

Donated Resource Center Release Policy

The N=1 Collaborative, Inc.

Principles of Resource Dissemination

Section 1.01. Purpose. According to the guiding principles of The N=1 Collaborative (NIC), we believe access to research tools and resources is a prerequisite for accelerating the development of individualized medicines. Following are guidelines for resource recipients to consider:

Section 1.02. Academic Freedom and Publication. Recipients of resources from the Donated Resource Center are expected to share and publish data generated by such resources and they should avoid entering into agreements that would prohibit these activities.

Dissemination Expectations

Section 2.01. General Guidelines. The Donated Resource Center complies with and adopts The N=1 Collaborative Donated Resource Center Review and Management Policy and The N=1 Collaborative Donated Resource Center Release Policy as its policies for acceptance, handling, and release of deposited material to the Donated Resource Center, release of associated depositor data for deposited material, and availability of any authentication and quality control.

Section 2.02. Depositor Requirements. Depositors and users of the Donated Resource Center should be aware of the following caveats regarding availability and release of deposited material and associated data. Factors that may influence acceptance of deposits include applicability to the mission of The N=1 Collaborative such as relevancy to NIC member needs and provision of necessary documentation.

N=1 Collaborative requests completed, institutionally approved deposit paperwork to process all deposits. Investigators must obtain necessary approvals from their technology transfer officials or equivalent institutional representatives.

Section 2.03. Section 2.03. Agreement for Donated Resources. Donated resources will be distributed under the terms of an agreement executed directly between the donor and the recipient. This agreement could be a Materials Transfer Agreement (MTA), a Supply Agreement, or another type of agreement as determined by the donor. The specific terms, including conditions of usage, will vary depending on the donor's requirements. Negotiations and execution of this agreement will occur solely between the donor and the recipient requesting access through the NIC. The NIC will not be a party to this agreement and will not assume any liability for the materials' use or any resulting outcomes.

Expectations on Production and Release of Deposited Resources into the Collaborative Resource Repository

Section 3.01. Processing. N=1 Collaborative maintains a queue of donated resources in the Collaborative Resource Repository, and materials will be processed as received or otherwise prioritized by NIC.

Section 3.02. Delays and Documentation Requirements. Depending on the category and resources available, advertised availability of fully documented deposited resources may be delayed.

Depositors may request an estimate of time required for release of approved resources to the Donated Resource Center at any time, but N=1 Collaborative cannot guarantee the estimated time span, due in part to the unpredictable nature, condition, viability, or other performance of newly received resources.

Section 3.03. Handling of Unsolicited and Incomplete Deposits. Unsolicited materials received by The N=1 Collaborative that have not been accepted by staff and volunteers and unsolicited or solicited materials for which fully completed paperwork and institutional authorization have not been met, will not be released to the Donated Resource Center online catalog, until all approvals and required paperwork are met.

Deposit forms lacking adequate information on the resources will result in delays in release of the deposited resources.

Section 3.04. Quality Issues. In the event of any quality issues with the deposited resources, the depositors will work with the recipient directly.

Section 3.05. Research and Intellectual Property Rights. NIC staff and volunteers may conduct research necessary to produce, document and accession the deposited materials into the Collaborative Resource Repository. Depositors are asked to supply information required to meet these needs. Information that is to be withheld from public release should be identified by depositors at the time of data transfer to the Collaborative Resource Repository

In the event N=1 Collaborative requires that some resources be shared to the research community with little to no authentication, N=1 Collaborative will only include depositor provided material/resources/data with a disclaimer the resource has not been fully authenticated or quality controlled by N=1 Collaborative.

N=1 Collaborative recognizes and acknowledges depositor intellectual property rights.

Section 3.06. Timely Release and Additional Research. In keeping with our mission to accelerate the development of individualized medicines, the NIC is committed to the timely release of deposited materials.

Any research not directly related to the activities described above requires explicit

notification and approval from, or formal agreement to collaborate with, the depositor and /or depositor's institution.