

APPENDIX Q: POLICY PROTOCOL FOR SATELLITE COCHLEAR IMPLANT UNITS

SUMMARY

A satellite cochlear implant programme is developed with the purpose of extending audiological (assessment, mapping and rehabilitation services) services to patients who have difficult accessing the core cochlear implant programme. The satellite programme falls under the umbrella of the Core Cochlear Implant Programme. This document outlines the structures, roles and functions of the satellite unit in relation to the Core CIP.

1. INTRODUCTION

The _____ Cochlear Implant Programme has established and developed Satellite Cochlear Implant Units with the purpose of extending the audiological services of the programme to the public.

The following are definitions, conditions and protocols that will apply in the establishment of these Satellite Units.

Abbreviations and Definitions

XXXXXCIP: XXXXXXXX Cochlear Implant Programme

S-CIU: Satellite Cochlear Implant Unit

Services: Appropriate management of adult and paediatric cochlear implant candidates and users

Identified audiologist: The specific audiologist who has been identified within the Satellite Unit who will provide cochlear implant management services

2. PURPOSE OF THE PROTOCOL

The purpose of this protocol is to identify and define the undertakings, roles and responsibilities of _____ CIP and the Satellite Unit(s) that will result in best practice and service delivery to cochlear implant users, new candidates and their families.

3. BACKGROUND

The first Cochlear Implant Programme in South Africa was established in November 1986 at Tygerberg Hospital-Stellenbosch University where patients from all over South Africa were referred to and received their cochlear implants.

In the 1990s new cochlear implant programmes were established in South Africa after surgical and audiological training of core team members. The following cochlear implant programmes were established: Pretoria (1990) and Johannesburg (1991). Since 2003 further cochlear implant programmes across South Africa were established due to an increased demand in service delivery.

The successful development of Cochlear Implant Programmes in South Africa can be attributed to the principle of a strong multidisciplinary team approach in the evaluation and management of patients for both the short and long term.

A cochlear implant programme is responsible for the lifelong follow-up management and care of cochlear implant users, specifically audiological services. As a result of an exponential increase in patient numbers, this places pressure on available audiological support in local programmes. In order to address this challenge of growing patient numbers, as well as to accommodate the travel and often accommodation requirements for visits by patients, the need arose for the development of satellite audiology services which would be able to support the primary CIP.

4. NAME AND ROLE OF THE COCHLEAR IMPLANT UNIT

The name of the programme is: _____ Cochlear Implant Programme. This is the primary/core programme.

5. NAMES OF SATELLITE COCHLEAR IMPLANT UNITS (S-CIU)

5.1

5.2

6. DESCRIPTION OF UNIT

COCHLEAR IMPLANT

_____ is the primary /core programme that services a specific geographic area of South Africa; namely _____. Services include complete surgical, audiological and (re)habilitative care, including assessment and selection of suitable cochlear implant candidates.

7. DESCRIPTION OF THE SATELLITE COCHLEAR IMPLANT UNIT (SU)

The satellite cochlear implant unit (S-CIU) is identified, developed and supported only by _____ CIU. The S-CIU provides only audiological and rehabilitative services to implant users. Surgical procedures are provided by the surgeon(s) of the core programme only.

Local, appropriate ENT care should be available for remote SUs where an ENT surgeon with specific otology experience is identified, trained appropriately and supported by the core programme. The ENT identified would be invited to join the South African Cochlear Implant Group (SACIG) in order to remain upskilled in the field of cochlear implantation.

8. QUALIFICATIONS OF ENT SURGEONS AND AUDIOLOGISTS

The ENT surgeons are trained in cochlear implant surgery according to the national South African Cochlear Implant Group (SACIG) guidelines.

The _____ CIU ENT surgeons are:

- 8.1
- 8.2
- 8.3
- 8.4

The audiologists belonging to _____ CIU and to the S-CIUs are required to have Additional Training in Cochlear Implant Mapping and Rehabilitation (accredited by HPCSA) with a Certificate of Competence provided by an accredited training institution in South Africa and to be registered with SACIG as a Cochlear Implant Audiologist.

All the audiologists are expected to have at least 5 years of experience in adult and paediatric audiology. An audiologist with less than this amount of experience should work under the supervision of an experienced, accredited audiologist.

9. TRAINING

9.1 A minimum of basic, ongoing support and training is required for the successful implementation and future sustained mutual function of the _____ CIU and the S-CIU. The S-CIU audiologist is expected to attend training and all the team meetings of the Core team.

9.2 Training functions include the development and maintenance of skills in order to ensure a continued and consistently high, appropriate standard of service delivery.

9.3 Training and support by _____ CIP will be provided in the following speciality areas to the S-CIU audiologist:

- Referral criteria of patients for cochlear implantation;
- Decision-making regarding referrals of cochlear implant users;
- Evaluation and management of potential and new cochlear implant users according to the _____ CIP and SACIG protocols;
- Ongoing monitoring and long-term management of existing cochlear implant users according to _____ CIP and SACIG protocols;
- Decision making with regards to referring patients back to the _____ CIP
- Programming of electrodes of existing cochlear implant users;
- Audiological rehabilitation and management of cochlear implant users;
- The _____ CIP coordinator will provide forms and protocols as required by the S-CIU. The forms should be named appropriately: e.g. _____ CIU Satellite Unit;
- Identification of faulty sound processors, replacement of these and sending of equipment for repair;
- Troubleshooting of equipment of cochlear implant users;

9.4 Training by Distributors of Cochlear Implant Systems will include the following:

- Continuous, timeous updates of information about cochlear implant systems (internal and external components), software, mapping, accessories and other new developments;
- Regular clinical and technical support will be provided by the relevant company/ies to the S-CIU;

- Distributors will provide the necessary hardware required for appropriate service delivery to new and existing cochlear implant users.

Training will be done at _____ CIP or on site and should be attended by all _____ CIP S-CIU audiologists. Training may also be offered at other centres and where appropriate S-CIU audiologists should attend this training.

10. THE ROLE AND CLINICAL FUNCTIONS OF _____ COCHLEAR IMPLANT PROGRAMME is located in _____.

_____ CIP (Coordinator) oversees and is responsible for all decisions regarding the selection of patients, policies, protocols, allocation of state funds for patients, skills development and academic training of staff members. Some of these decisions and activities are made/occur at monthly team meetings that are attended by the ENT surgeons, radiologists, audiologists and speech-language therapists, or on special request of other appropriate team members who are invited to attend the team meeting. The S-CIU audiologist is required to attend all team meetings.

Additional _____ meetings are attended by the audiologists alone to discuss general management and policy issues of _____ CIP, equipment, management decisions, internal issues, protocols as well as academic training. Additionally, patients are allocated and complex cases discussed. S-CIU audiologists are not expected to attend these meetings but are welcome to do so should they wish or they could be requested to attend for a specific reason.

An annual planning meeting is held once a year and should be attended by S-CIU audiologists.

A further role of _____ CIP is to support the S-CIUs with clinical support, discussion about patient management and MAPping as well as queries related to software. These consultations can take place telephonically or by email.

Visits can also occur by the Coordinator or a core audiology team member, in particular during the establishment phase of the SU.

Other clinical functions of _____ CIP include:

- 10.1 Patient selection;
- 10.2 Surgical services;
- 10.3 Audiological evaluation: pre- and post-operative assessment including establishment of hearing thresholds (aided and unaided, ear specific), speech perception testing (including assessment of assistive listening devices);
- 10.4 Self assessment scales and other questionnaires as per current _____ CIP and SACIG protocols;
Results may be required for partaking in research projects.
- 10.5 Intra-operative testing;
- 10.6 Counselling and consent: pre and post-operative;
- 10.7 Programming of electrodes (MAPping);
- 10.8 Audiological rehabilitation and patient management;
- 10.9 Case discussions (pre- and post-operative) with other team members;
- 10.10 Attendance of case discussions at schools and other locations;
- 10.11 Identification and troubleshooting of faulty sound processors or other equipment;
- 10.12 Fitting of loan / replacement sound processors;
- 10.13 Maintenance of parts and additional equipment;
- 10.14 School visits and training of school personnel as required;
- 10.15 Research projects (includes contribution to and initiating);
- 10.16 Appropriate forms and protocols (including as these develop and change) will be provided to the S-CIU by the _____ CIP Coordinator.
- 10.17 A team member audiologist should be available over holiday periods for emergency cases.

11. CURRENT SACIG-REGISTERED TEAM MEMBERS OF _____ CIU

<u>NAME</u>	<u>ROLE</u>

Name of Satellite Unit Audiology team member(s):

12. ACADEMIC ACTIVITIES OF _____ CIU

- 12.1 Presentations and attendances at workshops;
- 12.2 Monthly academic training;
- 12.3 Continued education and training by service providers.
- 12.4
- 12.5

13. RESEARCH

Any research undertaken is to take place in cooperation with and under the supervision of _____ CIP (Coordinator). Consent should be obtained from the Ethics Committee of _____. Any publication or presentation should acknowledge the _____ CIP/U audiologist who supported and assisted with the research project or presentation.

14. ADMINISTRATIVE ACTIVITIES OF _____ CIP

- 14.1 Maintenance of the database and record-keeping of all patients (inclusive of new referrals, allocation of patients, all surgeries (1st and 2nd ear), upgrades, complications, transfers.
- 14.2 Obtaining quotations for new implants (surgeries) and upgrades of sound processors;
- 14.3 Motivations for upgrades of sound processors;
- 14.4 Arranging appointments at appropriate intervals for patients as per _____ CIP/SACIG protocol or if required by patient before;
- 14.5 Ordering of implant systems and sound processors (upgrades);
- 14.6 Obtaining quotations from relevant distributors when required;
- 14.7 Provision of information about fundraising and procedures for prospective candidates;
- 14.8 Ensuring that all test, rehabilitation, patient management and administrative forms are correctly maintained, completed and filed;
- 14.9 Maintenance and stock management of brochures, test equipment, spares and demonstration equipment;
- 14.10 Supervision and management of staff of _____ CIP (Coordinator);
- 14.11 Collecting information for annual newsletter;
- 14.12 Annual year report (Coordinator).
- 14.13 Submission of required data annually to SACIG

15. EQUIPMENT

The following are the minimum requirements for equipment needed by the audiologists of _____ CIP and the S-CIUs:

- 15.1 Soundproof booth large enough to conduct free-field testing as per SACIG protocol via 2-3 loudspeakers that are appropriately positioned;
- 15.2 Double-channel audiometer (annually calibrated) with the following specifications: pure tones that can be presented as FM tones; channel for speech audiometry (with or without competing signals), a minimum of two

- loudspeakers; external port coupling to connect CD player or iPod or system for the presentation of recorded speech material;
- 15.3 Recorded speech material (monosyllabic words and sentences);
 - 15.4 Computer that has the required specifications to run the software required by the cochlear implant systems provided;
 - 15.5 An appropriate office space for comfortable seating for MAPping of children and adults;
 - 15.6 Programming cables and equipment for MAPping. The service provider of the Implant system(s) used by _____ CIP should provide the S-CIU with all the required equipment necessary for appropriate patient management for all types of sound processors in use, the same equipment should be available for the S-CIUs;
 - 15.7 Equipment and toys for paediatric conditioning activities;
 - 15.8 Furniture appropriate for adults and children;
 - 15.9 Provision of loaner / replacement sound processors and test equipment for all processor types in use.

16. ROLE AND CLINICAL FUNCTIONS OF THE SATELLITE COCHLEAR IMPLANT UNITS (S-CIUs)

- 16.1 Notification about new patients to be assessed and referral source to the Coordinator of _____ CIP for record-keeping and for allocation to the audiologist. This includes new referrals from other sources;
- 16.2 _____ CIP Coordinator should be informed about cochlear implant users that are transferred from other cochlear implant programmes to the S-CIU audiologist.
- 16.3 New patients: take a full case history (as per CIPs case history form) and evaluation of the patient's candidacy for possible cochlear implant in terms of audiological and other criteria according to _____ CIP and SACIG guidelines (Appendices B and F);
- 16.4 Distant S-CIUs: The full audiological results and information about the patient should be sent to the Coordinator of _____ CIP so that all the information is available for presentation at the team meeting if the satellite CI audiologist is not able to attend. Radiology should be done according to _____ CIP

protocol and SACIG guidelines (Appendix D) and be made available to _____CIP the week prior to the team meeting. The case will be presented by a _____CIP audiologist (representative) as allocated by the _____CIP Coordinator or by the S-CIU audiologist online. _____CIP is responsible for the final decision Regarding candidacy and finalising arrangements for the surgery;

- 16.5 Local S-CIUs: Monthly team meetings should be Attended by the local S-CIU audiologist (online or in person). The same information as in 16.4 should be presented and radiology provided to the _____CIP coordinator theweek before the team meeting. The Coordinator should be informed that the S-CIU audiologist wishes the patient to be discussed at the next team meeting and to be placed on the agenda;
- 16.6 Clinical questions about patients should be directed to the _____CIP Coordinator or other audiologists and not to the suppliers of cochlear implants. Problem cases should be reported to the Coordinator and referral of unresolved problems should be reported to the clinical support person of the distributor. Failing resolution thereof should be reported to the Company clinical support specialist.
- 16.7 Queries regarding equipment (hardware) or software should be directed to the distributor and the _____CIP Coordinator should be informed;
- 16.8 Additional clinical services provided by the S-CIU include:initial activation of the device and programming, rehabilitation and support, ongoing MAPping and assessment as per _____CIP protocol and SACIG guidelines (Appendix F) and management of equipment such as sound processors;
- 16.9 Academic activities (such as presentations) conducted should be done under the banner of _____CIP in order to protect the identity of _____CIP. The Coordinator of _____CIP should be informed of any presentations done or articles published;
- 16.10 Equipment: refer to #15 - the same equipment is required by the S-CIU,
- 16.11 Any changes in contact details as well as circumstances of patients under management should be provided to the Coordinator of _____CIP so that all information is up to date.
- 16.12 All registrations for new surgeries and for upgrades for each patient should be sent to the _____CIP Coordinator and administrator within a

week of the event (can be emailed). The registration details should be sent together with the order form which should include payment details. The service provider should be informed and registration details sent to the distributor.

- 16.1 Patients who wish to be transferred to another programme: a transfer report (Appendix M) should be written and the MAPping file emailed to the Coordinator of the programme. The _____ CIP Coordinator and administrator should be informed and copied in on the email. The Coordinator of the programme to which the patient is to be transferred should be contacted to ensure that programme is able to receive and manage the patient;
- 16.14 The Coordinator of the _____ CIP should be informed in writing / email timeously of all information required for the Annual Report (Appendix K). The information includes all referrals of new patients, transfers (in and out) of patients, total number of patients implanted (unilateral and bilateral), total number of patients under management, device failures, patients deceased and non-users. Information regarding academic activities, e.g., presentations, relevant conferences or workshops attended must be included.
- 16.15 Choice of device: patients should be informed of (3) device options and sign consent that they have been informed.
- 16.16 Patient files should be maintained with all information kept as per the HPCSA requirements for record-keeping. The S-CIU audiologist should endeavour to keep the files in the same format as the Core _____ CIP.

17. ROLE OF THE DISTRIBUTORS TO THE SATELLITE UNITS

- 17.1 Installation and upgrading of required software;
- 17.2 Provision of programming cables and equipment required for programming of all the devices in use at that S-CIU;
- 17.3 Provide support and assistance for software and clinical support queries;
- 17.4 Provision of loan/replacement sound processors and equipment as required;
- 17.5 Administrative support for orders, upgrades and repairs of sound processors;
- 17.6 The same level of support for courier and distribution services should be available as is for _____ CIP;
- 17.7 Should the S-CIU audiologist not be able to attend training provided by the distributor at _____ CIP or another location, personal visits as

needed should be provided. Financial aid should be provided by the Distributor to attend training events.

- 17.8 Brochures and necessary equipment should be provided as needed;
- 17.9 All S-CIUs should be kept informed of new, relevant developments by the service provider and the company.

18. PATIENTS

- 18.1 The identified S-CIU audiologist (_____) will market these audiological services to professionals and the public based on the principles of this agreement and with the understanding that the patients the S-CIU audiologist (_____) assesses, manages and administers are registered as patients registered by and falling under _____CIP;
- 18.2 All records, data, forms and information related to the cochlear implant of the patient of the S-CIU are the property of _____CIP;
- 18.3 Should the relationship between _____CIP and the S-CIU be terminated (for any reason), all patient records and equipment should be returned to _____CIP;
- 18.4 Should the satellite programme become an independent programme (i.e. have their own surgeon and appropriate infrastructure to function independently as per SACIG Quality Standards document), the Coordinator of _____CIP and the Chairperson of SACIG Exco should be informed in writing. The Coordinator of _____CIP and the S-CIU audiologist will then inform the patients under the care of the S-CIU.
- 18.5 Should the audiologist of the S-CIU leave the practice, a new audiologist who has the required accreditation as required by SACIG and the HPCSA, can be appointed within that S-CIU to manage the CI patients. The Coordinator of the CIP and the S-CIU audiologist should agree on the suitability of this person.

19. TERMINATION OF AGREEMENT

In the event of the S-CIU not complying appropriately with any of the conditions listed above and not committing to correct the issue within seven (7) days,

_____ CIP reserves the right to terminate the S-CIU relationship and agreement without further notice. The patients will be informed of this termination and will be re-allocated to an appropriate service.

20. CONFIDENTIALITY

- 20.1 It is agreed that as a result of the relationship and agreement between the two parties (S-CIU audiologist _____ and _____ CIP), the S-CIU audiologist will have access to information about patients, the _____ CIP protocols, distributor and company information;
- 20.2 The S-CIU audiologist will not during, or after termination of the agreement supply any information to any person or any confidential information about the _____ CIP or the matters to that programme, to the benefit or detriment of the _____ CIP.
- 20.2 The S-CIU audiologist understands that the patients managed by the S-CIU are the primary responsibility of _____ CIP for cochlear implant management;
- 20.3 The S-CIU audiologist will not, during the period of the agreement or thereafter, give any person access to confidential information about patients, other than with their specified written consent;
- 20.4 The S-CIU audiologist will not, during the period of the agreement or thereafter, give any person access to confidential information about _____ CIP without the express written approval of the Coordinator of _____ CIP.
- 20.5 In the event of the termination of the relationship between the S-CIU and _____ CIP, the S-CIU audiologist is to return all confidential information and CI-related patient records to the _____ CIP Coordinator and the equipment should be returned to the distributor of _____ CIP.

- 20.6 The S-CIU audiologist is not permitted to keep any copies of the above records or documentation for her/his own use without the written permission of the _____ CIP Coordinator.
- 20.7 Should the patient remain within the S-CIU under a different audiologist, the records will stay within that practice.

21. TERMS AND CONDITIONS

- 21.1 The core _____ CIP reserves the right to cancel the relationship and services provided by the Satellite Unit (S-CIU).
- 21.2 The difference between _____ CIP and the S-CIU is that the _____ CIP team includes core team members including ENT surgeons, audiologists and speech-language therapists. The team member(s) of the S-CIU consist only of audiologist(s). All cochlear implant surgeries are done by the _____ CIP ENT surgeons.

Name of Satellite Unit: _____

Name of Satellite Unit Audiologist: _____

Signature: _____ Date: _____

Name of _____ CIP Coordinator: _____

Signature: _____ Date: _____