W-12/3/2019-IPHW-MeitY
Government of India
Ministry of Electronics and Information Technology
(IPHW Division)

Electronics Niketan, 6,CGO Complex
New Delhi -110003.

Dated 29.04.2020

ADMINISTRATIVE APPROVAL

Subject: Setting up of Centre of Excellence on Medical Electronics and Bio-Physics at Andhra Pradesh MedTech Zone Limited(AMTZ),Visakhapatnam, to be implemented by M/s.Kalam Institute of Health Technology(KIHT), AMTZ, Visakhapatnam - reg.

I am directed to convey the administrative approval of the competent authority for the implementation of the project titled "Centre of Excellence on Medical Electronics and Bio-Physics"at Andhra Pradesh MedTech Zone Limited (AMTZ), Visakhapatnam,to be implemented by M/s. Kalam Institute of Health Technology (KIHT), located in AMTZ, Visakhapatnamat a total project outlay of Rs. 32,02,000,00/- (Rupees Thirty Two Crore and Two LakhOnly), including a Grant-in-Aid of Rs.18,67,000,00/- (Rupees Eighteen Crore and Sixty Seven Lakh Only) from Ministry of Electronics and Information Technology (MeitY). M/s.KIHT will implement the project as per the commitments made by AMTZ to MeitY for undertaking this project. The duration of the project is 3 years.

2 The Grant-in-Aid of Rs.18,67,000,00/- (Rupees Eighteen Crore Sixty Seven Lakh Only) will be released to M/s. Kalam Institute of Health Technology (KIHT), AMTZ, Visakhapatnam as per the terms and conditions and details of the project given in Annexure I.The general terms and conditions,governing the Grant-in Aid are atAnnexure II.

3. This issues with concurrence of IFD, MeitY dated 19.04.2020 and approval of Secretary, MeitY dated 20.04.2020 and 28.4.2020.

Yours faithfully,

-Sd-
(**Rajesh Suri**)
Joint Director

To

1. M/s. Kalam Institute of Health Technology (KIHT), AMTZ, Visakhapatnam
2. M/s. Andhra Pradesh MedTech ZoneLtd.(AMTZ),Visakhapatnam
3. PAO, MeitY
4. Principal Director of Audit, Scientific Departments, New Delhi
5. SS&FA/AS/ JS(Electronics)/GC(R&D Electronics)/SD(SKM)/OSD to Secretary /Scientist E(VC), MeitY
6. Sanction/Guard File

-Sd-
(**Rajesh Suri**)
Joint Director

Annexure I

Annexure to the administrative approval No.W-12/3/2019-IPHW-MeitY dated 29.04.2020 for the project entitled "Setting up of Centre of Excellence on Medical Electronics and Bio-Physics at Andhra Pradesh MedTech Zone Limited (AMTZ), Visakhapatnam"

<table>
<tr><th>Sr. No.</th><th>Subject</th><th>Particulars</th></tr>
<tr><td>1.</td><td>Name of the project</td><td>Setting up of Centre of Excellence on Medical Electronics and Bio-Physics at Andhra Pradesh MedTech Zone Limited(AMTZ), Visakhapatnam</td></tr>
<tr><td>2.</td><td>Objectives</td><td>i. To carry out functional research support to innovators, manufacturers, researchers in medical devices, for undertaking design, prototyping, manufacturing for Electronics System Design and Manufacturing (ESDM).

ii. Research and Development, prototyping and Printed Circuit Boards Assembly manufacturing of electronics and integration of components to make functional critical parts (assembly/sub-assembly) for medical devices.

iii. Identify key area of Bio-Physics research such as Bio-Organs/Electro-organs that perform or augment the performance of the functions of natural organs.

iv. Identify electro-potential based mechanisms for research and prototyping of key components such as piezo-electric crystals, key Bio-Inks and electro-physics pathway technologies and support their prototyping and production.</td></tr>
<tr><td>3.</td><td>Outcome/ Deliverable</td><td>
<table>
<tr><th>Objectives</th><th>Deliverables/Outcomes</th><th>Beneficiary</th></tr>
<tr><td>Objective1: Skill building on ESDM</td><td>i. Training to biomedical engineers on design of PCBs, boards and complex electro-medical circuits (concurrent activity from 4th month)

ii. Imparting training to about 30 engineers through 4-6 months hand-on work (concurrent activity from 4th month)</td><td>Human Resource engaged with medical device manufacturers, fresh graduates etc.</td></tr>
<tr><td>Objective2: Design, prototyping, manufacturing for ESDM</td><td>i. Research and design integration for start-ups; expected to support 30 projects on Medical Electronics design per year (concurrent activity from 4th month)

ii. Prototypes for medical device manufacturers, based on capacity of 45000 CPH (component per hour); expected to 100 boards per hour on an average to support batch production, and pilot manufacturing (concurrent activity from 4th month)</td><td>Start-ups; MSMEs; Medical Device Manufacturers.</td></tr>
<tr><td>Objective3: Electro-bio organs</td><td>i.Identification of biomaterial dyes with electro-potential properties (0-6 months)
ii. Developing intellectual property and prototype of electro-bio organs</td><td>Electro-Biomaterial Technology based product manufacturers/inn</td></tr>
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			and compatible dyes (7-24 months) iii. 3-D printing of electro-bio organs as prototypes (18-36 month) iv. Transfer of technology (30-36 month)	ovators
		Objective4: Complex electro-medical components such as piezo-electric crystals	i. Identification of pathways for development of Piezo electric crystals (4-12 months) ii. Developing Intellectual Property and prototype of piezo-electric crystals (7-24 months) iii. Batch production level Manufacturing (13-36 months)	Ultra-sonography/Piezo-electricity/Bio-physics/ non-ionising radiation basedproduct manufacturers/innovators

4.	**Immediate impact of the project**	• The infrastructure proposed to be created out of the project is to be used for manufacturing ventilators. • All outputs of the project particularly objectives 1 & 2 shall be used immediately for the production of ventilators at AMTZ and the cost of this service will be reduced to 60% of the market costs, for all manufacturing using the services of Centre of Excellence for Medical Electronics. • The project will help in reduction of the cost of all important medical equipment being manufactured in AMTZ.

5. **Activities**

S.No.	Activity associated with the Capital asset	Sub-Activities	Outcomes
1.	Design software's, Prototyping facility of PCB's and systems	Planning & Procurement – 0 to 4 months Selection of Trainees – concurrent activity every 6 months for a team of 30 professionals	Designs of 2 critical components for medical device every month; leading to production process of 2 devices every month
2.	Research and development, manufacturing of electronics and integration of components to make functional critical parts (assembly/sub-assembly) for medical devices	Planning & Procurement- 0 to 4months Prototyping and Assembly- 5 to 6 months Providing services and prototype assemblies – concurrent activity from 6th month	Production of boards for medical devices with boards for 100 devices per hour capacity; immediately upon installation. In first three months, 10000 units of ventilators will be supported for production by supply of critical parts. Subsequently, every month, 4000 devices production will be supported.

		3.	Research and prototyping of electro-bio organs	Planning & Procurement – 0 to 6 months Selection of projects- 0 to 6 months Research Activities – 7 to 24 months Filing of patents- 25-27 months Transfer of technology- 28 to 36 months	4 electro-organs such as Myo-electric arms (artificial arms), shall be developed within 2 years.	
		4.	Research & Development and production of Complex electro-medical components such as piezo-electric crystals	Planning & Procurement – 0 to 6 months Selection of projects- 0 to 6 months Research Activities – 7 to 24 months Filing of patents- 25-27 months Transfer of technology- 28 to 36 months	Sensors production: Oxygen sensors - 6th Month Flow sensors- 8th Month Pressure sensors- 10th Month Peizo-electric crystal- 12thMonth	

6.	**IPR**	The IPR generated out of the project shall originally be registered or reside in India. The IPR Terms and conditions will be worked out in mutual agreement between MeitYand KIHT.
7.	**Implementing Agency**	M/s. Kalam Institute of Health Technology (KIHT) is the implementing Agency. M/s. KIHT has been registered at the Registrar of Societies, Government of Andhra Pradesh, Visakhapatnam, Andhra Pradesh under the Andhra Pradesh Societies Registration Act., 2001.
8.	**Chief investigators of the project**	The Executive Director (ED), KIHT would be the nodal person for implementing the project. He will be coordinating with AMTZ for executing all the project related activities. AMTZ willfacilitate KIHT for execution of the project as per the commitments provided by them to MeitY.
9.	**Duration of the project**	The duration of the project is three years (36 months).
10.	**Measurable Milestones**	**Measurable Milestones six monthly wise**

Objectives	**Activity/Capital asset**	**Outcomes expected every six months**
1. ESDM research and skill building	Design software's, Prototyping facility of PCB's and systems	Complete functioning of facility - first six months; 30 professionals to be trained every 6 months

		2. Prototyping and manufacturing of medical electronic critical parts	Research and development, manufacturing of electronics and integration of components to make functional critical parts (assembly/sub-assembly) for medical devices	Complete functioning of facility - first six months; Providing prototyping & assembly support to 10 projects every six months	
		3. Electro Bio-Physics Research	Research and prototyping of electro-bio organs	Complete functioning of facility - first six months; Electro organs (core R& D)- 7 to 24 months Patents generation and filing)- 25-30 months Transfer of technology and production- 30 to 36 months	
		4. Electro-potential based component development	Research & Development and production of Complex electro-medical components such as piezo-electric crystals	Complete functioning of facility - first six months; Providing critical components to 3 projects every six months	
11.	**Stakeholders and Participating Agencies**	**M/s. Andhra Pradesh MedTech Zone Limited(AMTZ)** M/s. AMTZ has submitted the project proposal to MeitY. Based on his commitment, the project has been approved. Accordingly, M/s. AMTZ would be providing all necessary support to M/s. KIHT for implementing the projects. **M/s. Kalam Institute of Health Technology (KIHT)** M/s. Kalam Institute of Health Technology (KIHT) is the implementing Agency for the project. M/s. KIHT has been registered at the Registrar of Societies, Government of Andhra Pradesh, Visakhapatnam, Andhra Pradesh under the Andhra Pradesh Societies Registration Act., 2001. **Ministry of Electronics and Information Technology (MeitY)** MeitY is the overall Supervising Authority for execution of the project. KIHT will be ensuring the implementation of the project as per the commitments made by M/s. Andhra Pradesh MedTech Zone Limited(AMTZ) to MeitY on this project. Accordingly, KIHT can work out a suitable mechanism for ensuring compliance from AMTZ. (The Roles and Responsibilities of all the agencies will be enunciated in a MoU to be executed between MeitY and KIHT, Visakhapatnam)			
12.	**The project outlay and fund contribution**	Total Project outlay is Rs.32.02crore. Out of which, Rs.18.67 crore will be the Grant-in-Aid to be released over a period of 3 years. The Grant in-Aid amount will be released by MeitY. Out of the total outlay, Rs.13.35 crore (mainly towards space and manpower)			

will be contributed by AMTZ over a period of three years (36 months). The Grant-in-Aid is meant for utilisation for procurement of capital equipments etc. The procurement of items should be at reasonable rates keeping in view the Ministry of Finance extant guidelines.

i) Contribution by AMTZ

S.No.	Items	Descriptions	Contributions worth
1.	Infrastructure	12000 sq.ft. of air-conditioned space @Rs.5000 per SFT for objectives 1,3& 4	Rs.6.00 crore
2.	Infrastructure	6000 sq.ft of factory space @2300 for objective 2 (ESDM assembly)	Rs.1.38 crore
3.	Clean room	10000 particle count clean room	Rs.1.50 crore
4.	HR	20 scientists @Rs.60,000 per month X 3 years	Rs.4.32 crore
5.	Travel, marketing & admin expenses	Need basis @ Rs.5 lakhs per year X 3 years	Rs.0.15 crore
	Total		**Rs.13.35 crore**

ii) The Grant-in Aid for a period of three years

S.No.	Items	Amount budgeted in the DPR (in Rs.crore)	Proposed utilization of GIA from MeitY (in Rs. crore)			
			Year 1	Year 2	Year 3	Total
1.	Setting up of Centre of Excellence (CoE) in Medical Electronics and Bio-Physics at AMTZ, Visakhapatnam	**18.67**	**13.069**	**3.734**	**1.867**	**18.67**
	Total	**18.67**	**13.069**	**3.734**	**1.867**	**18.67**

13. **Project monitoring**

The objectives of the project are highly technical in nature. It aims to generate Intellectual Properties and prototype models. This is expected to generate value additions and import substitutions. The proposal has sufficient content for R&D and promotional aspects. Hence, in order to monitor, steer and implement the project, it is proposed to have two levels of Committees-

i) Apex Steering Committee (Strategic Level at MeitY)
ii) Field Level Sub-Committee

i) Apex Steering Committee

S.No.	Members	Position
1.	Joint Secretary/GC, IPHW Division, MeitY (currently, Shri Saurabh Gaur)	Chairman
2.	Group Coordinator (R&D in Electronics), MeitY (currently, Shri Arvind Kumar, Scientist G)	Member

3.	Shri S.K.Marwaha, Scientist G, IPHW Division, MeitY	Member
4.	Representative of Department of Health Research (DHR)	Member
5.	Representative of Department of Science and Technology (DST)	Member
6.	Representative of Department of Pharmaceuticals (DoP)	Member
7.	Shri Chinnasamy V, Scientist E, IPHW Division	Member-Convener

ii) Field level Sub-Committee

S.No.	Members	Position
1.	ED, KIHT	Chairman
2.	MD & CEO, AMTZ	Co-Chairman
2.	Clinical Research Scientist from ICMR	Member
3.	Upto two R&D experts from institutions with which KIHT has MoU	Member
4.	Representative of Medi-Valley incubation centre	Member
5.	Representative of MeitY	Member
6.	Representative of AiMeD	Member

- The field level sub-committee will monitor and review the project regularly so that the project gets the required mentoring and support.
- The Sub-committee meeting will be held once in six months for reviewing the status of the project.
- The Apex steering committee will review the project once in a year. Based on the review report of apex steering committee and UC submission,subsequent instalment for the project will be released.

14. **MeitY's Component wise Breakup for the project**

i) Head-wise Breakup

ii) Breakup of Expenditure as per Objectives

S.No.	Items	Amount budgeted in the DPR (in Rs. crore)	Proposed utilization of GIA from MeitY (in Rs. crore)			
			Year 1	Year 2	Year 3	Total
1.	Capital Asset equipment	**18.67**	**13.069**	**3.734**	**1.867**	**18.67**
2.	Manpower	**0**	**0**	**0**	**0**	**0**
3.	contingencies	**0**	**0**	**0**	**0**	**0**
4.	Overhead	**0**	**0**	**0**	**0**	**0**
	Grand Total	**18.67**	**13.069**	**3.734**	**1.867**	**18.67**

Objectives	List of capital assets to be procured with quantity/rate etc. with detailed descriptions	Cost (in Rs. crore)
1. ESDM research and skill building	Computers (i7 from GeM) along with specialised software(s) depending upon the project	2.14

		2. Prototyping and manufacturing of Medical Electronic critical parts	SMT line with laser inspection	6.25
		3. Electro Bio-Physics Research	Electro-3D printers capable of handling electronics and tissues	5.73
		4. Electro-potential based component development	Piezo-electric embedment set	4.55
			Total	**18.67**
15.	**Release of funds from MeitY**	1) First instalment of Rs.13,06,90,000/- (Rupees Thirteen Crore Six Lakh and Ninty Thousand Only) is to be released to M/s. Kalam Institute of Health Technology (KIHT), Visakhapatnamafter acceptance of Administrative Approval and execution of MoU between MeitY and KIHT, Visakhapatnam. 2) Second instalment of Rs.3,73,40,000/- (Rupees Three crore Seventy Three Lakh Forty Thousand Only) and third instalment of Rs.1,86,70,000/- (One Crore Eighty Six Lakh Seventy Thousand Only)would be released on submission of UCs and progress report on the recommendations of Apex-Steering Committee in the 2nd and 3rd year, respectively.		

-Sd-
(**Rajesh Suri**)
Joint Director

Annexure II

Ministry of Electronics & Information Technology
Government of India

The grant is for the specific project as approved by Ministry of Electronics & Information Technology (MeitY) and shall be subject to the conditions listed below. The proposal originating industry and grantee institution shall give an undertaking that they agree to be governed by these conditions.

1. The grant amount shall be i) spent for the project within the specified time; and ii) Any portion of the grant, which is not ultimately required for expenditure for the approved purposes, shall be duly surrendered to MeitY;
2. The grantee institution shall maintain an audited record in the form of a register in the prescribed proforma for permanent, semi-permanent assets acquired solely or mainly out of MeitY grant;
3. The assets referred to in (2) above will be property of MeitY and should not, without prior sanction of MeitY, be disposed off or encumbered or utilized for the purposes other than those for which the grant has been sanctioned;
4. At the conclusion of the project, MeitY will be free to sell or otherwise dispose of the assets which are the property of MeitY and grantee institution shall render to MeitY the necessary support for facilitating the sale of these assets;
5. The grantee institution shall send to the MeitY at the end of each financial year as well as at the time of seeking further instalments of the grant a list of assets referred to in (2) above;
6. Should at any time grantee institution cease to exist, such assets etc., shall revert to MeitY;
7. The grantee institution shall render progress-cum-achievement reports at interval of not exceeding six months on the progress made on all aspects of the project including expenditure incurred on various approved items during the period;
8. The grantee institution shall render an audited statement of accounts to MeitY;
9. The audited statement of accounts relating to grants given during financial year together with the comments of the auditor regarding the observance of the conditions governing the grant should be forwarded to the MeitY within six months following the end of the relevant financial year;
10. The utilization of grant for the intended purposes will be looked into by the Auditor of grantee institution according to the directives issued by the Government of India at the instance of the Comptroller and Auditor General and the specific mention about it will be made in the audit report;
11. MeitY or its nominee(s) will have the right of access to the books and accounts of the grantee institution for which a reasonable prior notice would be given;
12. The grantee institution should maintain separate audited account for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest, thus earned should be reported to this Department. The interest so earned will be treated as a credit to the grantee to be adjusted towards future instalments of the grant;
13. Institute may retain the sale proceeds of prototypes, etc fabricated as a result of the development of the project arising directly from funds granted by the Department. The Institute may use funds thus generated for furtherance of project objectives.
14. The Intellectual property and the rights associated with it shall be agreed between the participating organizations before the start of the project. The Industry/ Industry Consortium/ Institution(s) will make all efforts to protect intellectual property generated out of the project. The institution(s)/industry would submit the periodic report to MeitY

for a period of minimum 5years on the status of IPRs created/commercialization under the project. (5 years is the expected life time of product/technology). Furthermore, IPR must also reside in India so that India has access and complete control to these rights in times of emergency to protect our national interest.

15. Application by grantee institution for any other financial assistance or receipt of grant/loan from any other Agency/Ministry/Department for this project should have the prior approval of Ministry of Electronics & Information Technology.
16. The Grantee institution(s) is not allowed to entrust the implementation of this project for which grant-in-aid is received to another institution and to divert the grant-in-aid received from Ministry of Electronics & Information Technology as assistance to the later institution.
17. MeitY shall appoint an 'Apex Steering Committee (ASC)' comprising of representatives from MeitY and other experts. ASC will periodically monitor the project in all respects including technical and financial;
18. In case of any dispute on any matter, related to the project during the course of its implementation, the decision of the Secretary, MeitY, shall be final and binding on the proposal originating industry/ industry consortium and grantee institute.