****

Biological Sample Sharing and Submission

and Diagnostic Data-sharing

POLICY

- 16 July 2015 -

**I. PREDICT Collaboration**

PREDICT is a cooperative agreement between the US Agency for International Development (Emerging Pandemic Threats Program; USAID EPT) and a consortium comprised of the University of California, Davis, Wildlife Conservation Society, EcoHealth Alliance, Metabiota, Inc. and the Smithsonian Institution, as well as collaborating and subawardee institutions and organizations. The PREDICT consortium and their partners bring particular areas of subject and geographic expertise to the PREDICT endeavor, and all have committed to engaging in transparent communications and activities for the duration of the project.

**II. Purpose of this Policy**

Acquiring and analyzing biological samples from humans, livestock and wildlife (hereafter referred to as “samples”) is a primary PREDICT activity, and data obtained through laboratory analyses of these samples for known or emerging zoonotic pathogens is integral to the success of the project.

PREDICT personnel proactively collect samples at targeted high-risk human/animals (wildlife and livestock) interfaces, and gain access to samples from humans, livestock and wildlife through existing and new partnerships with outside (non-PREDICT) researchers (individuals, institutions, agencies, and organizations) working on species or in an areas of particular relevance to PREDICT project goals.

In the interest of achieving PREDICT objectives without causing professional misunderstandings that could undermine relationships and jeopardize PREDICT and the USAID EPT, and recognizing that PREDICT depends upon access to samples from, and data generated by, partnerships, it is imperative to clarify and agree on sample, data and sequence sharing guidelines, as well as terms for publishing jointly-generated data. Furthermore, it is possible that the results of this work may be commercially exploited. **It is an explicit goal of this document to define who owns Intellectual Property Rights (IP) to the samples, sequences, isolates, and techniques discovered or developed during this study**.

**III. Guiding Principles**

Sharing information among PREDICT partners, and with the USAID EPT, in as timely a manner as possible is essential for project success.

It is the intent and purpose of PREDICT and the USAID EPT to make data as widely and freely available as possible; that said, it is essential that information sharing is accomplished without sacrificing confidentiality and intellectual propriety.

Zoonotic disease surveillance data must be shared with local, state, and national animal and human health authorities at the earliest opportunity so that, as appropriate, authorities can act on the information to institute disease prevention and control measures, and can develop and disseminate accurate and timely risk communication messages to the public and other key audiences.

***PREDICT recognizes that in some situations, PREDICT partners will not be the legal “owners” of samples, as some governments retain ownership of all samples from humans, livestock and wildlife acquired in that country. In these situations, neither the PREDICT submitter(s) nor the laboratory can legally claim samples as their property. In these situations, intellectual property rights to discoveries in those samples need to be negotiated.***

*As the PREDICT project is ongoing, it is a PREDICT policy that all samples collected during the project will remain in the possession of the PREDICT submitter (and may be stored by the partner lab as defined in section IV), or if loaned out for collaborative research activities, be returned to the PREDICT submitter or laboratory for storage as soon as possible.*

**IV. Definitions**

* ***PREDICT***: Consortium among the University of California, Davis, Metabiota, Inc., Wildlife Conservation Society, EcoHealth Alliance, and the Smithsonian Institution.
* ***PREDICT Submitter:*** A member of the PREDICT consortium (above). The partner of the consortium which submitted, or organized submission of the sample for pathogen discovery. At the discretion of the PREDICT consortium partner, subawardees may jointly or solely submit samples, and thus retain a share of IP.
* ***PREDICT Partner lab:*** A diagnostic laboratory that regularly receives PREDICT funds (i.e., a subawardee) to participate in the PREDICT project on an ongoing basis, conducting PREDICT diagnostics or advanced molecular characterization. Examples include Columbia University and Institut Pasteur du Cambodge, and those designated as regional or in-country pathogen detection and discovery labs (including government and national research laboratories).
* ***PREDICT lab data***: Data, including test results, sequences and isolates generated by any laboratory from PREDICT samples, and pooled data prepared for joint analysis to meet PREDICT objectives.
* ***PREDICT publications***: Publications and presentations derived from unpublished PREDICT lab, field, and other analytical data, as well as PREDICT-generated and -specific methodologies and protocols.

**V. Guidelines for sample submission and data sharing**

**A) PREDICT sample submission to commercial laboratories**

Biological samples (e.g. blood, sera, plasma, urine, swabs, tissues) collected by PREDICT may be submitted to commercial (i.e. fee-for-service) diagnostic laboratories to test for pathogen exposure or detection.

The results, including lab data, sequences, and nucleic acid products, shall be the shared intellectual property of:

1st: the PREDICT submitter(s); and

2nd: the outside researcher or program that obtained the sample (if applicable, and except as otherwise specified in Section III).

The PREDICT submitter(s) shall retain ownership of any remaining sample or untested samples not utilized for PREDICT testing; it is the responsibility of the submitter(s) to arrange for return of remaining samples from the laboratory in a timely manner.

As is customary, the commercial laboratory will provide testing results to the client (PREDICT submitter(s)) only.

Posting and publication of test result and sequence (including submission to the Genbank database) data resulting from analysis conducted by a commercial laboratory are the sole responsibility and provenance of the PREDICT submitter(s) (see Section VII). The PREDICT submitter(s) shall duly identify/acknowledge the diagnostic laboratory for its service in all reports and publications.

**B) PREDICT sample submission to outside (non-PREDICT) research laboratories (non-commercial, non-fee-for-service), including laboratories at academic, governmental, or private institutions.**

Biological samples collected by PREDICT may be submitted to a research laboratory that is not a regular PREDICT Partner Laboratory (as defined above) to test for pathogen exposure or detection as part of a research collaboration.

The samples are wholly the property of the PREDICT submitter(s) (except as specified in Section III).

The PREDICT submitter(s) shall retain ownership of any remaining sample not utilized for PREDICT testing; it is the responsibility of the submitter(s) to arrange for return of remaining samples from the laboratory in a timely manner.

The results, including lab data, sequences, and nucleic acid products, shall be the shared intellectual property of:

1st: the PREDICT submitter(s); and

2nd: the research laboratory; and

3rd: the outside researcher or program that obtained the sample (if applicable, and except as otherwise specified in Section III).

The research laboratory shall immediately and only report test results and sequence data to the PREDICT submitter(s). The submitter(s) shall be responsible for entering the data into the EIDITH database, and for disseminating results to the PREDICT Executive Committee and to research or program partners (as applicable).

The PREDICT submitter(s) shall have the first right of refusal of first- and last- authorship on all data resulting from the submission of PREDICT samples if the planned paper’s primary focus is not on the diagnostic or laboratory techniques. Decision-making regarding publication of data resulting from submission of samples to a research laboratory by PREDICT shall be between the PREDICT submitter(s) and the research laboratory (see Section VI). Authorship decisions should be based on a reasonable and honest assessment by the parties of each parties’ intellectual contributions to the publication.

***Parties may jointly sign and date this section of this document to indicate that they have read and are willing and able to comply with PREDICT’s policies for biological sample submission, data-sharing and authorship of scientific papers.***

*PREDICT submitter:*

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Institution/Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Collaborating laboratory:*

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Institution/Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# C) PREDICT sample submission to PREDICT Partner Laboratories

Biological samples submitted by a PREDICT submitter(s) to PREDICT partner laboratories (as defined above) become the joint property of the PREDICT submitter(s) and the partner laboratory, except as otherwise specified in Section III.

Partner laboratories may perform PREDICT diagnostics as well as advanced pathogen detection diagnostic analyses and provide diagnostic support to PREDICT partners in a region on a non-fee-for-service basis.

Results, including lab data, sequences, and nucleic acid products, are the shared intellectual property of the PREDICT submitter(s) and the partner lab, except as otherwise specified in Section III.

All test result and sequence data generated by the partner laboratories on samples submitted by PREDICT shall immediately be made available by the partner laboratories to the PREDICT submitter(s). These data will immediately be posted to the EIDITH database. The PREDICT submitter(s) is responsible for disseminating results to the PREDICT Executive Committee and other researchers who may have contributed to sample acquisition, as applicable and appropriate.

The PREDICT submitter(s) shall have the right of first refusal of first- and last- authorship on all data resulting from the submission of PREDICT samples to the partner laboratories for pathogen exposure, detection and/or discovery if the planned paper’s primary focus is not on the diagnostic or laboratory techniques. In some cases, it may be appropriate for the PREDICT submitter(s) to be ‘joint first author’ with the partner laboratory’s pathogen discovery lead. Likewise, joint last-authorship is an option for the senior person from PREDICT and the partner laboratory. Authorship decisions should be based on a reasonable and honest assessment by the parties of each party’s intellectual contributions to the publication.

If an authorship decision is in dispute, the authors shall appeal to the PREDICT Executive Board, which will make a final and binding decision regarding authorship order.

***Parties may jointly sign and date this section of this document to indicate that they have read and are willing and able to comply with PREDICT’s policies for biological sample submission and data-sharing, and authorship of scientific papers.***

*PREDICT submitter:*

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Institution/Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*PREDICT Partner Laboratory:*

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Institution/Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**VI. PREDICT sample acquisition from other researchers/programs**

In order to meet PREDICT objectives, PREDICT may request access to a portion of human and animal biological samples collected by other researchers or programs noting that the appropriate authority must be consulted, which in most cases is the Principal Investigator of the project, and may include the government of the country in which the samples have been collected.

Sharing a portion of collected samples with PREDICT is wholly the decision of the researcher or program.

If the researcher or program agrees to provide samples to PREDICT, the samples become the joint property of the researcher/program and the PREDICT submitter(s) (except as otherwise specified in Section III).

In agreeing to provide a portion of collected samples to PREDICT for pathogen detection or discovery, the researcher or program gives implicit permission to PREDICT to submit the samples for testing to a diagnostic laboratory of the PREDICT submitter(s)’ choosing.

The results, including lab data, sequences, and nucleic acid products resulting from all PREDICT analyses of the samples are the shared intellectual property of:

1st: the PREDICT submitter(s); and the researcher/program that originally obtained the sample

2nd: the research laboratory that performed the diagnostics (as applicable, and except as otherwise specified in Section III)

Dissemination of test result and sequence data resulting from PREDICT sample analysis is the sole responsibility and provenance of the PREDICT submitter(s). The PREDICT submitter(s) is responsible for posting the data to the EIDITH database, and for disseminating results to the researcher/program that obtained the sample.

The PREDICT submitter(s) shall have first right of refusal of first- and last-authorship rights on publications resulting from submission of shared samples to diagnostic laboratories for PREDICT. That said, decision-making regarding publication of data resulting from submission of samples acquired from outside researchers or programs shall be made jointly by the PREDICT submitter(s) and the researcher (and the research laboratory, as applicable; see Section IV).

If an authorship decision is in dispute, the authors shall appeal to the PREDICT Executive Board, which will make a final and binding decision regarding authorship order.

***Parties may jointly sign and date sections or the entirety of this document to indicate that they have read and are willing and able to comply with PREDICT’s policies for biological sample acquisition from outside (non-PREDICT) researchers and programs.***

**VII. PREDICT Publications**

PREDICT shall prioritize collaborative publications of PREDICT data that have been pooled and analyzed in ways that serve and meet PREDICT objectives.

That said, individual PREDICT partners are encouraged to present and publish results based on their own data, if and only if such presentations and publications do not pre-empt or undermine the scientific value and contribution of a PREDICT collaborative publication.

In order to do so, individual PREDICT partners (the first author) must submit a publication proposal to the PREDICT Executive Board (EB), including (but not limited to) the following information:

* Working title for manuscript
* List of authors and affiliations
* Outline of the body of the manuscript, including objectives, hypotheses, and results
* A work schedule and expected date of submission
* A ranked list of peer-reviewed journals targeted for submission

The EB will review publication proposals on a regular basis and suggest ways to avoid overlap among proposed papers, by combining authorship for essentially identical work, or to better define papers to reduce overlap with others. Authorship decisions should be based on a reasonable and honest assessment by the parties of each parties’ intellectual contributions to the publication.

If an authorship decision is in dispute, the authors shall appeal to the PREDICT Executive Board, which will make a final and binding decision regarding joint publication of PREDICT-derived data.