This form will help confirm that you have **legitimate use** and **appropriate biorisk management** when ordering nucleic acid sequences of concern (SOCs). This form has three parts, all of which may be used for screening customers with flagged orders:

**■** Part 1. Order Information

*Completed by the customer placing the order.*

**■** Part 2. Legitimate Use

*Completed by the end user, i.e. the person who will work with the SOCs and understands the intended*

*use of the order. May or may not be the same individual as the customer.*

**■** Part 3. Biorisk Management

*Part 3 can be used to establish appropriate oversight for multiple orders that support the same project or*

*line of research.*

**●** 3A – Institutional Approval

*Completed by biosafety officer, biorisk manager, or another biosafety professional, if the end*

*user’s institution has such oversight.*

**●** 3B – Other Documentation

*Completed by the customer or end user if institutional approval is unavailable.*

**PART 1. ORDER INFORMATION**

**1.1 Does your order contain sequences of concern (SOCs)?**

*SOCs are sequences that may pose a biosafety or biosecurity risk, matching agents regulated by policies like export controls, the* [*UK Guidance*](https://www.gov.uk/government/publications/uk-screening-guidance-on-synthetic-nucleic-acids/uk-screening-guidance-on-synthetic-nucleic-acids-for-users-and-providers) *or the* [*US Framework*](https://aspr.hhs.gov/S3/Documents/OSTP-Nucleic-Acid-Synthesis-Screening-Framework-Sep2024.pdf) *or that contribute to pathogenicity, virulence, or toxicity.*

**Yes**, my order contains SOCs.

**No**. *You do not need to fill out this form.*

Unsure.

**1.2 Customer Information**

|  |  |
| --- | --- |
| Name | (Full legal name) |
| Institution | (Life sciences institution you are affiliated with, if any) |
| Email | (Institutional email address, if available) |

**1.3 Will your order require an export license?**

*Many countries have export controls regulating the transfer or some SOCs, including China, all 43 members of the*

*Australia Group (which include India, the EU, the USA, and Mexico), and Brazil, among others.*

**● Yes**, and:

**■** I have attached the required forms or licenses *(e.g., U.S. Form BIS-711, India IEC Certificate)*

**■** I need guidance on what forms or licenses are required

**●****No**, because:

**■**  My shipping address is in the same country as the provider

**■** My order is not subject to export controls

**●**Unsure.

**1.4 Will you or your close collaborators be the end users of the synthetic nucleic acids you order?**

**● Yes**, *I will use the sequences I order myself or will work closely with others using them. I understand*

*their intended use.* 🡪 Part 1 is complete. Please complete Part 2 and Part 3.

**● No**, *I am ordering on behalf of others and/or am not fully familiar with how these materials will be used.*

**1.5 What is your relationship with the end users?**

**●** I am ordering on behalf of someone else at my institution

🡪 Please have them complete Part 2 and Part 3.

**●** I am ordering for distribution outside my institution (e.g. to customers or collaborators)

🡪 Please answer Question 1.6.

**●** Other (please explain):

**1.6 For materials being distributed outside your institution, do you have biosecurity screening procedures?**

**● Yes**, I confirm we:

* Verify the end user’s identity and institutional affiliation
* Screen sequences against a database of sequences of concern
* (For orders with SOCs) Verify that the end user has legitimate end use and appropriate biorisk management

*You do not need to provide Part 2 or Part 3.*

**●** **No**.🡪 Please identify the end user and have them complete Part 2 and Part 3.

**PART 2. LEGITIMATE USE**

*This part should be completed by the end user. The end user is the person who will work with the SOCs and understands the intended use of the order. May or may not be the same individual as the customer.*

**2.1 End User Information**

|  |  |
| --- | --- |
| Name | (Full legal name) |
| Institution | (Life sciences institution the end user is affiliated with, if any) |
| Email | (Institutional email address, if available) |

If the end user is not affiliated with a life sciences institution, or if their email does not match the institution listed, please explain:

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**2.2 What is the intended end use for the SOCs?**

*Please briefly describe how the SOCs will be used, and peaceful purpose. You may wish to describe details of the context (e.g. PhD research program, diagnostic test development, DNA data storage) or experimental design (e.g. constructing a recombinant strain, CRISPR mutagenesis library).*

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**2.3 Attach or provide a link to one or more kinds of documentation to establish that you are a legitimate member of the scientific community.**

*You may include documentation that shows one or more of the following (check all that apply):*

**■** Research history

*(e.g. ORCID, Google Scholar or ResearchGate profile, links to publications or conference*

*participation)*

**■** Institutional affiliation

*(e.g. profile on institutional website, LinkedIn, employment documentation)*

**■** Project documentation

*(e.g. grant numbers, press releases, research plan)*

**■** Government-issued approvals

*(e.g. licenses to work with regulated pathogens, export control forms, business licenses)*

Describe the documentation you have provided and what it shows.

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Signature of End User

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

**PART 3. BIORISK MANAGEMENT**

*This part should establish that the end user has appropriate biorisk management when ordering nucleic acid sequences of concern (SOCs).*

**3.1 End User**

*The end user is the person who will work with the SOCs and understands the intended use of the order.*

|  |  |
| --- | --- |
| Name | (Full legal name) |
| Institution | (Life sciences institution the end user is affiliated with, if any) |
| Email | (Institutional email address, if available) |

If end user is not affiliated with a life sciences institution, or if their email or shipping address does not match the institution listed, please explain:

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**3.2 Intended End Use**

*Briefly describe the purpose for which the SOCs will be used; this description (and this part of the form) may apply to multiple orders for synthetic nucleic acids that support the same project or line of research.*

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**3.3 Has the intended end use been reviewed and approved by a biosafety officer, biorisk manager, or another biosafety professional?**

**●** Yes 🡪 Complete Section 3A.

**●** No 🡪 Complete Section 3B.

**3A. Institutional Approval**

*This section should be completed and signed by the biosafety officer, biorisk manager, or other biosafety professional responsible for overseeing the project.*

**3A.1 Institutional Oversight Contact**

|  |  |
| --- | --- |
| Name | (Full legal name) |
| Title |  |
| Email | (Institutional email address, if available) |
| Phone number | (+ \_\_ (\_\_\_) \_\_\_\_\_\_\_\_) |
| Link with additional information | (If applicable, e.g. biosafety office homepage, employee directory) |

If their email does not match the institution listed, please explain:

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**3A.2 What biorisk management practices are in place for the intended end use of the SOCs?** *(check all that apply)***:**

**■** Formal oversight

*(i.e., review and approval from institutional biosafety committee, biosafety officer, biorisk*

*manager, or another biosafety professional)*

**■** Laboratory biosafety

*(e.g., PPE, biosafety cabinets, waste management, emergency procedures)*

**■** Physical biosecurity

*(e.g., restricted laboratory access, secure specimen storage, controlled material transfers)*

**■** Personnel security

*(e.g., biosecurity training and certification, background checks, personnel reliability program)*

**■** Regulatory approval for working with controlled life sciences materials

**■** *(e.g., U.S. Federal Select Agent Program Registration, U.K. HSE form CU-1, Australia OGTR license)*

**■** None of these. Please explain:

**3A.3 Approval**

I, (Full legal name), as the biosafety professional responsible for overseeing this work, have reviewed the safety and security measures for this intended end use. I approve orders of SOCs in support of this work.

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Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date

**3B. Other Documentation of Biorisk Management**

*This section should be completed and signed by the customer or end user if Section 3A cannot be completed.*

**3B.1 Attach or provide a link to one or more kinds of documentation to establish that your institution is legitimate.** You may include documentation that shows one or more of the following *(check all that apply)*:

**■** Institution is an established legal entity

*(e.g. official incorporation documents, business license, tax documents)*

**■** Institution has a mission or purpose that includes life sciences

*(e.g. annual report, grant documents, contracts)*

**■** Institution provides biosafety oversight or training

*(e.g. documentation of biosafety oversight, codes of conduct)*

**■** Institution is part of the scientific community

*(e.g. scientific publications, participation in relevant conferences, Material Transfer Agreements with*

*established life sciences institutions)*

**■** Institution has obtained regulatory approval or official certification for work with life sciences

materials

*(e.g. local approvals such as fire safety inspections, national approvals to work with GMOs such as U.K.*

*HSE form CU-1 or Australia OGTR license)*

Describe the documentation you have provided and what it shows:

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**3B.2 What biorisk management practices do you have in place?**

Describe the biosafety and biosecurity practices that are in place for the intended end use. You may reference 3A.2 for examples of biorisk management practices.

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How are these practices appropriate for the intended end use of the SOCs?

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Signature

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Date