

Policy and Procedures Manual

Ownership of Data and Materials Policy

Policy Number: POL011.05
Version Date: 7/2/2020

1. Purpose

The purpose of this policy is to protect the property (data/materials) of NSABP Foundation.

2. Scope

This policy governs NSABP staff, Research Collaborators, and contracted entities participating in clinical trials.

3. Policy Statement

This Statement sets forth the policy of the NSABP Foundation, Inc. ("Foundation" or "NSABP") with respect to the guardianship and ownership of certain data, physical specimens and intellectual property resulting from the conduct of NSABP sponsored clinical research.

- 3.1. It is the policy of the Foundation that the aggregate data, serum, tissues and other materials resulting from the conduct of NSABP clinical research and provided by a participating facility to the Foundation or to a participating research site or designated contracted entity at the direction of the Foundation ("Data/Materials") constitute property entrusted to the care and management of the Foundation to be used for the benefit of the public, and that the Foundation is the guardian or owner of such Data/Materials. All worldwide right, title and interest in the intellectual property rights with respect to such Data/Materials shall be owned by NSABP, including the right of first publication as provided in the NSABP Publication Policy, all patent rights and all rights of copyright.
- 3.2. All Research Collaborators of the NSABP and all contracted entities of the NSABP participating in its clinical research shall be responsible for protecting and preserving the integrity of the Data/Materials in their possession and shall deliver the same to the Foundation or its designee as required by the contractual agreement and protocol.
- 3.3. The foregoing notwithstanding, nothing in this statement shall be construed as granting NSABP ownership of any intellectual property, including original works of authorship, inventions, discoveries or any patents or copyrights issued thereon, made by participants or their personnel independently of information, drugs or instructional materials provided by NSABP or the study sponsors. Research Collaborators and other contracted entities shall not, however, obtain intellectual property rights to any of the data, information, protocols or drugs provided by NSABP or study sponsors, nor shall Research Collaborators and other contracted entities have any interest in intellectual property rights resulting merely from their routine activities in carrying out the study protocols or other activities in accordance with instructions from NSABP or the study sponsors. Any invention or discovery made

jointly by staff or employees of NSABP and Research Collaborators or contracted entities shall be jointly owned and the parties shall confer regarding patenting/licensing.

- 3.4. Should any applicable and controlling federal or state laws or regulations be inconsistent with the intellectual property rights and obligations of the parties as set forth in this statement, then such laws or regulations shall control in lieu of the inconsistent provisions in this statement.
- 3.5. Entities such as laboratories and other service providers ("Service Providers") which are sent Data/Materials by or at the direction of the Foundation are custodians only of the Data/Materials developed or acquired during the conduct of NSABP clinical research. Service Providers have possession of Data/Materials only for the purpose of performing specific services, e.g., archiving, banking and analytical services, in some way related to the Data/Materials that enable the NSABP: (a) to reach conclusions about the safety, efficacy and comparative value in treating and preventing cancers in accordance with the various protocol studies; (b) to translate this information into medical/surgical practice standards and commercial products; and/or (c) to perform other specific services requested by the Foundation. Individual Service Providers do not have the right independently of the NSABP to disclose, publish or otherwise use the Data/Materials or work product produced by the Service Providers based upon the underlying Data/Materials. All work product provided to NSABP by Service Providers shall be deemed "work made for hire" pursuant to the U.S. Copyright Act.

4. Related references, forms, policies

4.1. NSABP Publication Policy

Signature Page

Reviewed and Approved by:



Jack Berkebile, Chief Executive Officer

07/20/20

Date

Effective Date 8/3/2020

Policy Version History:

Policy Version History			
Policy Version #	Author	Version Date	Policy Revisions
NA	Joan Beyer Goldberg	6/10/2000	New Policy
NA	Joan Beyer Goldberg	11/2015	Revised
NA	Joan Beyer Goldberg	3/14/2016	Revised
POL011.04	Joan Beyer Goldberg	9/12/2018	New format; added purpose, scope, effective date, and versions history
POL011.05	Stephen Pickios	7/2/2020	Added guardianship in reference to tissues or biological materials.