health
Department:
Health
REPUBLIC OF SOUTH AFRICA

SOUTH AFRICA
FREQUENTLY ASKED QUESTIONS (FAQs) IMPORT/EXPORT PERMIT PROGRAMME

(HUMAN TISSUE, BLOOD, BLOOD PRODUCTS, CULTURED CELLS, STEM CELLS, EMBRYOS, FOETAL TISSUE, ZYGOTES & GAMETES/ HUMAN PATHOGENS)

Number	Question	Comment / Answer
1.	When did the regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, zygotes and gametes come about?	2012
2.	How did the regulation come about?	Informed by the National Health Act, 2003 (Act No. 61 of 2003)
3.	Why did the regulations come about?	To control & manage Health Ports of entry. All regulations are promulgated to govern and control certain activities e.g. import/export of human tissue, blood, blood products etc.
4.	Who do the regulations apply to?	The regulations apply to all authorised individuals / institutions in South Africa i.e. people dealing with human biological specimens/human pathogens
5.	Where can a copy of the legislation/regulations be obtained?	www.doh.gov.za Resource centre Legislation
6.	Why is this process being enforced now?	The challenge is from the Health Ports who were not enforcing it
7.	Would this process apply to all UN3373 Biological Substance, Category A and B samples, human pathogens being exported / imported?	Yes – applies to all Biological Substance samples

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8.	Who are automatically authorised?	• Doctors • Hospitals • Universities • Technikons
9.	What needs to happen if an organisation / institution are not authorised?	A letter needs to be addressed to the Director-General: Health making application for authorisation
10.	Does each investigator site need to complete an export / import application form and obtain a permit?	Yes
11.	Is there a deadline for the investigator site/s to adhere to in terms of compliance with this regulation?	Need to make application before they export / import biological substance
12a.	Will an export / import permit be needed for investigator sites that are already participating on current or old clinical trials?	Yes, if they do not yet have a permit
12b.	If so, would the export / import permit application process be the same?	Yes
12c.	If so, is there a time frame or a sliding scale i.e. let us say that a study has 3 months left versus 1 that has 18 months left?	No. The permit will still be valid for a year
13.	Does an investigator need to apply for an export permit if Biological Substance samples are sent to a local laboratory for analysis and then the laboratory exports the samples overseas?	No, the laboratory is responsible for making application for an export permit NB. The Department may require proof of protocol

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14.	For what period of time is an export / import permit valid for?	12 Months
15.	Can an export / import permit be issued for longer than a period of 12 months?	No, permits are renewable on a 12 month period
16.	If an investigator site is running multiple clinical trial studies going to the same destination, would they need to make application for separate export permits?	Yes. A separate export / import permit is required per study / protocol
17a.	Can application be made for a combined export permit for more than one type of commodity (i.e. blood, urine etc.)?	Yes you can use one application for different types of samples per applicant and per study
17b.	Must a separate application be made per type of commodity; per applicant and per study?	No. Please refer to comments in point 18a
18.	From which National Authority must the approval of a shipment be obtained?	National Department of Health
19a.	Does a physical copy of the export permit have to be attached to the shipment when it is being exported?	Yes, otherwise the goods will not be allowed to go through the Port
19b.	Can a copy of the export permit not be physically attached to the shipment but a copy be kept on file should any queries arise?	No, it is required at the Port. They have been instructed to ask for the permit with regards to all shipments

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20.	How can one determine if an organisation / institution are authorised to export / import?	The Department of Health has records of all authorised institutions
21.	How can one determine who within an organisation / institution (i.e. lab) is authorised to apply for permits?	Laboratory Manager; Quality Manager; Doctors(and should be registered with HPCSA)
22.	Do people within an organisation / institution need to be on a specific level to be authorised? If so, who would normally be authorised in terms of titles?	Laboratory Manager; Quality Manager; Doctors, Scientist, Medical Technologists (and should be registered with HPCSA)
23.	How many people per organisation / institution can be authorised to export / import?	There is no limit
24a.	Can a blanket authorisation be issued to an organisation that has multiple people working with the export / import of biological samples?	The Department of Health does not issue blanket permits for organisations conducting clinical trials
24b.	If so, what process needs to be followed and whom does it need to be addressed with?	Not applicable
24c.	If not, then instead of applying for a new permit can an addendum of change be attached with a change in applicant information on the current valid permit?	No, reapply

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25.	In the case of staff turnover or changes within an organisation, how would it be determined what positions can be authorised?	The organisation should decide on who can be given the responsibility for applying for permits Provided the individual is registered with the HPCSA
26.	If a sponsor requests that samples be sent from an investigator to a lab for storage purposes, where they are stored over a period of time (say 3 to 6 months) before an instruction is received to ship them overseas but no local lab analysis takes place, which would be responsible for making application for the permit?	The laboratory exporting the samples, but the Department may require copy of protocol for issuing permit
27.	Can the Department of Health provide a copy of the organisational structure for the complete export / import permit process?	Yes
28.	Can the Department of Health provide a completed contact list in terms of export / import permit applications for biological substances/human pathogens?	Our contact details are as follows: Ms Lineo Motopi – Technical queries Tel: 2712 395 8366 Ms Oketsang Mohlamonyane – General/administrative queries Tel: 2712 395 8965 Mr Mpho Mahlane – Progress on application Tel: 2712 395 9045 Ms. P. Netshidzivhani – Complaints Tel: 2712 395 8856/9434

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29.	What is the Department of Health escalation process?	**Technical Enquiries:** Ms L Motopi **Administrative Enquiries:** Ms O Mahlamonyane Mr M Mahlane **Complaints:** Ms P Netshidzivhani
30.	What is the Department of Health operating hours?	Monday – Friday: 08h00 to 16h00 Weekends and public holidays: closed
31a.	Does the Department of Health have representation in the Bloemfontein and Cape Town regions?	The Department of Health operate on a National level only with the national office being based in Pretoria.
31b.	If so, please could the details of the other Department of Health offices be provided?	No offices in other provinces
32a.	Are there any planned changes in terms of roles and responsibilities with regards to the export / import permit sector of the Department of Health?	No
32b.	If so, what are the planned changes?	Not applicable

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33a.	Will there be any planned changes for the export / import permit sector?	Ms Motopi/Mohlamonyane will remain the main point of contact
33b.	If so, what are the planned changes?	Not applicable
34.	How many export / permit application forms are processed by the Department of Health per day?	On average 70 per day if there is only 1 person functional and approximately 200 per day if 2 people are functional
35.	How can SACRA help the Department of Health in terms of expediting the process?	Free to approach the Cluster Manager: Ms Pakiso Netshidzivhani
36.	Where can one obtain a copy of the export / import permit application document?	www.gov.za Depart of Health Documents Forms 2012 Permit applications
37.	What is the export / import permit application process?	The authorised individual correctly completes and signs the application form and emails it through to the Department of Health for processing
38.	What process other than that of the export / import permit application needs to take place?	No other process

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39.	Can guidelines be provided as to the best method to complete the export / import permit application form?	Simply follow the instructions on the form Complete the correct information: • Applicant details with full physical address; telephone and facsimile numbers • Product to be exported / imported and quantity • Protocol number • Period required for export / import • Full details (physical address; telephone and facsimile numbers) of whom the product is being exported to or imported from • Reasons for export / import
40.	What is the cost involved?	No cost involved
41.	What is the best method to use for submission of applications?	Send the export / import permit application to the email: importexportpermit@health.gov.za
42.	Are there any institutions; investigator sites or organisations that have made special arrangements to expedite their export / import permit applications?	No. All applicants are treated equally
43.	If so, please confirm what process needs to be followed to arrange the same for other organisations; investigators and organisations?	There is no special treatment for any client in place

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44a.	Are there any plans for an electronic application process to be made available by the Department of Health in the future?	Yes
44b.	If so, when is this expected to take place?	To be advised in future
45.	Will an electronic signature system be implemented in the near future?	Yes, we are working on implementing online applications and permit issuing. To be advised in future
46.	What is most important in terms of the applicant's signature?	The main issue is for the applicant themselves needs to sign the application document and not the coordinator of the project
47.	Are P.O. Box address details acceptable on the export / import permit application?	No. The Department needs the physical address for possible site inspection purposes
48.	Is a physical address required for both the sender and the receiver on the export / import permit application form?	Physical address of applicant is mandatory
49.	What purpose / reason should be included on the export / import permit application form?	Specific purpose i.e. clinical research
50.	What level of detail is required for the product description on the export / import permit application form?	Keep it simple i.e. blood; plasma; serum etc. Please include number of patients and volume per shipment.

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		Please note: Investigator may not export / import more than 5 litres at any given time. If there are too many patients participating on the clinical trial then the information will be split in order for multiple export / permits to be issued. It is the investigators responsibility to ensure that they monitor and manage the amount sent per shipment so the 5 litres limit is not exceeded.
51a.	Does a copy of the protocol need to be attached to the export / import permit application?	No. The Department of Health has requested that this please not be attached
51b.	Will the protocol number be included on the export permit?	The protocol number can be added on the same line as the doctor/principal investigator's name
52.	Can an organisation / institution (i.e. laboratory; courier etc.) make application for the export / import permit on behalf of the investigator?	No. The investigator is responsible for applying for the permit Organization / institution can assist with the export / import permit issue process
53.	Can an organisation / institution semi-complete an export / import permit application form, send it to the investigator for signature, and receive it back confirming information is correct and signed and submit application to the Department of Health on behalf of the investigator?	Yes. The critical part is that the applicant must sign the application and not the organisation / institution on their behalf

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54.	Could the CRO (Central Research organisation) complete the form and the investigator sign it?	Yes, provided all the information is correct and that the doctor/investigator realises that he / she is ultimately responsible if anything goes wrong or is incorrect
55.	Can an organisation / institution collect all the signed export permit applications from multiple participating investigators and submit directly to the Department of Health for processing in a batched format?	Yes, provided that the investigator has signed their own export permit application form as the actual sender
56.	Can a laboratory that is based overseas (i.e. Belgium) make application for the export permit on behalf of the local investigator in the case where biological samples are exported directly overseas for analysis?	No. Permits are only issued to South African citizens because the legislation is aimed at South Africans and is therefore only operational in South Africa
57.	What is average period of time that it takes to complete an export / import application process?	Takes on average 3 days to complete the process (submit; issue; fax back to client and post original to the applicant). Should take a maximum of 7 working days
58.	Do micro-organisms require an export permit?	Yes. Apply for the authority to export / import. Make use of the same Department of Health contacts
59.	Could an example of a correctly completed export / import permit application be made available?	Yes

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60.	What (if any) are the limitations / conditions related to the shipment of tumour samples?	There are no limitations or conditions
61.	Is an application and subsequent approval required before the shipment of tumour samples?	Yes
62.	Who needs to be the applicant in tumour samples shipment permission?	The doctor
63.	What documentation is required for the shipment permission application for tumour samples?	The same as other biological substances
64.	What is the duration of the shipment permission application process?	A year/12 months
65.	Can an organisation apply for one export permit for multiple protocols with the same destination?	Currently, each protocol must have its own permit. However, this may change in the future
66.	Can an organisation apply for one export permit for multiple protocols with the same destination?	Currently, each protocol must have its own permit. However, this may change in the future
67.	Can an organisation apply for one export permit for multiple protocols with the same destination with various sample sizes and containers put into one box (one type of commodity)?	Currently, each protocol must have its own permit. However, this may change in the future

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68.	Can an organisation apply for one export permit for multiple protocols with the same destination with various sample sizes and containers put into one box (multiple types of commodities)?	Currently, each protocol must have its own permit. However, this may change in the future
69a.	In Africa normally only P.O. Box addresses are available. Can this be used and what happens to these applications?	P.O. Box address is allowed for outside country recipients
69b.	Can a concession be implemented to allow for P.O. Box addresses?	P.O. Box address is allowed for outside country recipients
70a.	In Africa normally the facsimile number is not always available. Can this section on the application document be left blank?	Yes. Leaving it blank is acceptable
70b.	Can a concession be implemented to allow for the facsimile number to be left blank?	Yes. Leaving it blank is acceptable
71.	What application document would need to be used for tissue samples?	Same one used for biological substances
72.	What does the export / import permit issue process entail?	If the application form is completed properly, the export / import permit is processed, authorised and sent to the applicant 1. Application is received by the team at importexportpermit@health.gov.za 2. Permit is processed 3. Draft permit is reviewed by Ms Motopi/Ms Mohlamonyane

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		4. Draft permit is submitted to the Cluster Manager for final review and issuing 5. Issued permits are faxed through to the applicants 6. Copies are made by the Department of Health for record keeping
73.	How long does it take for an export / import permit to be issued?	Approximately 21 days
74.	What problems are being experienced in terms of delays in the issuing of export / import permits?	Since 2012 we received a higher number of applications than previous years. We communicate with applicants for applications not filled properly which generally lead to delays in finalising the permits thus creating a backlog.
75.	What steps can be taken to alleviate the backlog?	• Correct completion of the application • Correct signature on the application
76.	When is the backlog expected to be cleared?	Many factors contribute to the backlog and delay and this varies from application to application. Since 2012, it takes 15 working days to finalise the applications should the applicant have completed the form correctly
77.	What factors can contribute to causing a delay in the issue of export / import permits?	• Incorrect information completed on the application form • Incomplete application forms • Unauthorised person has signed the application form

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		• Backlog of applications • Department of Health currently only have one facsimile line
78.	Should the protocol number appear on the export / import permit?	Yes. The protocol number should appear next to the doctor's/principal investigator's name on the permit
79.	What happens if the Cluster Manager is not available to sign issued export / import permit applications?	There is always a person delegated to handle sign issued permits
80.	What is the Department of Health's contingency plan when export / import permit delays are experienced?	Ms Motopi & Ms Mohlamonyane will do the processing during the heavy backlogs
81.	Who can be contacted in the event that there is a delay in the signing of the export / import permit?	Enquiries can be referred to the Cluster Manager: Ms P Netshidzivhani (012) 395 8856/9434
82.	What is the application follow up process?	The applicant can phone the Department of Health to find out about the status of the permit request Phone Oketsang/Mpho on (012) 395-8965/9045 with the following information on hand: • Name of the applicant • Date sent to Department • Type of permit applied for Or Phone Ms Motopi on (012) 295-8366