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[*www.novaseekresearch.com*](http://www.novaseekresearch.com)

 *(888) 632-4311*

***Novaseek Research Biospecimen Request & Agreement***

This form will give Novaseek the details needed to ensure precise matching of biospecimens and data to your specifications. You may also contact Novaseek at ANY TIME to discuss your research needs or questions related to this form. Email *biospecimens@novaseekresearch.com*
or call (888) 632-4311*.* ***To initiate services with Novaseek, please:***

**4) Novaseek may contact you** to discuss your request(s).

**5) When your order / account is finalized**, you will receive a confirmation notice including details about accessing the

Novaseek platform. The platform maintains information about

your orders, shipments, biospecimens, and associated clinical

data. Unless otherwise stated: (a) researchers are responsible

for shipping charges, (b) service fees are $200 per biospecimen

for non-commercial accounts, and (c) payment is due within 30

days of invoicing. Billing of commercial accounts will be based

on a separate written quotation. Pricing is subject to change

with prior notice.

***Place your cursor and click in each blue area to fill-in the requested information. You can tab to the right in each row, and then use
your cursor to move to the next row.***

 **1) Complete this** form and sign the attached agreement.

To avoid delays, please DO NOT modify the agreement.

**2) Provide documentation** (if applicable) that the research

for which you are requesting biospecimens has been

reviewed by an IRB, human use committee or similar

body responsible for oversight at your institution.

**3) Email a PDF of this completed form** and attachments
to biospecimens@novaseekresearch.com or mail to:
***Novaseek Research***

***275 Grove Street, Suite 2-400***

***Newton, MA, 02466***

**PRINCIPAL INVESTIGATOR INFORMATION**

*First Name: Middle Name: Last Name:*

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*Salutation: Title:*

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*Institution: Department:*

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*Address 1: Address 2:*

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*City: State: Zip Code: Country:*

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*Tel #: Alt Tel #: Email:*

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**LABORATORY STAFF CONTACT INFORMATION**

*First Name: Middle Name: Last Name:*

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*Name: Title:*

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**SECONDARY CONTACT** *(Optional)*

*First Name: Middle Name: Last Name:*

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*Name: Title:*

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**RESEARCH PROJECT INFORMATION**

**PROJECT TITLE:** *(Box will expand based upon the amount of information placed).*

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**In the expandable box below, please provide a brief abstract describing how the biospecimens will be used.**

**DO NOT INCLUDE PROPRIETY INFORMATION.**

**EXAMPLE:** *“Development of a new saliva-based diagnostic test for esophageal cancer.”*

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**SHIPPING INFORMATION**

*Federal Express Account Number (Required) Shipping address same as mailing address Yes No*

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*Attention: Institution Department:*

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*Address 1: Address 2:*

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*City: State: Zip Code: Country:*

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**BILLING AND PAYMENT INFORMATION**

**BILLING CONTACT:**

*First Name: Last Name: Title:*

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*Tel #: Alt Tel #: Email:*

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**BILLING ADDRESS: *Same as mailing address: or***

*Attention: Institution:*

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*Address 1: Address 2:*

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*City: State: Zip Code: Country:*

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*Tel #: Alt Tel #: Email:*

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**PAYMENT DETAILS:**

*Purchase Order Number PO Expiration Date:*

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*Credit Card Number: Expiration Date:*

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**INFORMATION ABOUT NOVASEEK BIOSPECIMENS AND DATA**

**Unless otherwise agreed, biospecimens provided by Novaseek will:**

 **•** Be derived from material remaining from clinical testing.

 **•** Be stored (unless otherwise noted) for 1-10 days prior to shipment

 **•** Be shipped Federal Express priority overnight

 **•** Be coded samples, obtained with consent and authorization, and provided with a limited data set.

**NOTE:** Non-consented cases with deidentified data may also be provided if approved by the investigator.
Please sign here if you **agree to accept non-consented, deidentifed cases**.

*Approved by: Date:*

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**DEVELOP YOUR COHORT(S)**

Novaseek’s platform pulls information from the patient’s electronic medical record, so you may develop cohorts based upon donor demographics, medical/disease history, lab test values, medications, procedures, and/or LOINC or ICD-10 codes, etc. Please define each cohort below based on a set of donor criteria. You may request multiple specimen types from a single cohort (set of donor constraints); however, if you have multiple cohorts (different sets of donor constraints, such as more than one age range) please go to Cohort #2 and so on.

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| **COHORT #1,** *Brief title to describe this cohort:* |  |

**DONOR DEMOGRAPHICS**

 **Sex/Gender Age Range Race / Ethnicity Other**

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**OTHER DONOR / MEDICAL CONSTRAINTS** *(tab to add additional constraints if needed for this donor)*

 **Criterion Include Exclude Comments**

 *(E.g. condition, medication, lab result)* ***Required or Preferred Required or Preferred***

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| --- | --- | --- | --- |
| *Treated with Methotrexate* | *Required* | *Preferred* | *Other here* |
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| **COHORT #2,** *Brief title to describe this cohort:* |  |

**DONOR DEMOGRAPHICS**

 **Sex/Gender Age Range Race / Ethnicity Other**

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**OTHER DONOR / MEDICAL CONSTRAINTS** *(tab to add additional constraints if needed for this donor)*

 **Criterion Include Exclude Comments**

 *(E.g. condition, medication, lab result)* ***Required or Preferred Required or Preferred****?*

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| **COHORT #3,** *Brief title to describe this cohort:* |  |

**DONOR DEMOGRAPHICS**

 **Sex/Gender Age Range Race / Ethnicity Other**

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**OTHER DONOR / MEDICAL CONSTRAINTS** *(tab to add additional constraints if needed for this donor)*

 **Criterion Include Exclude Comments**

*(E.g. condition, medication, lab result) Required or Preferred? Required or Preferred?*

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**ADDITIONAL COHORTS**

Use this area if you need to add an additional cohort, or if you prefer to add a more general description of your needs.

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**SPECIMEN AND SHIPMENT REQUIREMENTS FOR COHORTS**

**(1)** Please identify the quantity and characteristics of the specimens requested. If the same specimens and quantities are needed for all cohorts, specify “ALL” in the first column; otherwise, list the cohort number that reflects the donor criteria you wish to apply to each specimen request line.

**(2)** The “additives” column refers to chemicals that may be present in the original collection tube or container (e.g. heparin, EDTA, clot activators or separating gels, sodium citrate, etc.). To maximize accrual, enter “any.” If your analyses require that a particular additive be included or excluded, please specify. **(3)** Specimen volumes typically fall between 0.5 to 2ml; urine may be provided in larger amounts, up to about 5ml. Investigators may adjust the minimum volume default setting below, but 0.5ml is recommended in order to maximize collection. Because Novaseek typically provides the full amount remaining in the collection tube, **some samples will exceed the specified minimum volume**.

**SPECIMEN CRITERIA** *(To add additional rows, simply hit the “tab” key after the last column, “Shipping;” the box will expand automatically).*

 **Cohort # (or “ALL”) Quantity Specmen Minimum Additives Shipping**

 **Type Volume** *Can Accept Avoid Cold Ambient*

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| --- | --- | --- | --- | --- | --- | --- | --- |
| *EXAMPLE COHORT #1* | *10* | *Serum* | *0.5 ml* | *Clot Activator* | *Gel (SST)* | *X* |  |
| *COHORT #1* | *5* | *Urine* | *0.5 ml* |  |  |  |  |
|  |  |  | *0.5 ml* |  |  |  |  |
|  |  |  | *0.5ml* |  |  |  |  |

***Continue to next page to review and sign the Novaseek agreement.***

**BIOSPECIMEN TRANSFER and DATA USE AGREEMENT Novaseek Research**

This Biospecimen Transfer and Data Use Agreement (“Agreement”) is made by and between Novaseek Research, a Delaware corporation with a principal place of business at 275 Grove Street, Suite 2-400, Newton, MA  02466, and the authorized recipient (“Recipient”), named in the Application to Receive Biospecimens (“Application”), which is incorporated herein by reference

Novaseek’s approval of the Application in its sole discretion is a condition precedent to the formation of this Agreement.

**1. Use of Biospecimens and Restrictions.** The Recipient may use the Biospecimens for research purposes only
as specified in the Application. Recipient will not use the Biospecimens for the purpose of testing on human subjects,
or in clinical trials involving human subjects, or for testing on animals which are intended for human consumption, pursuant to all applicable U.S. Federal, state, and local laws. Individuals who have supplied human tissue to Novaseek have not agreed to have clinical tests performed on this tissue (for example, for the presence of infective agents such
as HIV or hepatitis), therefore, the Recipient agrees not to perform such tests on the tissues supplied by Novaseek.
Any Biospecimens delivered pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. Recipient agrees to comply with all applicable U.S. Federal, state, and local laws and regulations, in the procurement, use, handling, storage, and disposal of the Biospecimens.

**2. No Identifying Information.** The Recipient is strictly prohibited from obtaining or attempting to obtain information identifying the individuals providing the Biospecimens.

**3. Biospecimen Handling.** Novaseek does not claim and does not validate that the Biospecimens provided to Recipient will be free of any highly infective agents (such as Hepatitis or HIV). All Biospecimens should be handled
as if potentially infectious. The Recipient agrees that it will comply with, and is solely responsible for such compliance, all U.S. Occupational Safety and Health Administration (OSHA) regulations for the safe handling of human biological samples and safe laboratory practices. Further, the Recipient assumes all responsibility for informing and training personnel in the dangers and procedures for the safe handling and shipping of Biospecimens. Recipient agrees to comply with all applicable Federal, state, and local laws and regulations, in the procurement, use, handling, storage, and disposal of the Biospecimens.

**4. Data and Access.** Use or disclosure of Protected Health Information (“PHI”) is subject to protection under state and U.S. Federal laws, including the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, as amended (“HIPAA”) and implementing regulations. Novaseek will disclose and provide Recipient with access to certain PHI which may include demographic and clinical data that have been rendered a Limited Data Set, in compliance with 45 CFR 164.514 (e) (1). Under no circumstances is Novaseek required to provide Recipient with any PHI that is excluded as part of a “Limited Data Set” under its current definition (45 CFR 164.514 (e), as of the date of this Agreement.

**5. Conditions for Use and Disclosures of PHI.** Recipient may use and disclose the PHI in a manner consistent with and limited to the Recipient’s research purpose, as disclosed in the Application. The individuals or classes of individuals permitted to use or receive the limited data set include the Recipient and other researchers or individuals named in the Application. Further, Recipient agrees as follows:

 **a.** Not to use or further disclose the PHI, other than as permitted by this Agreement
 or as required by applicable law;

 **b.** To report promptly to Novaseek any access, use or disclosure of the PHI or any part of it
 not provided for by this Agreement of which Recipient or other agents become aware;

 **c.** To ensure that any agents, including subcontractors, to whom Recipient provides the PHI or any part
 of it, agree to the same restrictions and conditions that apply to the Recipient under this Agreement;

 **d.** Not to use the information contained in the PHI to identify the individuals whose information is contained
 in the PHI, nor to contact them under any circumstances;

 **Novaseek Agreement, Page 1 of 2**

**6. Proprietary and Other Intellectual Property Rights.** Novaseek will have no proprietary or other rights in or to
the Biospecimens, or any Progeny, Unmodified Derivatives, or Modifications of Specimens, or any other substances created by Recipient through the use of Biospecimens, or in any related PHI. For purposes of this Agreement:
**(a)** “Progeny” means unmodified descendants from Specimen, such as virus from virus, cell from cell, or organism from organism; **(b)** “Unmodified Derivative” means substances as created by Recipient, constituting an unmodified functional subunit or product expressed by Biospecimens, such as subclones of unmodified cell lines, purified or fractionated antibodies secreted by a hybridoma cell line; and **(c)** “Modifications” means substances created by Recipients which contain, incorporate, or include the Biospecimens.

**7. Publications.** Recipient has the right to publish or present the results of the Recipient’s research using the Biospecimens and PHI, without further approval of Novaseek.

**8. Biospecimen Orders and Payment.** Payment will be due to Novaseek in accordance with the terms agreed
upon by Novaseek and the Recipient at the time of approval of the Application. Terms and conditions for Biospecimen orders will be those in effect at the time of each Biospecimen shipment as mutually agreed by Novaseek and the Recipient. Fulfillment of biospecimen orders is subject to availability. Novaseek reserves the right, within its sole discretion, to serve or not to serve any Biospecimen orders.

**9. No Warranties, Limitation of Liability.** NOVASEEK MAKES NO REPRESENTATIONS OR WARRANTIES OF
ANY KIND, EITHER EXPRESSED OR IMPLIED, REGARDINGMERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NOVASEEK ACCEPTS NO RESPONSIBILITY FOR ANY INJURY (INCLUDING DEATH), DAMAGES, OR LOSS THAT MAY ARISE DIRECTLY OR INDIRECTLY FROM THE USED OF BIOSPECIMENS
OR DATA.

**10. Acceptance of Terms of this Agreement.** By affixing his or her signature below and returning a signed original copy of this Agreement to Novaseek, Recipient consents to be bound by all of the terms of this Agreement.

***Signed: Recipient: Title:***

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***Other Institutional Authorization (if any):***

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***Title: Date:***

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**Novaseek Agreement, Page 2 of 2**