we recommend omitting from final rule.
58371 / § 58.31 Testing facility management with executive responsibility (b)	The Proposed Rule suggests that the same individuals who developed, approved, and implemented the quality system also review the suitability and effectiveness of the quality system at defined intervals. However, this cannot be performed in a method that controls bias. Furthermore the specificity of how this activity will be conducted was not discussed in detail (*i.e.,* how this will be measured, to what criteria, and how to eliminate subjectivity).	To eliminate any perception of bias, this rule may force facilities and test sites to enlist contract services that will likely cause unnecessary burden for compliance. As such, we recommend omitting this proposed change from the final rule.
58371 / § 58.31 Testing facility management with	As indicated in our comments for § 58.31 (a), GLPs already incorporate a quality system approach and do	BIO recommends omitting these proposed changes from the final rule.

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executive responsibility (c) (d)	not require additional SOPs for the conduct of compliant nonclinical studies.	
58371 / § 58.31 Testing facility management with executive responsibility (e) (1) (2)	The GLPs already incorporate a mechanism for testing facility management to ensure the establishment, maintenance and reporting of the current GLP quality system at each testing facility or test site. As stated previously in the 1978 preamble, the Commissioner agreed that periodic reports to management are the means for assurance of the continuing conformity of study conduct to the provisions of these regulations.	BIO recommends omitting these proposed changes from the final rule.
58371 / § 58.31 Testing facility management with executive responsibility (h)	The Proposed Rule discusses the need to document that all study personnel are trained appropriately.	This proposal appears to duplicative with the requirement in §58.29 (a) that personnel engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study have the appropriate education, training and experience to perform their assigned functions. As such, we recommend omitting this proposed change from the final rule.
58371 / § 58.31 Testing facility management with executive responsibility (m)	As stated above, BIO strongly believes that the Study Director should remain as the single point of control.	This proposal dilutes the Study Director's responsibilities and also may present additional time constraints with protocol finalization. As such, we recommend eliminating this requirement.
58371 / § 58.31 Testing facility management with	The Proposed Rule discusses the responsibility of testing facility management with executive	The overall responsibility ensuring compliance lies with testing facility management as the single point of control for the testing facility. We believe this proposal implies some

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executive responsibility (q)	responsibility to establish procedures to ensure QAU review of SOPs. However, BIO believes that QA personnel typically do not have the expertise on methodology to dictate how study conduct is performed.	transfer of this responsibility to the QAU that creates a direct conflict of role and responsibilities with Testing Facility Management. As such, we recommend that the Rule establish procedures, to be included in SOPs to ensure QAU review study protocols and amendments to verify that they meet GLP requirements. This review will be documented.
58371 / § 58.31 Testing facility management with executive responsibility (r)	The Proposed Rule discusses reviewing of suitability and effectiveness of the QAU or lead QAU. However, it is unclear who is responsible for review of the QA. It is unlikely that executive management has the competences to perform these tasks.	BIO suggests editing the text to read: (r) "Ensure a mechanism is in place to review the suitability and effectiveness of the QAU or lead QAU, as applicable at defined intervals and with sufficient frequency, and with support of QA expert."
58371 / § 58.31 Testing facility management with executive responsibility (t)	While testing facility management normally ensure SOPs are established for QAU activities, the QAU typically establish these SOPs and are also responsible for their content.	BIO suggests editing the text to read: (t) "~~Establish SOPs,~~ Testing facility management must ensure SOPs are established with appropriate timeframes, for the conduct of QAU inspections and for the receipt, review, and followup of all concerns, problems, and regulatory deviations reported by the QAU."
58372 / § 58.33 Study Director (a) (2)	The Proposed Rule suggests that the Study Director is responsible for implementing adequate communication among study personnel and the sponsor. However, this appears to contradict the proposal in § 58.5 (f), page 58370, that this a Sponsor responsibility.	This proposed rule appears to contradict Test Facility Management responsibilities in 58.31(o). As above, BIO recommends this responsibility lie with the Study Director as single point of control and suggests the following revision "(a)(2) The implementation of procedures to ensure adequate communication ~~among all study personnel and with the study sponsor, as applicable;~~ and"

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58372 / § 58.33 Study Director (b) (3)	The Proposed Rule requires the Study Director to ensure that the testing facility management with executive responsibility has committed adequate resources for the conduct of the specific study. However, it is unclear how the Study Director can document this information.	As such, BIO recommends deleting this section.
58372 / § 58.33 Study Director (b) (12)	The Proposed Rule requires the Study Director to document all communications that involve the sponsor. However, as above in § 58.5, we do not believe that all communications warrants capture in permanent record.	In the definition of Raw Data (See section 58.3), correspondence defined as part of the "raw data" is more narrowly defined as that which is "necessary for the reconstruction and evaluation of the report of that study." We recommend improving consistency throughout the document by using this wording and editing the text to read: (12) "Document ~~all~~ communications that involve the sponsor, which are necessary for the reconstruction and evaluation of the report of that study."
58372 / § 58.33 Study Director (b) (14)	The Proposed Rule gives a timeline of 2 weeks for the Study Director to archive all information after study completion.	BIO notes that the 2 weeks prescribed here is shorter than the general industry practice of up to one month for archiving. As such, we suggest editing the text to be consistent with general practice: (14) "Archive all raw data, documentation, protocols, specimens, reserve samples, and final reports no later than ~~2 weeks~~ one month after the study completion date."
58372 / § 58.35 Quality assurance unit (QAU) (b)(3)	The Proposed Rule requires the review of protocols before study initiation.	BIO recommends removing this requirement.

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	However, review of protocols prior to finalization and implementation is not feasible and will likely cause delays that adversely affect the study.	
58372 / § 58.35 Quality assurance unit (QAU) (b)(4)	The Proposed Rule requires the QAU review all SOPs. BIO notes that the QAU receives copies of protocols and all amendments and can comment on any necessary language via request for amendment, if required. We are concerned that this new requirement could cause a significant impact on resources for QAU to implement and maintain the review of all SOPs.	BIO recommends deleting this section.
58372 / § 58.35 Quality assurance unit (QAU) (b)(7)	The Proposed Rule requires the QAU to submit status reports on each study. However, BIO believes that QAU has compliance oversight and should be separate and independent from requirements to report study status.	BIO recommends removing this requirement.
58372 / § 58.35 Quality assurance unit (QAU) (b)(8)	The Proposed Rule requires the QAU to determine that no deviations from the approved protocols or SOPs were made. BIO notes that the responsibility proposed here already lies with the test site QAU and principal investigator and is in conflict with these roles and responsibilities. Additionally, double reporting of study deviations to the study director would cause	In order to avoid a conflict of responsibilities, BIO suggests editing the text to read: (8) "Determine that no deviations from approved protocols or SOPs were made without proper ~~authorization and~~ acknowledgment and impact assessment documentation. For multisite studies, the ~~lead~~ test site QAU ~~is responsible for identifying all deviations that occur across the entire study, including deviations identified by all other QAUs participating in the study, as described in SOPs in § 58.81(b)(17).~~ would be responsible to comply with this part for delegated study phases, as necessary."

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	unnecessary duplicate impact assessments for deviations.	
58373 / § 58.35 Quality assurance unit (QAU) (b)(11)(iii)	The Proposed Rule requires the QAU to verify the dates of QAU audits of the reports. However, this proposed responsibility already lies with the test site QAU and principal investigator and is in conflict with these roles and responsibilities.	In order to avoid a conflict of responsibilities, BIO recommends omitting this proposed change from the final rule.
58373 / § 58.35 Quality assurance unit (QAU) (e)	The Proposed Rule requires the QAU to certify appropriate actions were taken regarding process-based inspections. However, BIO notes that this proposed change contradicts QAU's requirement to be separate and independent from study conduct. The proposal stipulates a "certification" requirement for a person conducting a phase in the event they perform a process inspection; this scenario is in violation of part 58.35 (a) (1).	BIO recommends omitting this proposed change from the final rule.
Subpart E – Testing Facilities Operation		
58374 / § 58.81 Standard operating procedures (SOPs) (b)	The Proposed Rule requires the testing facility establish SOPs. BIO believes that testing facility management and testing site management should not have responsibility to establish SOPs, but rather ensure they are established.	BIO suggests editing the text to read: (b) "The testing facility and all test sites must ~~establish~~ ensure SOPs are established for all applicable phases of a nonclinical laboratory study. Where appropriate, SOPs must include the following: …"

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Subpart F – Test and Control Articles		
58375 / § 58.105 Test, control, and reference article characterization (a)	The Proposed Rule discusses the requirements for test, control, and reference articles. BIO strongly believes that sponsors should not be required to use GMP-compliant/quality material for these studies, as long as methods generating non-GMP data meet appropriate standards.	BIO suggests editing the text to read: "(a) For all test, control, and reference articles other than tobacco products, the identity, strength, purity, and composition or other characteristics which will appropriately define the test, control, or reference article must be determined for each batch and must be documented. The test article is not required to be manufactured under compliance to Good Manufacturing Practices.
Subpart G – Protocol for and Conduct of a Nonclinical Laboratory Study		
58376 / § 58.120 Protocol (a)(3)	The Proposed Rule discusses the required contact information for the sponsor, the testing facility, and the study director. We believe the requirement for contact information for the testing facility and sponsor to include a "facsimile number" is outdated and should no longer be required.	BIO suggests editing the text to read: "(3) The name and contact information (including address, phone number, email address~~, and facsimile number~~) for the sponsor and the testing facility and the name and affiliation of the study director. Also, for multisite studies, the contact information for all persons conducting a phase of the nonclinical laboratory study, including all principal investigators and independent contributing scientists."
58376 / § 58.130 Conduct of a nonclinical laboratory study (a)	The Proposed Rule discusses the demonstration of all analytical methods be accurate and of sufficient sensitivity. It is unclear whether the activities required to demonstrate that a method is accurate and of sufficient sensitivity to measure, with appropriate	BIO asks the FDA to please specify if this activity is considered part of the GLP study and consequently to be done in GLP.

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	precision, the analytes in question are to be conducted in GLP.	
Subpart J – Records and Reports		
58376 / § 58.180 Data quality and integrity (c)	The proposed rule discusses that all data accrued from a nonclinical study must be included in the final study report.	BIO believes that this proposal's use of "all" data could be interpreted to include information on the report, including LIMS data, such as ECG telemetry, photomicrographs, statistical analysis data sets, etc. that may not be relevant to the final study report. Typically, while all data produced as raw data are stored in the study folder, not all data are reported. BIO suggests editing the text to read: "(c) All relevant data accrued as required"
58377 / § 58.185 Reporting of nonclinical laboratory study results (a)(13)	The Proposed Rule discusses that the final study report must contain all data generated. As with § 58.180, BIO affirms that while all data produced as raw data are stored in the study folder, not all data are reported. Moreover, requiring signatures of contributing scientist and any other person involved in the study incurs a heavy administrative burden without any consummate benefit.	BIO suggests editing the text to read: "(13) The original, and any amended, signed and dated reports of each of the ~~contributing scientists,~~ principal investigators~~, or any other person involved in the study, including each person who conducted an analysis or evaluation of data or specimens from the study~~ after data generation was completed. These reports must ~~contain~~ include an assessment or summary of all data generated or a specific reference to any data not included, a reason for exclusion, and where those data are retained."

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38377 / § 58.190 Storage and retrieval of records and data (a)	The Proposed Rule discusses storage of data, documentation, protocols, final reports, reserve samples, and specimens. BIO notes that for certain tissues, notably tissue for gene therapy, archived storage at -80°C may incur a significant burden without any appreciable benefit.	As archived storage for gene therapies may incur a significant burden without appreciable benefit, BIO requests that tissue used for gene therapy is exempted from this requirement.
38377 / § 58.190 Storage and retrieval of records and data (f)	It is unclear that this proposal intends that a study should be amended and then a short report issued.	BIO suggests editing the text to read: (f) "… Once the study has been determined to be discontinued, the study director must amend the study and prepare a summary report, as required by § 58.185(d)…"
58377 / § 58.190 Storage and retrieval of records and data (g)	The proposed rule indicates that an individual must be identified as responsible for the archives. One individual may not have the expertise to properly archive and retrieve all types of raw data, (*e.g.*, paper, specimens, and electronic data). As a result, there may be the need for special knowledge and expertise in handling these items. Allowing for more than one archivist could provide a reasonable solution to the problem without compromising the quality and integrity of the data.	BIO suggests the GLPs should allow for more than one individual to be assigned as an archivist.