APPENDIX Q: POLICY PROTOCOL FOR SATELLITE COCHLEAR IMPLANT UNITS

1. INTRODUCTION

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

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

Abbreviations and Definitions

XXXXXCIU	XXXXXXX Cochlear Implant Unit
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 _____ CIU and the Satellite Units that will result in best practice and service delivery to cochlear implant users, new candidates and their families.

3. BACKGROUND

The first Cochlear Implant Unit 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 units were established in South Africa after surgical and audiological training. The following cochlear implant units were established: Pretoria (1990 and Johannesburg (1991). Since 2003 cochlear implant units across South Africa were established due to an increased demand in service delivery.

The successful development of Cochlear Implant Units 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 unit 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 placed pressure on available audiological support in local units. 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 programmes which would be able to support the primary CIU.

The first satellite unit was established by Tygerberg Hospital-Stellenbosch University (TH-SU) CIU in 2005 in East London (based at Frere Hospital), followed by a SU in Port Elizabeth in 2006, in Windhoek in 2014, Panorama Hospital, Cape Town 2021 and in Paarl in 2017. Port Elizabeth and Windhoek Sus became independent functioning units in 2017, in 2021 East London joined the Port Elizabeth programme as a SU.

4. NAME AND ROLE OF THE COCHLEAR IMPLANT UNIT

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

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

5.1

5.2

6. DESCRIPTION OF _____ COCHLEAR IMPLANT UNIT

_____ 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 _____ CIU as a cochlear implant ENT surgeon is not associated with the S-CIU.

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 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 that 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.

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 _____ CIU 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 _____CIU and SACIG protocols;
- Ongoing monitoring and long-term management of existing cochlear implant users according to _____CIU and SACIG protocols;
- Decision making with regards to referring patients back to the _____ CIU
- Programming of electrodes of existing cochlear implant users;
- Audiological rehabilitation and management of cochlear implant users;
- The _____ CIU 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 _____ CIU or on site and should be attended by all _____ CIU 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 UNIT is located in _____.

_____ CIU 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 _____CIU, equipment, management decisions, 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 _____ CIU 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 _____ CIU 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 _____CIU 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 _____CIU Coordinator.

11. CURRENT SACIG-REGISTERED TEAM MEMBERS OF _____ CIU

NAME	ROLE

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 _____ CIU. Consent should be obtained from the Ethics Committee of _____. Any publication or presentation should acknowledge the _____CIU audiologist who supported and assisted with the research project or presentation.

14. ADMINISTRATIVE ACTIVITIES OF _____ CIU

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 _____CIU 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 and completed;

14.9 Maintenance and stock management of brochures, test equipment, spares and demonstration equipment;

14.10 Supervision and management of staff of _____ CIU (by Coordinator);

14.11 Collecting information for annual newsletter;

14.12 Annual year report.

15. EQUIPMENT

The following are the minimum requirements for equipment needed by the audiologists of _____CIU 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 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 _____CIU 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 to the Coordinator of _____CIU for record-keeping and for allocation to the audiologist. This also includes new referrals from other sources;

16.2 _____CIU 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 and evaluation of the patient's candidacy for possible cochlear implant in terms of audiological and other criteria according to _____CIU 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 THUSCIU so that all the information is available for presentation at the team meeting. Radiology should be done according to _____ CIU protocol and SACIG guidelines (Appendix D) and be made available to _____CIU the week prior to the team meeting. The case will be presented by a _____CIU audiologist (representative) as allocated by the _____CIU Coordinator or by the S-CIU audiologist online.

_____CIU is responsible for the final decision regarding candidacy and finalising arrangments for the surgery;

16.5 Local S-CIUs (_____): Monthly team meetings should be attended by the local S-CIU audiologist. The same information as in 16.4 should be

presented and radiology provided to the _____CIU Coordinator the week 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 _____CIU 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 _____CIU 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 _____CIU 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 _____CIU in order to protect the identity of _____CIU. The Coordinator of _____CIU 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 _____CIU so that all information is up to date.

16.12 All registration cards for new surgeries and for upgrades for each patient should be sent to the _____CIU Coordinator within a week of the event (can be emailed). The registration card should be sent together with the order form which should include payment details. The original form can be sent directly to the service provider of the particular implant system.

16.13 Patients who wish to be transferred to another programme: a transfer report (template attached) should be written and the MAPping file emailed to the Coordinator of the programme. The _____CIU coordinator 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 All information required for the Annual Report (Appendix K) should be kept at the S-CIU and at the end of the year sent to the _____CIU Coordinator. The information includes 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 in the report.

16.15 Choice of device: patients should be informed of device options and sign consent that they have been informed.

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 _____CIU;

17.7 Should the S-CIU audiologist not be able to attend training provided by the distributor at _____CIU 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 _____CIU;

18.2 All records, data, forms and information of the S-CIU are the property of _____CIU;

18.3 Should the relationship between _____CIU and the S-CIU be terminated (for any reason), all patient records and equipment should be returned to _____CIU;

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 _____CIU and the Chairperson of SACIG Exco should be informed in writing. The Coordinator of _____CIU and the S-CIU audiologist will then inform the patients under the care of the SU.

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, _____ CIU 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 appopriate 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 _____CIU), the S-CIU audiologist will have access to information about patients, the _____CIU 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 _____ CIU or the matters to that programme, to the benefit or detriment of the

_____CIU.

20.2 The S-CIU audiologist understands that the patients managed by the S-CIU are the primary responsibility of _____CIU 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 _____ CIU without the express written approval of the Coordinator of _____CIU.

20.5 In the event of the termination of the relationship between the S-CIU and _____CIU, the S-CIU audiologist is to return all confidential information and patient records to the _____ CIU Coordinator and the equipment should be returned to the distributor of _____CIU.

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 _____CIU Coordinator.

21. TERMS AND CONDITIONS

21.1 The _____ Cochlear Implant Unit reserves the right to cancel the relationship and services provided by the Satellite Unit (S-CIU).

21.2 The difference between _____CIU and the S-CIU is that the _____CIU team includes core team members including ENT surgeons, audiologists and speech-language therapists. The team member(s) of the S-CIU consist only of audiologists. All cochlear implant surgeries are done by the _____ CIU ENT surgeons.

Name of Satellite Unit: _____

Name of Satellite Unit Coordinator and Audiologist: _____

Signature:_____ Date:_____

Name of _____CIU Coordinator: _____

Signature: _____ Date: _____