USDA Animal Plant Health and Inspection Service
Scientific Collections Management and Access Policy
September 2014 (updated August 2016)

Beginning in 2005, the White House's Office of Science and Technology Policy (OSTP) and Office of Management and Budget (OMB) included in its priorities for interagency activity a call to "focus attention on integrated support and planning for the care and use of federally held scientific collections." This call gave rise to the formation of an Interagency Working Group on Scientific Collections (IWGSC) under the Committee of Science of the National Science and Technology Council (NSTC). The IWGSC issued a report entitled, "Scientific Collections: Mission-Critical Infrastructure for Federal Science Agencies," in December 2008 that made recommendations for the improvement of management, accessibility and impact of scientific collections owned by U.S. government departments and agencies.

On October 6, 2010, OSTP issued a memorandum to the heads of executive departments and agencies entitled, "Policy on Scientific Collections," that directed IWGSC to develop plans for: i) budgeting for collections, ii) ensuring best management practices for collections, and iii) making collections more accessible.

On March 20, 2014, OSTP issued a memorandum to the heads of executive departments and agencies entitled, "Improving the Management of and Access to Scientific Collections." In the memorandum, OSTP directed federal agencies that own, maintain or otherwise financially support permanent scientific collections to develop a scientific collections management and access policy. The following document is a response to the 2014 memorandum. It summarizes the management and access policies for institutional scientific collections owned, maintained, or otherwise financially supported by the Animal Plant Health and Inspection Service (APHIS), an agency of the United States Department of Agriculture. These policy requirements were developed with input from NSTC and IWGSC to also comply with the policy memorandum on scientific collections issued by OSTP in 2010 and the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science Act or America COMPETES Reauthorization Act of 2010.

APHIS SCIENTIFIC COLLECTIONS PHILOSOPHY

This document focuses on institutional collections. The APHIS policy is that all scientific objects that make up an APHIS scientific collection are publicly funded assets and great care and caution should be taken in regards to their care and preservation. As with real and personal property, APHIS exercises reasonable oversight over the inventory and control of scientific objects. These assets are resources obtained and/or produced for the purposes of supporting APHIS mission and should therefore have been obtained and/or produced as part of an APHIS staff member's official duties. As such, barring regulatory restrictions, restrictions due to non-disclosure agreements, restrictions of national and/or personal security, these objects are considered publicly owned and are generally in

the public domain. APHIS regards all scientific objects with the same appreciation as government property. Scientific collections are a national and international resource.

APHIS staff should inform management of any major proposed change in acquisition, care, transfer, or de-acquisition/disposal of scientific collections. While it is not expected that an exhaustible resource asset such as culture specimens collected during a specific project or investigation are in effect a permanent collection, it is the policy of APHIS that specimens that have achieved reference status as a long-term voucher or that are shared among laboratories for purposes of research or diagnostics must be given consideration as part of a potential institutional collection which deserves long-term care. If specimens or cultures are used to support research or diagnostic findings, especially in a new publication or technical report, then researchers should deposit representative specimens or cultures on which that work is based in an appropriate APHIS institutional or other permanent collection that has the assigned responsibility for long-term maintenance of such essential reference materials.

THE ROLE AND IMPORTANCE OF COLLECTIONS FOR APHIS

In addition to protecting the health of livestock, poultry, and crops from foreign diseases and pests, APHIS helps defend the environment from invasive species, promote animal welfare, regulate the movement and environmental release of certain genetically engineered organisms, ensure commodities traded internationally are free of animal and plant pests and diseases, limit agricultural damage caused by wildlife, and protect natural resources while contributing to efforts to ensure public health and safety. As part of this mission, program units throughout the Agency have developed resources such as scientific collections to: ensure preparedness activities against incursions of plant and animal diseases and pests; develop effective countermeasures as insects and pathogens evolve; assist in emerging disease diagnosis; facilitate assay methodology validation; and to reference for retrospective studies.

Examples of scientific collections maintained by APHIS or APHIS collaborators are as follows:

- The **Tuberculosis (TB) Serum Bank,** curated by Veterinary Services (VS) at their National Veterinary Services Laboratories (NVSL), provides well-characterized serum samples collected from both uninfected bovines (cattle) and cervids (deer and elk) and animals infected with Mycobacterium bovis, the causative agent of bovine TB. The bank currently contains approximately 9000 samples, with additional samples being added annually. This bank has been used by diagnostic companies developing tests to detect TB in both bovines and cervids, and by University researchers studying this disease.
- PPQ contributes samples to the Agriculture Research Service (ARS) at their: Systematic Botany and Mycology Lab (SBML); National Seed Storage Lab (NSSL); Systematic Entomology Lab (SEL); and to the Smithsonian Institution (SI) U.S. National Entomology Collection curated at the National Museum of Natural History. Through these contributions, PPQ adds to the breadth and therefore the value of the collections.
- The NVSL Foreign Animal Disease Diagnostic Laboratory (FADDL) Transboundary Animal Disease Agent Repository at the Plum Island Animal Disease Center (PIADC), contains virus

strains and isolates that serve as reference standards for validating and conducting diagnostic tests for foreign animal diseases."

- The **Tissue Archive,** curated by Wildlife Services (WS) National Wildlife Disease Program (NWDP) was established in 2003 as part of USDA APHIS. The program headquarters is located in Fort Collins, Colorado. The mission of the program is to provide a nationally coordinated system of surveillance and emergency response to diseases of concern in wildlife. The collection is unique in the quantity of samples, the diversity of species, the broad geographic range and consistent sampling effort over extended periods of time.

- The types of studies supported by the tissue archive include emerging disease diagnosis, wildlife health studies, assay method validation, and a variety of retrospective studies.
- By 2014, the archive had loaned about 4,700 avian swab samples, over 250 feral swine serum samples, and about 1,000 Nobuto dried blood filter paper strips from a variety of species.
- Collaborations using the archive have involved at least eight universities, four other federal agencies, and two State agencies. These have resulted in at least 8 journal publications so far.
- Some examples of supported research include:
    - Texas A&M University — Studying the distribution of Avian Bornavirus in wild birds
    - Department of Defense (DOD) —Validated portable field PCR system for avian influenza detection
    - USDA ARS — Studying transfer of parasites between pasture-raised domestic pigs and feral swine.

Within the NWDP **Tissue Archive** are several disease specific archives including:

- The **Avian Tissue Archive** is cooperatively managed with Colorado State University's Veterinary Diagnostic Laboratory. The archive consists of nearly 300,000 wild bird swab samples collected for highly pathogenic avian influenza surveillance in the United States from 2006-2011. Since then about 3,000 samples a year are added. Samples from 260 wild bird species and all 50 States and several U.S. territories are represented. The samples are maintained at –80°C.
- The **Feral Swine Serum Archive Collection** consists of serum samples from feral swine collected in 36 states. Two to three thousand samples are added to the archive each year. The current sample count is about 18,000. The samples are used to monitor nearly a dozen diseases carried by feral swine. Serum samples are maintained at –80°C.
- The **Plague and Tularemia Archive** consists of Nobuto strips (whole blood on immunochromatographic paper) from 92 species of carnivores,

rodents and other mammals, as well as several bird species. The most frequently sampled species are coyotes, beaver, raccoons, skunks and feral swine. Samples are stored in labeled envelopes and maintained at –20°C. The collection currently contains about 25,000 samples. Approximately 5,000 Nobuto samples may be added to the archive each year.

Scientific collections play a critical role in supporting the APHIS mission as well as scientific endeavors conducted by other collaborating institutions in North America and around the world. However, if collections are not appropriately maintained, significant losses can occur, lowering their value to the global scientific community. APHIS recognizes value in the request for policies currently in place to protect these National resources.

DEFINITIONS

SCIENTIFIC COLLECTION

For the purposes of this document, scientific collections are broadly defined as sets of physical objects, living or inanimate, and their supporting records and documentation, which are used in science and resource management and serve as long-term research assets that are preserved, cataloged, and managed by or supported by federal agencies for research, resource management, education, and other uses. These collections are created for the purpose of supporting or doing science or providing germplasm, rather than for their market value as collectibles or their historical, artistic, cultural, or other significance. The focus is on institutional collections. The focus is not on specimens, or parts of specimens used temporarily that document individual-based observations (e.g., individuals alive or dead from an ecological census wherein data pertaining to each individual is not captured in the study–although, permanently accessioned taxon vouchers are always a recommended practice). Similarly excluded are objects considered an exhaustible resource (e.g., a biotic reagent as part of a protocol). However, since all project or working scientific collections were obtained through public funding, are federal assets, and may be candidates for designation as institutional collections for long-term preservation, they must be cared for by means appropriate as a federal asset. Collections that are part of confidential agreements are exempt from this policy. It will be the Agency's discretion to share resources in such a manner that specimens and collections are not destroyed or damaged. The following criteria differentiate institutional from project collections. Each institutional collection is:

- Subject to a formal accessioning process, including associated documentation and archival material (e.g., notes, photographs and maps);
- Under the authority of scientific collection curators or scientists and housed in facilities devoted to long-term collection storage;

- Inventory validated on a schedule determined by the Agency to ensure accountability of the collection;
- Physically labeled in some way with catalog numbers or other unique identifiers linked to a corresponding record in a database or other record-keeping system;
- Routinely made available to all qualified users, with certain exceptions;
- Made available for examination to qualified parties through formal procedures for research, education, or exhibition such as Material Transfer Agreements;
- Preserved long-term, except under certain conditions which may justify de-accessioning under a set of formal de-accessioning procedures.

SPECIMEN METADATA

Specimen metadata is information that describes a specimen that is part of a scientific collection. Generally, metadata make a specimen uniquely identifiable and more easily searchable. Specimen metadata also often provide important scientific information about the specimen that may have its own research or education value. Examples of specimen metadata include:

- Source specific information (i.e., date of isolation, source, spatial-temporal information, etc.);
- Phenotypic and genotypic scientific information (i.e., toxin producer, serotype, or sequence type);
- Species identification;
- Digital images of macroscopic specimens or cultures of microscopic specimens.

RECORDS AND REGISTRIES

The following are suggested ways to document records. Each institutional collection curator or working collection researcher will need to document collections appropriate to their intended use.

SPECIMEN RECORD

A specimen record is composed of all metadata for a single specimen in a scientific collection.

SCIENTIFIC COLLECTION DATABASE

-A scientific collection database is a listing or compilation of all records associated with collection activity including specimens, taxa, accessions, transfers, loans, borrows, inventory, physical location, collection manager(s), and other relevant information.

SCIENTIFIC COLLECTION RECORD

-A record of a scientific collection, or a scientific collection record, is a descriptive guide to a scientific collection.
The record contains essential information such as the title of the scientific collection, contact information, and the physical location of the specimens. Each scientific collection record is made available to the public via an online registry and points to the location of the associated scientific collection database.

SCIENTIFIC COLLECTION REGISTRY

-A scientific collection registry is defined as an online digital repository that stores and makes publicly available the scientific collection records and, as appropriate, the scientific collections database associated with that record. The Smithsonian Institution has identified the Global Registry of Scientific Collections or GRSciColl (http://www.GRSciColl.org) as an appropriate federal scientific collection registry to gather and disseminate basic information about scientific collections. APHIS has chosen to adopt GRSciColl as its scientific collections registry to record links to records or host scientific collection records, with the option to store scientific collection databases.

LEGISLATIVE AND REGULATORY REQUIREMENTS AND AUTHORITIES

This policy is in compliance with the U.S. Code of Federal Regulations Title 42, Chapter 79, Section 6624. This regulation establishes the requirement for all federal agencies to develop policies for the management and use of Federal scientific collections to improve the quality, organization, access, including online access, and long-term preservation of such collections for the benefit of the scientific enterprise.

APHIS has specific authorities under the following statutes:

- Plant Protection Act (7 U.S.C. §§ 7701 *et seq*.)
- Animal Health Protection Act (7 U.S.C. §§ 8301 *et seq*.)
- Agricultural Bioterrorism Protection Act (7 U.S.C. §§ 8401 *et seq*.)

Additional authorities include:

- Agricultural Research Act of 1935 (7 U.S.C. 427)
- Research and Marketing Act of 1946 (Pub. L. 79-733), as amended (7 U.S.C. 427, 1621 note)
- Food and Agriculture Act of 1977 (Pub. L. 95-113), as amended (7 U.S.C. 1281 note)
- Food Security Act of 1985 (Pub. L. 99-198) (7 U.S.C. 3101 note)
- Food, Agriculture, Conservation, and Trade (FACT) Act of 1990 (Pub. L. 101-624) (7 U.S.C. 1421 note)
- Federal Agriculture Improvement and Reform (FAIR) Act of 1996 (Pub. L. 104-127)
- Agriculture Research, Extension, and Education Reform Act of 1998 (Pub. L. 105-185)
- Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171) (also known as the 2002 U.S. Farm Bill Agricultural Act of 2001)
- Purposes of Agricultural Research, Extension, and Education (Pub. L. 104-127, Title VIII, Sec. 901, Apr. 4, 1996, 110 Stat. 1156)
- Trade Secrets Act (18 U.S.C. 1905)
- Copyright Act (17 U.S.C. 101 *inter alia*)
- Federal Acquisition Regulations System, Solicitation Provisions and Contract Clauses (48 C.F.R. Part 52)
- Federal Accounting Standards Advisory Board (FASAB) (FASAB, 2005)
- Government Performance and Results Act (GPRA) of 1993 (P.L. 103-62)
- Executive Order 12862 of 1993 on Customer Service Standards
- America COMPETES Reauthorization Act of 2010 (Pub. L. No. 111-358), Section 104 requires the OSTP Director to "develop policies for the management and use of federal scientific collections to improve the quality, organization, access, including online access, and long-term preservation of such collections for the benefit of the scientific enterprise."
- OSTP, Memorandum for the Heads of Executive Departments and Agencies, Policy on Scientific collections (October 6, 2010)

- OSTP, Memorandum for the Heads of Executive Departments and Agencies, Improving the Management of and Access to Scientific Collections (March 20, 2014)

RESPONSIBILITIES: ORGANIZATIONAL COMPONENTS AND AGENCY OFFICIALS THAT SUPPORT AND IMPLEMENT COLLECTIONS POLICY IN APHIS

Organizational Components

With an extensive network of laboratories and research facilities, APHIS draws from among the most advanced and specialized scientific resources available today. APHIS relies on the unique skills of its highly trained staff—as well as its unmatched access to the most advanced technical resources—for the benefit of U.S. agriculture, producers, and consumers. The four operational program units within APHIS that maintain collections in order to carry out this mission are; Animal Care (AC), Plant Protection & Quarantine (PPQ), Veterinary Services (VS), and Wildlife Services (WS). These program units are responsible for developing and applying scientific methods to benefit agricultural producers and consumers, protect the health of domestic animal and plant resources, sustain agricultural ecosystems, and promote animal welfare by:

• Identifying and analyzing pest and disease pathways,
• Conducting diagnostic testing,
• Developing and adapting technologies,
• Conducting risk assessments, and
• Serving as a leader and resource in agricultural science and best practices.

APHIS facilities covered by this document include:

- **Center for Plant Health Science and Technology** (CPHST) **(PPQ)**, where scientists evaluate risks associated with the introduction of plant pests and develop methods to exclude, detect, and manage invasive plant pests and weeds;
- **Center for Epidemiology and Animal Health** (CEAH) **(VS)**, where multidisciplinary specialists track emerging animal health threats, monitor U.S. livestock management and production, design comprehensive animal health surveillance programs, and conduct risk assessments to identify situations that could impact the health of U.S. animal agriculture, and serve as a Collaborating Centre for the World Animal Health Organization;
- **National Wildlife Research Center** (NWRC) **(WS)**, the world's only research center devoted entirely to the development of methods for effective wildlife damage management;
- **National Veterinary Services Laboratories** (NVSL) **(VS)**, the Nation's premier animal health diagnostic laboratory and a World Animal Health Organization reference laboratory for animal diseases of importance to the Americas;
    - **Foreign Animal Disease Diagnostic Laboratory** (FADDL) **(VS)**, a high-security bio-containment facility, part of the NVSL, where experts diagnose and develop

tests for foreign animal diseases that threaten U.S. animal agriculture, as well as maintain forensic capabilities that can be used in the event of potential bioterrorist releases;

• **Center for Veterinary Biologics** (CVB) **(VS)**, the Nation's sole laboratory involved in the testing and regulation of commercial veterinary biologics (primarily vaccines and diagnostic kits) in the United States;

• **Center for Animal Welfare** (CAW) **(AC)**, where APHIS specialists collaborate with a diverse network of external partners and experts to serve as a national and international resource for animal welfare science, training, education, and policy strategy.

Agency Officials

The APHIS Administrator carries out the agency's broad mission of protecting and promoting American agriculture, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage management activities. Two Associate Administrators share responsibilities for administering APHIS policy, including support of APHIS' emergency response community, which includes the work of Plant Protection and Quarantine (PPQ), Veterinary Services (VS), Wildlife Services (WS), International Services (IS), and Animal Care (AC). Each of the Deputy Administrators for the operational program units is responsible for overall planning, coordinating, direction and enforcement of regulatory actions pertaining to APHIS.

Because scientific collections developed by the above scientific facilities support the overall APHIS goal of protecting animal and plant health, ultimate authority and accountability of these collections reside with the APHIS Administrators, Associate Administrators and Deputy Administrators, and their offices are responsible for implementing this policy on scientific collections across all APHIS programs. Unless stated otherwise, all decisions as to the maintenance, accession, and de-accession of APHIS scientific collections should be routed through the current authority structure as appropriate, which may also include Directors of the APHIS scientific facilities as identified above.

DIFFERENCES THAT MAY EXIST BETWEEN DEPARTMENT-WIDE POLICIES AND COLLECTIONS-SPECIFIC POLICIES ESTABLISHED BY APHIS

Federal Select Agent Program (FSAP): Certain bacterial, toxins and viral isolate collections held within APHIS must comply with the Agricultural Select Agent Program. Therefore, in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act (PHSBPRA) of 2002, entities requesting access to these collections must meet requirements as established by the Department of Health and Human Services

(42 CFR Part 73) and by the US Department of Agriculture (7 CFR Part 331 and 9 CFR Part 121).

The PHSBPRA of 2002 requires that the United States improve its ability to prevent, prepare for, and respond to acts of bioterrorism and other public health emergencies that could threaten either public health and safety or American Agriculture. It necessitates that individuals possessing, using, or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Before registration is granted, the facility must also meet biosafety requirements that are commensurate with the risk that the select agent or toxin poses and must establish security measures that provide graded protection in accordance with the threat that the agent or toxin poses.

Collections Maintained in Collaboration with Other Federal Agencies: In the course of its regulatory actions, APHIS PPQ collects or receives from other agencies specimens that are considered worthy of maintaining as part of permanent, curated collections. Those specimens are treated as follows. Arthropod specimens are deposited with The Smithsonian Institution (SI); fungus specimens are deposited with USDA ARS National Fungus Collection; nematode specimens are deposited in the USDA National Nematode Collection; and mollusk specimens are deposited at the Academy of Natural Science in Philadelphia (ANSP). Voucher cultures of other plant pests not specifically listed here are likewise are placed in established culture collections.

GenBank: Genetic sequences determined by APHIS to be significant may be submitted to National Center for Biotechnology Information (NCBI) GenBank®, the publically available genetic sequence database of the National Institutes of Health (NIH) for archival purposes. The appropriateness of a submission and the appropriate archival remains the discretion of the Agency.

Collections Maintained in Collaboration with International Agencies: APHIS NVSL maintains a consolidated collection of rinderpest virus containing materials as a global scientific resource for protection against the return of rinderpest, a recently eradicated animal disease. In addition to being subject to regulations of the Federal Select Agent Program (FSAP), maintenance of this scientific collection adheres to guidelines and recommendations set forth by the United Nations' Food and Agriculture Organization (FAO) and the World Organization for Animal Health (OIE) Joint Rinderpest Advisory Committee. An international collection of foot-and-mouth disease antigens, also maintained by APHIS NVSL, follows guidelines of the North American Foot-and-mouth Disease Vaccine Bank (NAFMDVB) administered by a scientific steering committee representing the US, Mexico and Canada in addition to guidelines that may be provided

by vaccine companies contracted by the NAFMDVB to produce vaccines.

METHODOLOGIES USED FOR THE ASSESSMENT AND PROJECTION OF COSTS ASSOCIATED WITH THE DEVELOPMENT, MANAGEMENT, AND PRESERVATION OF AGENCY SCIENTIFIC COLLECTIONS

The curator/responsible person shall estimate cost of maintaining collection; costs shall be authorized according to existing delegation of spending authority.

HOW APHIS BUDGETS FOR THE STEWARDSHIP OF SCIENTIFIC COLLECTIONS, INCLUDING A DESCRIPTION OF THE OVERALL FUNDING STRATEGY TO SUPPORT SCIENTIFIC COLLECTIONS AND ENSURE ONLINE ACCESS TO INFORMATION ABOUT SCIENTIFIC COLLECTIONS AND INDIVIDUAL OBJECTS

Costs of collection stewardship, including process for online access information about the collection shall be budgeted within the applicable program unit or agency line item. Approval of the cost will be through existing delegation of funding authority.

PROCEDURES FOR OBTAINING OR SUPPORTING THE DEVELOPMENT OF NEW SCIENTIFIC COLLECTIONS

The need to initiate a new collection to meet agency needs will be proposed in writing by personnel requesting creation of the collection along with supporting documentation outlining the value gained by the agency. Review of the proposal will be conducted at the level of the Center Director, or the proposal will be considered by the Program Management Team. The review and acceptance will be based on factors including cost/benefit, possible alternate sources, projected costs to maintain, and budgetary climate. Requests to transfer existing collections from outside collaborators will follow the same evaluation path and will also include consideration for ownership right issues and condition and documentation of collection samples included in the collection and will be stated in a Material Transfer Agreement (MTA) between the agency and the collection provider/providers institution.

AGENCY REQUIREMENTS FOR LONG-TERM PRESERVATION, MAINTENANCE, AND ACCESSIBILITY OF NEW AND EXISTING COLLECTIONS TO MAXIMIZE PUBLIC BENEFIT FROM THEIR USE

Collections will be maintained in appropriate storage conditions under security levels and containment conditions that apply to the individual collections. Most APHIS collections consist of animal and plant parasites, and pathogens or serum or tissue samples from animals and plants. Some of these collections are stored as frozen samples and require minimal attention for preservation. Collections are currently advertised to and utilized by the scientific community

and by industry. APHIS will continue to advertise the availability of these collections to the appropriate stakeholders and the general public where appropriate by website postings, presentations at scientific meetings, and direct communication to industry. When APHIS program units cooperate with other agencies/ institutions such as the Smithsonian Institute or ARS for maintenance of collections, those institution's protocols and policies are followed.

STANDARDS USED BY THE AGENCY FOR MANAGING COLLECTIONS

Standards for managing scientific collections are varied due to the nature of the diversity of collections, and APHIS recognizes that the scientific staff is best-suited to determine the current methodologies for this task. Therefore, each scientific collection should be assigned a curator with appropriate qualifications –as determined by the Agency- and responsibility to oversee each collection. This curator should be assigned by the Agency (authority delegated to the level of the Program Management Team or Center Director), and be provided with sufficient resources needed to maintain the approved collection. The Curator shall develop a Standard Operating Procedure (SOP) for the physical access and use of its institutional scientific collections.

PRACTICES FOR SAFEGUARDING INDIVIDUAL PRIVACY, CONFIDENTIALITY, INTELLECTUAL PROPERTY RIGHTS, AND NATIONAL SECURITY

APHIS collections consist mainly of well characterized: animal/plant parasites, pathogen isolates, animal serum, tissue samples, and biological specimens collected from herds or premises of known disease status or large surveillance studies. Varying degrees of personally identifiable information (PII) may be associated with the specimens at the time of collection but shall not be released from the Agency when materials from collections are provided.

Some isolates and animal samples are submitted anonymously through surveillance programs specifically designed for creating scientific collections (e.g. swine surveillance program, National Animal Health Monitoring System [NAHMS]). Other collection specimens have identification numbers assigned to them by the collection program unit which are unique and specimens are stored and released only with reference to this number. And still other specimens are cataloged with limited metadata that does not include PII of the submitter nor specific collection site origin information. Metadata are typically limited to isolate genus and species, animal/plant species of origin and state of animal/plant/isolate origin.

In addition, in order to protect PII, APHIS shall work with the USDA Chief Information Officer (CIO) and the USDA APHIS Information Technology Division 's CIO to adopt and implement department-wide policies to ensure data security, especially records that could be used to access or derive PII information, including those associated with collections of biological specimens. Materials obtained through Memorandums of Understanding (MOUs) or Material Transfer Agreements (MTAs) with other entities shall not be made part of any collection.

APHIS complies with all applicable FSAP regulations and Department of Commerce (DOC) requirements for the exportation of controlled substances as well as all Department of

Transportation (DOT), International Air Transport Association (IATA), and APHIS' regulations and requirements for the shipping of infectious substances.

BIOSAFETY AND BIOSECURITY

To ensure safety and environmental protection, APHIS employees are required to comply with all federal, state, and local regulations regarding the movement of pests and pathogens (human, animal, and/or plant) within or into the United States, and safeguarding of those samples/specimens. Specimens and samples are distributed and transported only under authority of a permit (e.g., from the USDA APHIS, the Department of HHS, or the DOC, as appropriate) and a MTA. Permitting agencies must specify the level of containment as well as conditions for limiting access to specimens and samples, and shall include final disposal methods. Acceptable disposal methods (usually autoclaving) for specimens received under permit shall be specified in the permit. This is out of concern for protecting the Agency from liabilities as well as protecting the end-user/requestor from potential harm/infection/contamination/etc. Inventories of pathogens and pests present in APHIS are maintained by APHIS.

A STRATEGY FOR PROVIDING ONLINE INFORMATION ABOUT THE CONTENTS OF THE AGENCY'S SCIENTIFIC COLLECTIONS AND WHERE APPROPRIATE, FOR MAXIMIZING ACCESS TO INDIVIDUAL OBJECTS IN DIGITAL FORM FOR SCIENTIFIC AND EDUCATIONAL PURPOSES

APHIS works very closely with stakeholders in the agriculture research community and advertises the availability of collections in several ways including: direct communication at industry and scientific meetings, web postings on industry associated websites (e.g. availability of archived serum samples on the American Association of Swine Practitioners website), and in published manuscripts.

Access to the scientific collections will be determined on a case by case basis with the review at the level of the Center Director, or the Program Management Team in accordance with existing protocol. Flexibility is required since some collections contain finite volumes of valuable materials, and scientific judgment is required to obtain the most value from the resource. Collection specific processes may be needed and should be made transparent if there is a justified reason to limit access to protect the integrity of a resource.

HOW THE AGENCY WILL PROVIDE ACCESS TO THE PUBLIC OR OTHER MEMBERS OF THE RESEARCH COMMUNITY, INCLUDING HOW COLLECTIONS AND INFORMATION ABOUT COLLECTIONS WILL BE DISSEMINATED EQUALLY

Multiple methods shall be used within APHIS to assure appropriate dissemination of collections. Many of the VS collections contain viable micro-organisms that can be expanded if needed so there is an infinite source. When finite volumes of valuable collection materials exist, APHIS can at times utilize user fees authority to recover associated costs, thus ensuring that some value

is placed upon the collection materials and therefore a cost associated with dissemination. A collection such as a reference animal ecto-parasite collection may be utilized on site by collaborators and is not consumed by usage. Specific collection material dissemination process protocols, may also be developed and made available to the research community; e.g. the protocol used by the National Wildlife Disease Program.
APHIS also utilizes program-specific scientific review panels to review proposals submitted based on scientific merit. The overall APHIS policy allows some flexibility in the selection process and bases the authority at the level of the appropriate Center Director or Program Management Team to make judgments on the most judicious use of limited materials for the overall advancement of scientific knowledge.

Access and Use Plan

Specimens within an APHIS scientific collection are the property of the United States Government. APHIS will provide reasonable physical access to its institutional scientific collections to qualified researchers, academics, and others as feasible, appropriate, and consistent with Agency mission and pursuant to the scientific collections SOP. Those seeking physical access to the institutional scientific collection must adhere to the procedures outlined in the collection's SOP.
Physical and digital access to the collections must be balanced against human resources, preservation, and security concerns. Scientific collection curators, working with their direct supervisors and the corresponding Deputy Administrator, will have the discretion to temporarily, or permanently, limit the access to institutional scientific collections and related catalogs, databases, records, and metadata for purposes of:

- Safeguarding individual privacy, confidentiality, trade secrets, copyright, and intellectual property rights;
- Adhering to laws, regulations, treaties, and international or tribal agreements;
- Protecting national security;
- Resource limitations;
- Specimen availability;
- Preservation constraints; or,
- Addressing general security concerns.

Limits to public access to the institutional scientific collection must be disclosed in the scientific collections policy, including:
- Restrictions, and justification, for physical access to the scientific collection; and,
- Redactions, and justification, for the digital access to the scientific collection.

Liability for any negative impacts that may result from accessing a scientific collection will reside with the person that requests access. The Agency will take appropriate measures such that access occurs in such a manner and following protocols meant to minimize risks.

Scientific collection databases, which include all specimen records and metadata, are made available to the public through GRSciColl (http://www.GRSciColl.org). A collection curator may also choose to separately provide public access to the scientific collection database online through an APHIS website, provided the scientific collection record in GRSciColl directs users to the location of the online database.

All restrictions on digital access shall be limited to the subset of specific records and metadata as possible, with all other collection content made public. Where possible, redaction of specific metadata should be favored over limiting digital and physical access to the entire specimen or subset of specimens.

Metadata format

When constructing and formatting the institutional scientific collection metadata, scientific collection curators must employ machine-readable and open formats, data standards, and common-core and extensible metadata for all new information creation and collection to facilitate search and discoverability and provide clear public guidance for accessing collections materials, consistent with the Executive Order on Making Open and Machine Readable the New Default for Government Information.

When available and where not limited by law, this policy, or resources, APHIS will make freely and easily accessible to the public all digital metadata in the highest available fidelity and resolution, including, but not limited to photographs, videos, and associated records and documentation, that describe or characterize specimens in a scientific collection.

Third-Party Management of Institutional Scientific Collections

Third-party collections are those not owned, but supported, by APHIS. For example, APHIS partially funds collections maintained by the Smithsonian Entomology Lab (SEL). Thus, these collections follow the same guidelines as APHIS collections.

To start a new third-party collection and, whenever practicable and appropriate, a scientific collection curator should work with public or private outside entities qualified to manage scientific collections. Those entities must agree to take responsibility for the stewardship and access to institutional scientific collections.

- If the outside entity is a federal agency, then the entity's scientific collection's policy applies to the institutional collection. An interagency agreement should be executed and included with a scientific collections plan (if available) and annual report.
- If the outside entity is not a federal agency, and does not have a relevant scientific collections management and access policy, then the institutional scientific collection will be governed by the APHIS policy. All Agency grants, contracts, and cooperative agreements that direct an outside non-federal entity to obtain or create an institutional collection must require the entity to comply with the existing scientific collections policy. The agreement or contract should be included with the scientific collection section of the annual report.

Access Plans include Access and Use Standard Operating Procedures and Protocols:

1. Detailed instructions for digital access to the scientific collection, including:
   -Step by step instructions and timelines for the process of providing digital public access to newly accessioned specimens
   -A detailed description of which records or specimen metadata fields are restricted from disclosure and why
   -A timeline from accession of a specimen to digital public access
   -A detailed description of which records and metadata to be redacted
2. Detailed instructions for physical access to the scientific collection, including:
   -Outline procedures to properly aliquot, or parse, bio-specimens to ensure ease of distribution
   -A detailed description of which specimens, records, and metadata will not be available for physical access
   -Procedures used to respond to and accommodate physical access and loan requests
   -A standard timeline to respond to a request

THE PROCESS FOR DE-ACCESSIONING, TRANSFERRING, AND DISPOSING OF SCIENTIFIC COLLECTIONS, INCLUDING DOCUMENTATION PROCEDURES AND THE PROCEDURES FOR MOVING COLLECTIONS ACQUIRED FOR INDIVIDUAL PROJECTS TO INSTITUTIONAL COLLECTIONS

APHIS policy for collections necessitates evaluation of the need to establish a collection as well as a periodic review to determine the ongoing relevancy of previously established collections. Authority for both the need evaluation and annual relevancy review are delegated to the appropriate Center Director or the Program Management Team to ensure that the scientific needs for the local scientific staff and their stakeholders are being met.

The policy also includes a decommissioning process designed to evaluate the scientific value of any collection, or parts thereof, identified for phase out along with a strategy to reach out to the appropriate scientific community to determine if: others could obtain value from a collection transfer, and if potential recipients were deemed suitable and capable of complying with all appropriate existing policies and regulations. Special consideration will be given to voucher collections where authors of scientific publications make reference samples available through APHIS to fulfil ethical obligations. Should the need to phase out such a collection be determined, efforts to transfer or return samples will be made and use of an MTA will be the mechanism for their transfer and return.

RESOURCES WITHIN THE EXISTING AGENCY BUDGET TO IMPLEMENT THE POLICY

Implementation of the APHIS policy for the handling of scientific collections will have limited financial impact. Resources can be redirected from within existing programs.

APPLICABILITY OF POLICY

This policy applies to all current and future institutional scientific collections that the Agency owns or manages.

ANNUAL REPORTING

To maintain proper oversight of the management of institutional scientific collections, the scientific collection curator submits an annual report summarizing the status of the collection as a component of its internal annual report. The status of Scientific Collections in the annual report is reviewed and approved by the Chair of COSTA, the APHIS Administrator or designee. The annual report that addresses status of institutional collections must include:

- A link to the catalog in GRSciColl (http://www.GRSciColl.org)
- A summary of major changes to the digital or physical public access to the scientific collection;
- The current interagency agreement, memorandum of understanding, or contract with a third party entity responsible with the management of the scientific collection, if applicable;
-Any Materials Transfer Agreements (MTAs) that may have been developed;
- A summary of any significant changes in practices, procedures, technology, law, or regulation that impact the collection.