



The British Society for Antimicrobial Chemotherapy

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Policy for the Supply of Isolates and Data from the BSAC Resistance Surveillance Project

Background and Principles

1. The BSAC exists to facilitate the acquisition and dissemination of knowledge in the field of antimicrobial chemotherapy.
2. The BSAC Resistance Surveillance Project began collecting and testing current clinical isolates in 1999 and has since built up a unique resource comprising a large number of bacterial isolates (the 'Isolate Collection') together with extensive information on their microbiology and provenance (the 'Data').
3. The BSAC Resistance Surveillance Project has been supported by the BSAC and largely funded by sponsorship from pharmaceutical companies ('Sponsors').
4. The Isolate Collection is held on behalf of the BSAC by other organisations ('Central Laboratories') under contract.
5. Allowing access to the Isolate Collection for further research is perfectly aligned with the BSAC's charitable purpose, and hence there is a general presumption in favour of isolate supply for academic research. However, there is an overriding priority to protect the long-term viability of the Resistance Surveillance Project for future benefit, and this may sometimes conflict with the wish to supply isolates, particularly to commercial organisations.
6. As a charity, the BSAC has a duty to protect its assets, including intellectual property, and to ensure, as far as reasonably possible, that any value they generate is applied to its charitable purposes.
7. The level of scrutiny used to assess requests for access to the Isolate Collection or to the Data will be proportionate to the nature and scale of the proposed use, taking into account (by way of example) whether a large number of isolates are involved, whether their use could undermine the sustainability of the Resistance Surveillance Project, and whether there are considered to be potentially contentious issues involved.
8. The authority to decide whether or not to supply Isolates and Data in any particular case rests with BSAC Council, which may delegate this responsibility to the BSAC Working Party on

Resistance Surveillance (the 'Working Party'), or to an individual, in order to give requests a proportionate level of scrutiny.

Key Points

9. The BSAC makes a distinction between academic and commercial projects. Academic projects are generally conducted by researchers in a non-commercial organisation, with funding from public or charitable sources. Commercial projects are generally conducted by, or in partnership with, a commercial organisation.
10. The BSAC will continue to own its Isolates and Data, and all rights associated with them. These are not sold to Researchers but licensed to them on a non-exclusive basis - the BSAC can supply the same Isolates and Data to other researchers; the receiving Researcher cannot.
11. The license lasts for the duration of the project, as specified by the Researcher in their application. If no time-limited project is specified, typically in the case of a Sponsor, the license lasts for a fixed period which is specified in terms and conditions.
12. For academic projects, the results of the research can only be kept confidential for a limited period before being returned to the BSAC. The results can then be made available for the BSAC and other Researchers to use in conjunction with the BSAC Isolates and Data, so that the value of the Isolate Collection is enhanced for the public good. If commercial benefit arises from inventions and intellectual property rights developed by Researchers using the Isolates or Data, the BSAC and other parties involved will negotiate to share any profits remaining after the costs of development and commercialisation.
13. For commercial projects, results may be kept confidential and, during the initial term of the licence, the BSAC will not share in commercial benefit arising from inventions and intellectual property rights developed by Researchers using the Isolates or Data
14. In all cases, the BSAC requires that inventions and intellectual property rights developed by Researchers using the Isolates or Data are not used to restrict health-related research and/or access to healthcare unreasonably anywhere in the world. (For example, without limitation, BSAC would consider it unreasonably restrictive for naturally-occurring genetic sequences, biomarkers, proteins or biochemical processes to be made the exclusive preserve of one party.)
15. The Researcher is primarily responsible for publication, and is not required to clear any report of its results and findings with the BSAC, but publications must include a credit to the BSAC and Researchers will provide the text to the BSAC for preview before submitting it for publication.

Policy

16. Standard terms and conditions for isolate supply approved by BSAC Council embody the principles and points outlined above, and cover use of both Isolates and Data supplied with them. The terms and conditions may be amended by Council from time to time.
17. The terms and conditions differ in detail between academic and commercial projects. Commercial terms (other than price) apply to Sponsors.
18. Researchers must accept the standard terms and conditions before isolates are supplied. For small* academic projects, acceptance by the principal investigator will suffice. For larger

academic projects, and all commercial projects, written acceptance by another authorised representative of the organisation is also required.

19. Price.
 - a. The actual cost of supplying isolates is defined annually by contract between the BSAC and the Central Laboratories.
 - b. The price for academic supply and supply to Sponsors will not exceed the actual cost.
 - c. The price for commercial supply (other than to Sponsors) will be set initially to give approximate parity with commercial rates charged by, for example, HPA Culture Collections and similar bodies but may include a sliding scale of discount depending on the number of isolates required.
20. Isolates will normally be made available only after publication of data for the relevant surveillance season e.g. on the BSAC surveillance website.
21. Data requested without accompanying isolates will be shared according to prevailing academic norms, which do not generally require formal acceptance of terms and conditions.
22. The Data does not include sensitive information but, nonetheless, suitable steps will be taken to protect confidentiality in line with current guidance.

Delegation and guidance

23. BSAC Council delegates to the Working Party the responsibility for deciding whether a particular project should be considered academic or commercial.
24. BSAC Council delegates to the Working Party the responsibility for setting the exact price for commercial isolate supply, including any discounts depending on the number of isolates required.
25. Requests for small numbers of isolates for academic use will normally be fulfilled. BSAC Council delegates the authority to approve such requests to the Working Party, which may further delegate it to an individual.
26. Requests for larger numbers of isolates for academic use will be considered by the Working Party. BSAC Council delegates the authority to approve such requests to the Working Party.
27. Requests from current Associate Sponsors for small numbers of isolates collected during the period of their sponsorship will normally be fulfilled. Council delegates the authority to approve such requests to the Working Party, which may further delegate it to an individual.
28. Requests from current full Sponsors for any number of isolates collected during the period of their sponsorship will normally be fulfilled. Council delegates the authority to approve such requests to the Working Party and, where the request is for a small number of isolates, the Working Party may further delegate the approval to an individual.
29. Requests from organisations other than Sponsors for isolates for commercial use will be considered by the Working Party. Where the request is for a small number of isolates, BSAC Council delegates the authority to approve such requests to the Working Party. In other cases, the Working Party will make recommendations to BSAC Council for final decision.
30. BSAC Council delegates the responsibility for decisions about the sharing of Data (separate from isolates) to the Working Party, which may further delegate it to an individual.
31. In all cases, the Working Party or individual with delegated responsibility will use their judgement and refer the decision to a higher level of responsibility as they consider

appropriate if there are unusual circumstances or doubts about the suitability of the proposed project, organisation or researcher.

Process

32. Requests for isolates and/or data will be referred initially to the BSAC Resistance Surveillance Co-ordinator
33. The Co-ordinator will liaise with the requesting Researcher to obtain relevant details of their proposed research.
34. The Co-ordinator will deal with the request, informing or referring to the Working Party as appropriate depending on the nature and scale of the proposed project. The Working Party likewise will inform or refer to BSAC Council.
35. The Co-ordinator will inform the Central Laboratory if and when supply is approved. The Central Laboratory will not supply any isolates before receiving this approval.
36. The Central Laboratory and the Researcher will make practical arrangements between themselves for the preparation and transport of isolates. The Central Laboratory will supply sufficient information with the isolates to identify them and enable them to be handled safely and efficiently (typically, their BSAC identity code and their genus/species).
37. The BSAC, through the Working Party and Co-ordinator, will supply any further information about the isolates as has been agreed with the Researcher.
38. Payment
 - a. For supply at cost price (to academic projects and Sponsors) payment will be made directly to the Central Laboratory.
 - b. For supply at commercial price, payment will be made to the BSAC, and the BSAC will pay the agreed cost price to the Central Laboratory promptly following receipt of invoice.

***Small**

For the purposes of this policy, a small number of isolates means not more than 20 isolates from any one testing group and not more than 60 isolates in total in any one year. A small project means a project using a small number of isolates.

Last reviewed and approved: April 2012

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