Telemedicine-Delivered Nutritional Counselling versus Standard Care for Cancer Cachexia in Pakistani Cancer Patients: A Pilot Randomized Controlled Trial

(TELE-CACHE Trial)

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Principal Investigator	Muhammad Nabeel Saddique, MBBS (Final Year)
Supervisor	Prof. Dr. Muhammad Abbas Khokhar, MD — Head of Department, Radiotherapy & Medical Oncology, KEMU
IRB Approval	Approved from KEMU IRB No. 337/RC/KEMU, March 17, 2026
Trial Registration	ClinicalTrials.gov — NCT07606417

Note: This document contains the full study protocol, statistical analysis plan, and informed consent form (English version) for the TELE-CACHE Trial. The Urdu-language patient consent form is maintained on file at King Edward Medical University for local regulatory compliance and is available upon request.

SYNOPSIS PROFORMA

Submitted By:

Muhammad Nabeel Saddique

Final Year MBBS

Supervisor:

Prof. Dr. Muhammad Abbas Khokhar, MD

Head of Department, Department of Radiotherapy and Medical Oncology

King Edward Medical University, Lahore 54000, Pakistan

King Edward Medical University

Lahore – Pakistan

SYNOPSIS PROFORMA

Title of Research Project: Telemedicine-Delivered Nutritional Counseling versus Standard Care for Cancer Cachexia in Pakistani Cancer Patients: A Randomized Controlled Trial (TELE-CACHE Trial)	
Synopsis Submitted For: ■ **MD / MS / MDS** ☐ **Ph. D** ☐ **M. Phil** ☐ **Research Grant**	**Discipline:** MBBS
Name Of the Applicant: Muhammad Nabeel Saddique	**D.O.B:** 14-10-2000
Nationality: Pakistani	**NIC #:** 33105-6214502-7
Address: KEMU Boys Hostels, Link McLeod Road, Lahore 54000, Pakistan.	
Phone #: +92 309 0527441	**Email:** nabeelsaddique@kemu.edu.pk
Qualifications (list all; with date of graduation):	

Qualification	Year	Institution
MBBS	2022-2026	King Edward Medical University, Lahore.
F.Sc.	2019-2021	Aspire College Samundri, Faisalabad.

Practical Experience (list all; with dates of employment):

Name of Parent Institution (if on Deputation):		
Name of Academic Supervisor / Principal Investigator: Prof. Muhammad Abbas Khokhar	**Signature:**	**Date:**
Name of Co Supervisor / Co-Principal Investigator	**Signature:**	**Date:**
Name of Chairman/ Head of Department	**Signature:**	**Date:**
Name of Principal/ Dean	**Signature:**	**Date:**
Convener, Institutional Review Board PROF. DR. SAQIB SAEED	**Signature:**	**Date:**

Chairman (Advanced Studies & Research Board)	Signature:	Date:
☐ Approved ☐ Not Approved **Vice Chancellor, KEMU**		

TITLE:

Telemedicine-Delivered Nutritional Counseling versus Standard Care for Cancer Cachexia in Pakistani Cancer Patients: A Pilot Randomized Controlled Trial (TELE-CACHE Trial)

INTRODUCTION:

Cancer cachexia is a devastating metabolic syndrome characterized by progressive involuntary weight loss and skeletal muscle depletion, affecting 50-80% of cancer patients and contributing to 30% of cancer-related deaths.(1,2) It is defined as weight loss exceeding 5% of body weight within 6 months in the presence of underlying illness.(3) Cachexia profoundly impairs quality of life, reduces treatment tolerance, increases treatment-related toxicity, and significantly worsens survival outcomes.(4)

International guidelines recommend nutritional counselling as a cornerstone of multimodal cachexia management. (5) However, evidence supporting specific nutritional interventions remains limited, particularly in resource-constrained settings. (6) The American Society of Clinical Oncology (ASCO) 2020 guidelines acknowledge that dietary counselling may increase body weight but emphasize the need for more high-quality evidence. (5)

In Pakistan, cancer poses an escalating health burden with 178,388 new cases and 117,149 deaths reported in five years.(7) Pakistani cancer patients face unique challenges including widespread malnutrition (31-97% prevalence), nutritional deficiencies (vitamin D, A, zinc, iron), late-stage diagnosis (89% in rural areas), and catastrophic out-of-pocket healthcare expenditure pushing 50-90% of lower-income patients into poverty.(7,8,9) Traditional in-person nutritional counselling is limited by geographical barriers, transportation costs, and shortage of trained nutritionists.(10)

Telemedicine offers a promising solution to overcome access barriers. Recent evidence demonstrates that telemedicine-delivered nutritional interventions improve dietary adherence, nutritional status, and quality of life in cancer patients. (11,12) A 2025 systematic review found that mobile health interventions for cancer nutrition improve body weight, nutritional intake, and patient outcomes. (13) However, no randomized controlled trials have evaluated telemedicine-based nutritional counselling for cachexia in Pakistan or South Asia.

This study aims to compare bi-weekly telemedicine-delivered nutritional counselling versus bi-weekly standard in-person counselling for cancer cachexia management, eliminating frequency bias and isolating the effect of delivery modality. Given low technology literacy in our population, we will employ simple video consultations without requiring patients to use complex dietary tracking applications. This pragmatic approach addresses real-world barriers while generating urgently needed evidence for scalable, cost-effective nutritional care delivery in low-and-middle-income countries.

OBJECTIVES:

Primary Objective:

To compare the mean change in body weight at 12 weeks between cancer patients receiving bi-weekly telemedicine-delivered nutritional counselling versus those receiving bi-weekly standard in-person nutritional counselling.

Secondary Objectives:

1. To determine the proportion of patients achieving adequate daily energy intake (≥25 kcal/kg/day) in both groups at 12 weeks.
2. To determine the proportion of patients achieving adequate daily protein intake (≥1 g/kg/day) in both groups at 12 weeks.
3. To compare mean change in mid-upper arm circumference (MUAC) as a proxy measure for muscle mass between groups at 12 weeks.
4. To compare mean change in Patient-Generated Subjective Global Assessment (PG-SGA) scores between groups at 12 weeks.
5. To compare mean change in quality-of-life scores (EORTC QLQ-C30) between groups at 12 weeks.
6. To assess patient adherence to scheduled nutritional counselling sessions in both groups.
7. To evaluate patient satisfaction with nutritional counselling delivery modality (telemedicine vs. in-person).
8. To compare total intervention costs and patient out-of-pocket costs between the two delivery modalities.

OPERATIONAL DEFINITION:

Cancer Cachexia:
Weight loss >5% of body weight in the past 6 months OR Body Mass Index (BMI) <20 kg/m² with >2% weight loss in 1 week OR unintentional weight loss <5% within 6 months with evidence of systemic inflammation (C-reactive protein >5 mg/L), in patients with histologically confirmed cancer. (3)

Adequate Energy Intake:
Daily energy consumption ≥25 kilocalories per kilogram of actual or adjusted body weight per day, as per European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines for cancer patients. (14)

Adequate Protein Intake:
Daily protein consumption ≥1.0 gram per kilogram of actual or adjusted body weight per day, as per ESPEN guidelines for cancer patients. (14)

Telemedicine-Delivered Nutritional Counselling:
Individual video consultation session lasting 20-30 minutes between patient and registered dietitian using WhatsApp Video Call (primary platform), or alternatively Zoom/Microsoft Teams based on patient preference. Sessions conducted from the Department of Medical Oncology, King Edward Medical University by the dietitian, while the patient participates from home or any convenient private location with internet access (mobile data or Wi-Fi). Each session includes dietary assessment, personalized counselling, goal-setting, symptom management strategies, and family education

Standard Nutritional Counselling:
In-person consultation session lasting 30-45 minutes between patient and registered dietitian at hospital nutrition clinic, including same components as telemedicine counselling.

Patient-Generated Subjective Global Assessment (PG-SGA):
Validated nutritional screening tool scored 0-35, where higher scores indicate greater malnutrition risk. **Categories**: Well-nourished (0-1), Moderately malnourished (2-8), Severely malnourished (≥9). (15)

Quality of Life:
Measured using validated EORTC QLQ-C30 questionnaire (30 items), scored 0-100 where higher scores represent better functioning or worse symptomatology depending on scale. (16)

Mid-Upper Arm Circumference (MUAC): Circumference of the non-dominant arm measured at the mid-point between the acromion process and olecranon process using a non-stretchable

measuring tape, with arm relaxed at the side. Measured in centimeters to nearest 0.1 cm. MUAC <23 cm indicates malnutrition; decrease indicates muscle wasting, increase indicates muscle gain.(17)

Treatment Adherence:
Percentage of scheduled nutritional counselling sessions actually completed by patient. Calculated as (sessions attended / sessions scheduled) × 100%.

Healthcare Cost per Kilogram Weight Gained:
Direct costs including: (1) Healthcare system costs: dietitian time (valued at standard hourly rate), telemedicine platform subscription/internet costs, equipment; (2) Patient costs: transportation expenses, time off work (valued at minimum wage), caregiver time, internet/mobile data charges. Costs calculated per patient in each group and compared between groups. Cost per patient achieving clinically significant weight gain (≥5% of baseline weight) will be calculated as exploratory outcome.

HYPOTHESIS:

Null Hypothesis (H_o):
There is no significant difference in mean body weight change at 12 weeks between cancer patients receiving bi-weekly telemedicine-delivered nutritional counselling and those receiving bi-weekly standard in-person nutritional counselling.

Alternative Hypothesis (H_1):
Telemedicine-delivered nutritional counselling is non-inferior to standard in-person nutritional counselling for body weight change at 12 weeks (non-inferiority margin: -1.0 kg).

Rationale: Since both groups receive equal frequency of counselling, we hypothesize non-inferiority rather than superiority. The study will also assess superiority in secondary outcomes (adherence, costs, satisfaction, accessibility)

MATERIAL AND METHODS:

STUDY DESIGN:

Single-centre, parallel-group, randomized controlled trial with 1:1 allocation ratio.

SETTING:

Department of Community Medicine and Public Health, and Department of Radiotherapy and Medical Oncology, King Edward Medical University/Mayo Hospital Lahore.

DURATION OF STUDY:

12 months

SAMPLE SIZE:

Using G*Power software for independent samples t-test:

- Effect size: Cohen's d = 0.75 (medium-large effect based on literature)(11,13)
- Alpha (α): 0.05 (two-sided)
- Power (1-β): 85%
- Calculated n per group: 29
- Adjusted for 20% dropout: 29/0.80 = 36
- Final: 40 patients per group (80 total**)**
- Expected evaluable sample**:** 64 patients (32 per group)

Rationale: Pilot RCT designed to generate robust preliminary evidence for larger multi-centre trial. Sample size accounts for realistic dropout rates observed in cancer cachexia studies.

Recruitment Feasibility:
Based on departmental records, approximately 50-60 new cancer patients are seen monthly in the Medical Oncology Department at [Hospital Name]. Literature reports 50-60% prevalence of cachexia in cancer patients, yielding approximately 25-35 eligible patients per month. With an anticipated 60-70% consent rate, we expect to enrol 15-25 patients per month, making the target of 80 patients in 4 months feasible.

SAMPLING TECHNIQUE:

Non-probability consecutive sampling.

SAMPLE SELECTION:

Inclusion Criteria:

1. Age ≥18 years (adults of either gender)
2. Histologically confirmed solid tumour malignancy (any type, any stage)
3. Cancer cachexia defined as: Weight loss ≥3% in past 3 months OR ≥5% in past 6 months
4. Currently receiving or planned to receive anti-cancer treatment (chemotherapy, radiation, targeted therapy, or immunotherapy)
5. Eastern Cooperative Oncology Group (ECOG) performance status 0-2
6. Access to smartphone or tablet with video calling capability
7. Reliable internet connectivity (mobile data or Wi-Fi)
8. Able to communicate in Urdu or English
9. Willing to provide written informed consent

Exclusion Criteria:

1. Severe dysphagia requiring enteral nutrition (nasogastric/PEG tube feeding)
2. Complete bowel obstruction or inability to eat orally
3. Refractory cachexia (ECOG performance status 3-4, bed-bound, cachexia management not clinically appropriate per treating oncologist)
4. Uncontrolled diabetes mellitus (HbA1c >9%)
5. End-stage renal disease requiring dialysis
6. Severe heart failure (NYHA class IV)
7. Active psychiatric illness precluding participation
8. Cognitive impairment preventing informed consent
9. Already enrolled in another nutritional intervention trial
10. Unable to attend baseline and 8-week in-person assessments

DATA COLLECTION PROCEDURE:

Randomization:
After obtaining informed consent and completing baseline assessment, patients will be randomly allocated 1:1 to intervention or control arm using computer-generated randomization with variable block sizes (4-6). Randomization will be stratified by cancer type (gastrointestinal vs. non-gastrointestinal) and conducted by statistician not involved in patient care.

Baseline Assessment (Week 0 - Both Groups):

1. Demographic data: age, gender, education, residence (urban/rural), household income
2. Clinical data: cancer type, stage, current treatment, comorbidities, ECOG performance status
3. Anthropometric measurements: weight (calibrated digital scale ±0.1kg), height, BMI
4. Mid-upper arm circumference (MUAC): Measured on non-dominant arm at midpoint between acromion and olecranon processes using non-stretchable tape (recorded to nearest 0.1 cm)
5. Nutritional assessment: Two non-consecutive 24-hour dietary recalls (one weekday and one weekend day, conducted on separate occasions within same week), Food Frequency Questionnaire assessing usual intake patterns over past month, Patient-Generated Subjective Global Assessment (PG-SGA).
6. Laboratory investigations: serum albumin, hemoglobin, C-reactive protein
7. Quality of life assessment: EORTC QLQ-C30 questionnaire (Urdu version)
8. Technology literacy assessment (intervention arm only)

Intervention Arm - Telemedicine Nutritional Counselling:

Week 0: In-person baseline assessment + telemedicine platform training (30 minutes)

- Week 2: Video consultation (20-30 minutes)
- Week 4: Video consultation (20-30 minutes)
- Week 6: In-person mid-assessment + video consultation (30 minutes)
- Week 8: Video consultation (20-30 minutes)
- Week 10: Video consultation (20-30 minutes)
- Week 12: In-person final assessment (45 minutes)
- Total: 5 video consultations + 2 in-person visits (baseline and final)

Video Consultation Content:

1. Dietary intake review (patient verbal recall of past week)
2. Weight monitoring (self-reported home weight measurement)
3. Symptom assessment (appetite, nausea, taste changes, early satiety)
4. Nutritional counseling tailored to symptoms and preferences

5. Education on high-protein, high-energy Pakistani foods (daal, eggs, yogurt, chicken, nuts)
6. Culturally-adapted meal planning
7. Family involvement and caregiver education
8. Collaborative goal-setting for upcoming week

Control Arm - Standard Nutritional Counseling:

Week 0: In-person baseline assessment + nutritional counselling (45 minutes)

- **Week 2:** In-person nutritional counselling (30 minutes)
- **Week 4:** In-person nutritional counselling (30 minutes)
- **Week 6:** In-person mid-assessment + nutritional counselling (30 minutes)
- **Week 8:** In-person nutritional counselling (30 minutes)
- **Week 10:** In-person nutritional counselling (30 minutes)
- **Week 12:** In-person final assessment + nutritional counselling (45 minutes)
- **Total:** 7 in-person visits
- Same counselling content as intervention arm, delivered in-person bi-weekly

Both Groups Receive:

- Individualized nutrition care plans with energy target ≥25 kcal/kg/day and protein target ≥1.0 g/kg/day
- Culturally-adapted meal plans incorporating traditional Pakistani foods
- Supplementation recommendations for vitamin D, vitamin A, zinc, iron deficiencies
- Oral nutritional supplements if unable to meet >75% of needs through regular food
- Contact number for urgent nutritional questions

Mid-Point Assessment (Week 6 - Both Groups):

1. Weight measurement
2. 24-hour dietary recall
3. PG-SGA score
4. Brief symptom assessment

Final Assessment (Week 12 - Both Groups):

1. Weight, height, BMI
2. 24-hour dietary recall
3. PG-SGA score
4. EORTC QLQ-C30 questionnaire
5. Laboratory investigations (albumin, hemoglobin, CRP)
6. Session attendance record
7. Patient satisfaction survey (5-point Likert scales)

8. Cost questionnaire (transportation, time, out-of-pocket expenses)

Study Variables:

Independent Variable:
Type of nutritional counseling delivery (telemedicine vs. standard in-person)

Primary Dependent Variable:
Body weight change (kilograms) from baseline to Week 12

Secondary Dependent Variables:

- Proportion achieving adequate energy intake
- Proportion achieving adequate protein intake
- PG-SGA score change
- Quality of life score change
- Session attendance rate
- Patient satisfaction scores
- Cost per kilogram weight gained

Confounding Variables (controlled through randomization and exclusion criteria):

- Cancer type and stage
- Treatment modality
- Baseline nutritional status
- Performance status
- Comorbidities

Telemedicine Infrastructure and Implementation:

Video consultations will be conducted using WhatsApp Video Call as the primary platform, given its universal accessibility, familiarity, and low bandwidth requirements in Pakistan. Zoom or Microsoft Teams will be offered as alternatives for patients who prefer these platforms or do not use WhatsApp. All platforms provide end-to-end encrypted communication ensuring patient confidentiality.

Implementation Details:

- Dietitians will conduct video consultations from the Department of Medical Oncology Nutrition Clinic, King Edward Medical University
- Dedicated workspace with computer/laptop, high-speed internet, and privacy ensured
- Patients will join from home or any convenient private location with internet access

- Study coordinator will provide technical support and troubleshooting
- Backup contact number available for connection issues
- Session scheduling coordinated via phone call or WhatsApp message 24-48 hours in advance
- Sessions recorded (with consent) for quality assurance and protocol adherence monitoring

Patient Technology Requirements:

- Smartphone or tablet with camera and microphone
- WhatsApp application installed (or web browser for Zoom/Teams)
- Stable internet connection (mobile data or Wi-Fi)
- Quiet, private space for consultation
- Optional: family member present for support

DATA ANALYSIS PRODECURE:

Software: SPSS version 26.0 (IBM Corp., Armonk, NY, USA)

Descriptive Statistics:

- Continuous variables: Mean ± standard deviation (if normally distributed) or median with interquartile range (if non-normally distributed)
- Categorical variables: Frequency and percentages
- Normality assessed using Shapiro-Wilk test and visual inspection (histograms, Q-Q plots)

Inferential Statistics:

Primary Outcome (Body Weight Change):

- Primary analysis: Independent samples t-test (if data normally distributed) or Mann-Whitney U test (if non-normally distributed)
- Adjusted analysis: Analysis of Covariance (ANCOVA) adjusting for baseline weight, cancer type (GI vs non-GI), baseline ECOG status, and treatment changes during study
- 95% confidence intervals for mean difference
- Cohen's d for effect size calculation
- Sensitivity analysis: Per-protocol analysis excluding patients with major treatment interruptions (>2 weeks) or hospitalizations >7 days

Secondary Outcomes:

- Proportions (adequate intake): Chi-square test or Fisher's exact test
- Continuous variables (PG-SGA, QoL): Independent samples t-test or Mann-Whitney U test as appropriate
- Repeated measures: Paired t-test within groups, independent t-test between groups
- Session adherence: Independent samples t-test for mean attendance rates
- Satisfaction scores: Mann-Whitney U test
- Cost analysis: Independent samples t-test for mean cost per kg gained

Adjusted Analysis:

- Analysis of Covariance (ANCOVA) adjusting for baseline weight, cancer type, and stratification factors

Missing Data:

- Multiple imputation using chained equations for <20% missing data
- Complete case analysis as sensitivity analysis
- Intention-to-treat analysis (all randomized patients analysed in allocated groups)

- Per-protocol analysis (patients completing ≥75% sessions) as secondary analysis

Level of Significance: p-value <0.05 (two-tailed) considered statistically significant

Subgroup Analyses (Exploratory):

- By cancer type (gastrointestinal vs. non-gastrointestinal)
- By baseline cachexia severity (3-5% vs. >5% weight loss)
- By gender
- By urban vs. rural residence

OUTCOME & UTILIZATION:

Expected Outcomes:

1. Telemedicine-delivered nutritional counselling will be non-inferior to standard in-person counselling for body weight gain at 12 weeks, with both groups expected to achieve mean weight gain of 2-3 kg due to equal counselling frequency.
2. Telemedicine group will demonstrate superior outcomes in: (a) higher session adherence rates due to reduced travel burden, (b) lower patient out-of-pocket costs, (c) higher patient satisfaction, and (d) greater accessibility for rural patients
3. Higher proportions of patients in the telemedicine group will achieve adequate energy and protein intake targets.
4. Improved nutritional status (PG-SGA scores) and quality of life in the telemedicine group.
5. High patient adherence (≥70%) and satisfaction with telemedicine delivery.
6. Lower cost per kilogram weight gained with telemedicine delivery due to reduced transportation and time costs.

Clinical Utilization:

- If positive, study will provide first evidence from Pakistan/South Asia supporting telemedicine-based nutritional care for cancer cachexia.
- Results will inform development of scalable telemedicine nutritional services in Pakistani cancer centres, particularly benefiting rural and underserved populations.
- Findings will guide resource allocation and health policy decisions regarding telemedicine infrastructure investment.
- Evidence will support training programs for dietitians in telemedicine service delivery.

Research Utilization:

- Pilot data will justify larger multi-centre randomized controlled trial across Pakistan.
- Methodology can be adapted for other chronic diseases with nutritional challenges (chronic kidney disease, heart failure, COPD).

- Cost-effectiveness data will inform health economics research and policy.
- Publication in international journals will contribute to global evidence on telemedicine nutrition interventions in low-middle-income countries.

Public Health Impact:

- Improved access to specialized nutritional care for cancer patients regardless of geography.
- Reduced financial burden on patients and families through decreased travel costs.
- Enhanced quality of life and treatment tolerance, potentially improving cancer survival outcomes.
- Model for scaling telemedicine services across Pakistan's healthcare system.

SCHEDULE/PHASING:

Phase	Activity	Duration	Timeline
Phase 1: Preparation	IRB/Ethics approval submission	2 weeks	January 2026 (Weeks 1-2)
	Staff hiring and training	2 weeks	January 2026 (Weeks 3-4)
	Telemedicine platform setup and testing	1 week	January 2026 (Week 4)
Phase 2: Enrolment	Patient screening and recruitment (80 total)	16 weeks	February 2026 - May 2026
	Target: 20 patients/month, 5 patients/week		
Phase 3: Intervention	12-week intervention delivery (overlapping)	28 weeks	February 2026 - August 2026
	Bi-weekly telemedicine sessions (intervention arm)		
	Bi-weekly in-person sessions (control arm)		
Phase 4: Data Collection	Week 6 mid-assessments	Ongoing	March - September 2026
	Week 12 final assessments	Ongoing	May - October 2026
	Last patient completes final assessment		End of October 2026
Phase 5: Analysis	Data entry and cleaning	3 weeks	November 2026 (Weeks 1-3)
	Statistical analysis	1 week	November 2026 (Week 4)
Phase 6: Reporting	Manuscript writing and submission	4 weeks	December 2026

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DATA COLLECTION INSTRUMENT:

PATIENT BASELINE DATA COLLECTION FORM

Study ID: _____ **Date:** /_____ **Group:** ☐ Telemedicine ☐ Standard Care

Section A: Demographics

1. Age: _____ years
2. Gender: ☐ Male ☐ Female
3. Education: ☐ Illiterate ☐ Primary ☐ Secondary ☐ Higher
4. Residence: ☐ Urban ☐ Rural
5. Monthly household income: ☐ <30,000 PKR ☐ 30,000-60,000 ☐ >60,000

Section B: Clinical Information

6. Cancer type: _____
7. Cancer stage: ☐ I ☐ II ☐ III ☐ IV
8. Current treatment: ☐ Chemotherapy ☐ Radiation ☐ Targeted ☐ Immunotherapy
9. ECOG Performance Status: ☐ 0 ☐ 1 ☐ 2
10. Comorbidities: ☐ Diabetes ☐ Hypertension ☐ heart disease ☐ Other: _____

Section C: Anthropometrics

11. Weight: _____ kg
12. Height: _____ cm
13. BMI: _____ kg/m²
14. Weight loss in past 3 months: _____ kg (_____%)
15. Weight loss in past 6 months: _____ kg (_____%)

Section D: Nutritional Assessment

16. PG-SGA Score: _____
17. Category: ☐ Well-nourished ☐ Moderately malnourished ☐ Severely malnourished

24-Hour Dietary Recall:

- Total Energy: _____ kcal/day (_____ kcal/kg/day)
- Total Protein: _____ g/day (_____ g/kg/day)
- Adequate energy intake (≥25 kcal/kg/day): ☐ Yes ☐ No
- Adequate protein intake (≥1 g/kg/day): ☐ Yes ☐ No

Section E: Laboratory Investigations

18. Serum Albumin: _____ g/dL
19. Hemoglobin: _____ g/dL
20. C-Reactive Protein: _____ mg/L

Section F: Quality of Life (EORTC QLQ-C30)

Global Health Status Score: _____/100

PATIENT FOLLOW-UP DATA COLLECTION FORM

Study ID: _____ **Visit:** ☐ Week 6 ☐ Week 12 **Date:** //_____

Section G: Anthropometrics

21. Weight: _____ kg
22. Change from baseline: _____ kg (_____%)

Section H: Nutritional Assessment

23. PG-SGA Score: _____

24-Hour Dietary Recall:

- Total Energy: _____ kcal/day (_____ kcal/kg/day)
- Total Protein: _____ g/day (_____ g/kg/day)
- Adequate energy intake: ☐ Yes ☐ No
- Adequate protein intake: ☐ Yes ☐ No

Section I: Laboratory (Week 12 Only)

24. Serum Albumin: _____ g/dL
25. Hemoglobin: _____ g/dL
26. C-Reactive Protein: _____ mg/L

Section J: Quality of Life (Week 12 Only)

Global Health Status Score: _____/100

Section K: Adherence

27. Scheduled sessions: _____
28. Attended sessions: _____
29. Adherence rate: _____%

Section L: Patient Satisfaction (Week 12 Only)

Rate the following (1=Very Dissatisfied to 5=Very Satisfied):

30. Overall satisfaction with nutritional counseling: 1 2 3 4 5
31. Convenience of session scheduling: 1 2 3 4 5
32. Quality of dietary advice received: 1 2 3 4 5
33. Helpfulness in managing eating difficulties: 1 2 3 4 5
34. Would recommend this service to others: ☐ Yes ☐ No

Investigator Signature: _____ Date: //_____

NOTE FOR BOS MEMBERS:

Title: Telemedicine-Delivered Nutritional Counseling versus Standard Care for Cancer Cachexia in Pakistani Cancer Patients: A Pilot Randomized Controlled Trial (TELE-CACHE Trial)

Name: _____ Signature: _____

A. VALIDATED INSTRUMENTS TO BE USED:

1. Patient-Generated Subjective Global Assessment (PG-SGA)

Description: Gold standard validated nutritional assessment tool for cancer patients, comprising patient-completed section (weight history, food intake, symptoms, activities) and professional-completed section (disease, metabolic stress, physical examination).

Scoring: 0-35 points total

- 0-1: Well-nourished
- 2-8: Moderately malnourished
- ≥9: Severely malnourished

Validated for: Cancer patients globally, including diverse populations(1)

Access/Download:

- Official website: https://pt-global.org/
- Free for clinical use with registration
- Available in multiple languages including Urdu

Reference:

1. Ottery FD. Definition of standardized nutritional assessment and interventional pathways in oncology. Nutrition. 1996 Jan;12(1 Suppl):S15-9.

Permission: Public domain for clinical and research use

2. EORTC QLQ-C30 (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30)

Description: Cancer-specific quality of life questionnaire with 30 items measuring:

- Global health status/QoL (2 items)
- Functional scales: Physical (5), Role (2), Emotional (4), Cognitive (2), Social (2)
- Symptom scales: Fatigue (3), Nausea/vomiting (2), Pain (2), Dyspnea (1), Insomnia (1), Appetite loss (1), Constipation (1), Diarrhea (1), Financial difficulties (1)

Scoring: Raw scores linearly transformed to 0-100 scale

- Higher scores = better functioning (functional scales)
- Higher scores = worse symptoms (symptom scales)

Validated for: Cancer patients worldwide, extensively validated in Pakistani population(2,3)

Urdu Version: Available and validated

Access/Download:

- Official website: https://qol.eortc.org/questionnaire/eortc-qlq-c30/
- Registration required (free for academic research)
- License agreement needed

Reference: 2. Aaronson NK, Ahmedzai S, Bergman B, Bullinger M, Cull A, Duez NJ, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst. 1993 Mar 3;85(5):365-76.

3. Qayyum A, Zafar W, Noor S, Lal S, Zahid N, Fatima I. Translation and validation of EORTC QLQ C-30 in Pakistani cancer patients. Asian Pac J Cancer Prev. 2014;15(11):4689-93.

License: Free for non-profit academic research with proper citation

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3. Eastern Cooperative Oncology Group (ECOG) Performance Status Scale

Description: Simple validated tool to assess functional status/disease burden

Scoring:

- Grade 0: Fully active, able to carry on all pre-disease activities
- Grade 1: Restricted in physically strenuous activity but ambulatory
- Grade 2: Ambulatory and capable of all self-care but unable to work; up >50% of waking hours
- Grade 3: Capable of only limited self-care; confined to bed/chair >50% of waking hours
- Grade 4: Completely disabled; cannot carry on any self-care; totally confined to bed/chair

Validated for: Cancer patients globally(4)

Access: Public domain, freely available

Reference: 4. Oken MM, Creech RH, Tormey DC, Horton J, Davis TE, McFadden ET, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982 Dec;5(6):649-55.

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4. 24-Hour Dietary Recall

Description: Standardized method where patient reports all food and beverages consumed in previous 24 hours; dietitian records and analyzes using food composition database.

Validated Method: Multiple-pass 24-hour recall method developed by USDA(5)

- Quick list
- Forgotten foods probe
- Time and occasion
- Detail cycle
- Final probe

Analysis Software:

- **NutriSurvey** (free): https://www.nutrisurvey.de/
- **Pakistani Food Composition Database** from National Institute of Health, Islamabad

- Alternative: **USDA FoodData Central** adapted for Pakistani foods

Reference: 5. Moshfegh AJ, Rhodes DG, Baer DJ, Murayi T, Clemens JC, Rumpler WV, et al. The US Department of Agriculture Automated Multiple-Pass Method reduces bias in the collection of energy intakes. Am J Clin Nutr. 2008 Aug;88(2):324-32.

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5. Patient Satisfaction Questionnaire (Modified from CSQ-8)

Description: Adapted from validated Client Satisfaction Questionnaire-8 for nutritional counseling

8 Items rated on 4-point Likert scale:

1. How would you rate the quality of nutritional service you received?
2. Did you get the kind of nutritional service you wanted?
3. To what extent has nutritional counseling met your needs?
4. If a friend were in need of similar help, would you recommend this service?
5. How satisfied are you with the amount of help you received?
6. Have the nutritional services helped you to improve your eating?
7. Overall, how satisfied are you with the service you received?
8. If you were to seek help again, would you come back to this program?

Scoring: Sum of 8 items (range 8-32); higher scores = greater satisfaction

Original CSQ-8 Reference: 6. Larsen DL, Attkisson CC, Hargreaves WA, Nguyen TD. Assessment of client/patient satisfaction: development of a general scale. Eval Program Plann. 1979;2(3):197-207.

Validation: CSQ-8 validated across healthcare settings; adapted versions used in nutrition studies (7)

7. Attkisson CC, Zwick R. The Client Satisfaction Questionnaire: psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program Plann. 1982;5(3):233-7.

B. STUDY-SPECIFIC DATA COLLECTION FORMS:

FORM 1: PATIENT SCREENING & ELIGIBILITY FORM

Date of Screening: /_____ Screener Initials: _____

Patient Hospital Number: _____ Screening Number: _____

Inclusion Criteria Check:

Criteria	Yes	No
1. Age ≥18 years	☐	☐
2. Histologically confirmed solid tumor	☐	☐
3. Weight loss ≥3% (3 mo) OR ≥5% (6 mo)	☐	☐
4. Receiving/planned cancer treatment	☐	☐
5. ECOG performance status 0-2	☐	☐
6. Has smartphone with video capability	☐	☐
7. Has internet connectivity	☐	☐
8. Speaks Urdu or English	☐	☐
9. Able to provide informed consent	☐	☐

Exclusion Criteria Check:

Criteria	Yes	No
1. Severe dysphagia/tube feeding	☐	☐
2. Complete bowel obstruction	☐	☐
3. Refractory cachexia (ECOG 3-4)	☐	☐
4. Uncontrolled diabetes (HbA1c >9%)	☐	☐
5. End-stage renal disease on dialysis	☐	☐
6. Severe heart failure (NYHA IV)	☐	☐
7. Active psychiatric illness	☐	☐
8. Cognitive impairment	☐	☐
9. Enrolled in other nutrition trial	☐	☐
10. Cannot attend in-person visits	☐	☐

Eligible for Study: ☐ Yes ☐ No

If no, reason: _____

If yes, proceed to informed consent

Investigator Signature: _____ Date: /_____

FORM 2A: PATIENT INFORMED CONSENT (ENGLISH)

I agree to participate in the study **"Telemedicine-Delivered Nutritional Counselling versus Standard Care for Cancer Cachexia in Pakistani Cancer Patients: A Pilot Randomized Controlled Trial (TELE-CACHE Trial)"**

The doctor has informed me all the details of the study in detail. I have been told that the objectives of the study are to compare nutritional counselling provided through video calls (WhatsApp/Zoom/Microsoft Teams) from home versus counselling provided during hospital visits. I agree to follow the diet plan and nutritional advice given to me by the dietitian. Due to this research, doctors will be able to determine whether telemedicine nutritional counselling is as effective as standard hospital-based counselling for cancer patients with weight loss.

I understand that I will be randomly assigned (like flipping a coin) to either receive counselling through video calls or hospital visits. Both groups will receive the same nutritional advice every 2 weeks for 12 weeks. I will have my weight, arm measurements, and blood tests done at the start, middle, and end of the study. I will answer questions about my diet and quality of life.

I have also been informed in detail about possible benefits and side effects of the study. The benefits include free nutritional counselling, personalized dietary advice, regular monitoring of my nutrition status, and reimbursement for travel or mobile data costs. The risks are minimal and include minor discomfort from blood tests, time required for assessments, and possible technical difficulties with video calls (if in telemedicine group).

I understand that I am free to withdraw from the study whenever I want to and I have been told that my doctor will continue to give me all positive care even after my discontinuation of study. Furthermore, I allow my doctor or any other person authorized by my doctor to contact me at my home or through phone/WhatsApp for treatment and follow up.

I have been assured that the information provided by me will be kept confidential and will be used for research purpose only.

Patient Name: _____
NIC No: _____
Signature/Thumbprint: _____
Contact Number: _____
Date: _____ / _____ / 2026

Consent Obtained: ☐ Yes ☐ No
Study ID: _____
Group Assignment: ☐ Telemedicine ☐ Standard Care

FORM 3: BASELINE DATA COLLECTION FORM

Study ID: _____ **Enrolment Date:** /_____

Randomization Group: ☐ Intervention (Telemedicine) ☐ Control (Standard Care)

Stratification: ☐ GI Cancer ☐ Non-GI Cancer

SECTION A: DEMOGRAPHIC DATA

1. **Date of Birth:** /_____ **Age:** _____ years
2. **Gender:** ☐ Male ☐ Female ☐ Other
3. **Marital Status:** ☐ Single ☐ Married ☐ Widowed ☐ Divorced
4. **Education Level:**
   ☐ Illiterate
   ☐ Primary (Grade 1-5)
   ☐ Middle (Grade 6-8)
   ☐ Secondary (Grade 9-10)
   ☐ Higher Secondary (Grade 11-12)
   ☐ Bachelor's degree
   ☐ Master's degree or higher
5. **Occupation:** _____
6. **Residence:**
   ☐ Urban ☐ Rural
   City/Town: _____ District: _____
7. **Distance from Hospital:** _____ km
8. **Monthly Household Income:**
   ☐ <PKR 30,000
   ☐ PKR 30,000-60,000
   ☐ PKR 60,001-100,000
   ☐ >PKR 100,000
9. **Number of Household Members:** _____
10. **Primary Caregiver:** ☐ Spouse ☐ Adult Child ☐ Parent ☐ Sibling ☐ Other: _____

SECTION B: CLINICAL INFORMATION

11. **Cancer Diagnosis:** _____ **Date of Diagnosis:** //_____

12. **Cancer Type (Primary Site):**
    - ☐ Head & Neck
    - ☐ Esophageal
    - ☐ Gastric
    - ☐ Colorectal
    - ☐ Pancreatic
    - ☐ Hepatobiliary
    - ☐ Lung
    - ☐ Breast
    - ☐ Gynecological
    - ☐ Genitourinary
    - ☐ Other: _____
13. **Cancer Stage:** ☐ I ☐ II ☐ III ☐ IV
14. **Current Anti-Cancer Treatment (check all that apply):**
    - ☐ Chemotherapy (specify regimen): _____
    - ☐ Radiation therapy
    - ☐ Targeted therapy (specify): _____
    - ☐ Immunotherapy (specify): _____
    - ☐ Hormonal therapy
    - ☐ Surgery planned: ☐ Yes ☐ No
15. **Treatment Start Date: //**_____
16. **ECOG Performance Status (See validated scale):**
    - ☐ Grade 0 (Fully active)
    - ☐ Grade 1 (Restricted strenuous activity)
    - ☐ Grade 2 (Ambulatory, >50% waking hours up)
17. **Comorbidities (check all that apply):**
    - ☐ Diabetes mellitus (Type: ___ HbA1c: ____ %)
    - ☐ Hypertension
    - ☐ Ischemic heart disease
    - ☐ COPD/Asthma
    - ☐ Chronic kidney disease (Stage: ___)
    - ☐ Liver disease
    - ☐ Other: _____
18. **Current Medications:** _____

SECTION C: ANTHROPOMETRIC MEASUREMENTS

19. **Weight:** _____ kg (calibrated scale, light clothing, no shoes)
20. **Height:** _____ cm (stadiometer)

21. **BMI:** _____ kg/m² (calculated: weight/height²)

BMI Category:
☐ Underweight (<18.5)
☐ Normal (18.5-24.9)
☐ Overweight (25-29.9)
☐ Obese (≥30)

22. **Weight History:**

Time Period	Weight (kg)	Weight Loss (kg)	Weight Loss (%)
Current		-	-
1 month ago			
3 months ago			
6 months ago			
Usual adult weight			

23. **Cachexia Classification:**
☐ Pre-cachexia (weight loss <5% in 6 months)
☐ Cachexia (weight loss ≥5% in 6 months OR BMI <20 + >2% loss)
☐ Refractory cachexia (ECOG 3-4, very advanced)

SECTION D: NUTRITIONAL ASSESSMENT

D1. Patient-Generated Subjective Global Assessment (PG-SGA)

Instructions: Administer complete PG-SGA tool (available at https://pt-global.org/)

PG-SGA Total Score: _____ (0-35)

PG-SGA Category:
☐ Well-nourished (0-1)
☐ Moderately malnourished (2-8)
☐ Severely malnourished (≥9)

Triage Recommendation:
☐ No intervention required (0-1)
☐ Education by dietitian (2-3)
☐ Intervention by dietitian + nurse/physician (4-8)
☐ Urgent symptom management (≥9)

D2. 24-Hour Dietary Recall

Instructions: Use USDA 5-step multiple-pass method

Date of Recall: //_____ Day of Week: ☐ Weekday ☐ Weekend

Recall Period: Yesterday from midnight to midnight

Interview Start Time: _____ End Time: _____

Quick List (Step 1): Record all foods/beverages consumed

[Continue with full 24-hr recall protocol - detailed food/beverage list, amounts, preparation methods, timing]

Dietary Analysis Results (using Pakistani Food Composition Database):

Nutrient	Amount/Day	Per kg Body Weight	Adequate?
Total Energy	_____ kcal	_____ kcal/kg	☐ Yes (≥25) ☐ No
Protein	_____ g	_____ g/kg	☐ Yes (≥1.0) ☐ No
Carbohydrate	_____ g		
Fat	_____ g		
Fiber	_____ g		

Micronutrients:
Calcium: _____ mg | Iron: _____ mg | Vitamin D: _____ IU | Vitamin A: _____ IU

Dietary Adequacy:
☐ Adequate energy intake (≥25 kcal/kg/day)
☐ Adequate protein intake (≥1.0 g/kg/day)
☐ Inadequate energy intake (<25 kcal/kg/day)
☐ Inadequate protein intake (<1.0 g/kg/day)

D3. Dietary Symptoms Assessment

In the past week, have you experienced: (Rate severity: 0=None, 1=Mild, 2=Moderate, 3=Severe)

Symptom	Severity (0-3)
Loss of appetite	
Early satiety (feeling full quickly)	
Nausea	
Vomiting	
Taste changes	
Dry mouth	
Difficulty swallowing	
Diarrhea	
Constipation	
Mouth sores/pain	
Fatigue affecting eating	

Impact on Food Intake:
☐ No change
☐ Eating <50% of usual amount
☐ Eating 50-75% of usual amount
☐ Eating >75% of usual amount

SECTION E: LABORATORY INVESTIGATIONS

Blood Draw Date: //_____ Fasting: ☐ Yes ☐ No

24. **Serum Albumin:** _____ g/dL (Normal: 3.5-5.0)
25. **Hemoglobin:** _____ g/dL (Normal: M 13-17, F 12-15)
26. **C-Reactive Protein (CRP):** _____ mg/L (Normal: <5)
27. **HbA1c** (if diabetic): _____ %
28. **Serum Creatinine:** _____ mg/dL
29. **Other relevant labs:**
    Total Protein: _____ g/dL
    Lymphocyte count: _____ cells/µL
    Transferrin: _____ mg/dL (if available)

SECTION F: QUALITY OF LIFE ASSESSMENT

EORTC QLQ-C30 Questionnaire

Instructions: Administer complete EORTC QLQ-C30 (Urdu version)
Available from: https://qol.eortc.org/ (license required)

Raw Scores Recorded: [Use official scoring sheet]

Computed Scores (0-100 scale):

Scale	Score
Global Health Status/QoL	_____
Functional Scales:	
Physical Functioning	_____
Role Functioning	_____
Emotional Functioning	_____
Cognitive Functioning	_____
Social Functioning	_____
Symptom Scales:	
Fatigue	_____
Nausea/Vomiting	_____
Pain	_____
Dyspnea	_____
Insomnia	_____
Appetite Loss	_____
Constipation	_____
Diarrhea	_____
Financial Difficulties	_____

Note: Higher scores = better for functional scales; higher scores = worse for symptom scales

SECTION G: TECHNOLOGY LITERACY (Intervention Arm Only)

30. **Smartphone Ownership:**
    - ☐ Personal smartphone
    - ☐ Family member's smartphone (specify: _____)
    - ☐ Borrowed smartphone
31. **Smartphone Type:** ☐ Android ☐ iPhone ☐ Other: _____
32. **Internet Access:**
    - ☐ Home Wi-Fi
    - ☐ Mobile data
    - ☐ Both
    - ☐ Public Wi-Fi only
33. **Prior Video Call Experience:**
    - ☐ Never
    - ☐ Rarely (1-2 times)
    - ☐ Occasionally (few times/month)
    - ☐ Frequently (weekly or more)

34. **Apps Used Previously:** ☐ WhatsApp ☐ Zoom ☐ Microsoft Teams ☐ IMO ☐ Other: _____
35. **Confidence in Using Video Calls:** (1=Not confident to 5=Very confident)
    1 2 3 4 5
36. **Language Preference for Counseling:**
    ☐ Urdu
    ☐ English
    ☐ Punjabi
    ☐ Other: _____

SECTION H: BASELINE COSTS

37. **Transportation Cost for Today's Visit:** PKR _____
38. **Time Spent (Total):**
    Travel time: _____ hours
    Waiting time: _____ hours
    Consultation time: _____ hours
39. **Accompanying Person:** ☐ Yes (specify: _____) ☐ No
    If yes, lost work time: _____ hours

Form Completed By: _____ **Designation:** _____

Date: //_____ **Time:** _____

Principal Investigator Review: _____ **Date:** //_____

FORM 4: MID-POINT ASSESSMENT (WEEK 6)

Study ID: _____ **Visit Date:** //_____ **Group:** ☐ Intervention ☐ Control

Weight Measurement

Weight: _____ kg
Change from Baseline: _____ kg (_____%)
BMI: _____ kg/m²

Mid-Upper Arm Circumference (MUAC):

Non-dominant arm measured: ☐ Right ☐ Left

MUAC: _____ cm (to nearest 0.1 cm)

Measured by: _____ Date: _____

24-Hour Dietary Recall (Brief assessment)

Total Energy: _____ kcal/day (_____ kcal/kg/day)
Total Protein: _____ g/day (_____ g/kg/day)
Adequate energy: ☐ Yes ☐ No
Adequate protein: ☐ Yes ☐ No

PG-SGA Score: _____

Symptom Assessment (Rate severity 0-3)

Appetite loss: ___ Nausea: ___ Early satiety: ___ Fatigue: ___

Treatment Changes Since Last Assessment:

- Treatment status: ☐ No change ☐ Completed ☐ Interrupted ☐ Changed regimen
- New chemotherapy regimen: ☐ Yes (specify: _____) ☐ No
- Dose modifications: ☐ Reduction ☐ Delay ☐ None
- Hospitalizations: ☐ Yes (dates: _____ reason: _____) ☐ No
- New complications: ☐ Yes (specify: _____) ☐ No

Session Attendance Record

Scheduled sessions (since baseline): _____
Attended sessions: _____
Adherence rate: _____%

Reasons for missed sessions: _____

Adverse Events: ☐ None ☐ Yes (describe): _____

Assessor Signature: _____ **Date:** //_____

FORM 5: FINAL ASSESSMENT (WEEK 12)

Study ID: _____ **Visit Date:** //_____

[Repeat all sections from Baseline Form including:]

- Complete anthropometric measurements
- Complete 24-hour dietary recall
- Complete PG-SGA
- Laboratory investigations
- Complete EORTC QLQ-C30
- Session attendance summary
- Final costs assessment

FORM 6: PATIENT SATISFACTION SURVEY (Week 12)

Adapted from Client Satisfaction Questionnaire-8 (CSQ-8)

Instructions: Please circle the answer that best describes your feelings about the nutritional counseling service you received.

1. How would you rate the quality of nutritional service you received?
4 = Excellent | 3 = Good | 2 = Fair | 1 = Poor

2. Did you get the kind of nutritional service you wanted?
4 = Yes, definitely | 3 = Yes, generally | 2 = No, not really | 1 = No, definitely not

3. To what extent has nutritional counseling met your needs?
4 = Almost all needs met | 3 = Most needs met | 2 = Only few needs met | 1 = None of my needs met

4. If a friend were in need of similar help, would you recommend this service?
4 = Yes, definitely | 3 = Yes, I think so | 2 = No, I don't think so | 1 = No, definitely not

5. How satisfied are you with the amount of help you received?
4 = Very satisfied | 3 = Mostly satisfied | 2 = Indifferent/Mildly dissatisfied | 1 = Quite dissatisfied

6. Have the nutritional services helped you to improve your eating?
4 = Yes, they helped a great deal | 3 = Yes, helped somewhat | 2 = No, not really | 1 = No, made things worse

7. Overall, how satisfied are you with the service you received?
4 = Very satisfied | 3 = Mostly satisfied | 2 = Indifferent/Mildly dissatisfied | 1 = Quite dissatisfied

8. If you were to seek help again, would you come back to this program?
4 = Yes, definitely | 3 = Yes, I think so | 2 = No, I don't think so | 1 = No, definitely not

Total Satisfaction Score: _____ (Range: 8-32, higher = more satisfied)

Additional Questions (Telemedicine Group Only):

9. How convenient was video counseling compared to hospital visits?
Much more convenient | Somewhat more | About the same | Less convenient

10. Did you experience any technical difficulties?
☐ Never ☐ Rarely ☐ Sometimes ☐ Often

11. Would you prefer to continue telemedicine counseling after the study?
☐ Yes ☐ No ☐ Undecided

12. What did you like most about telemedicine counseling?

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13. What problems did you face with telemedicine?

Patient Signature: _____ **Date:** //_____

Sanctity of data - Affidavit

I, Mr/Ms_____S/o_____
Student of_____
working in _____
Under Supervisorship of _____

Hereby undertake to abide by the following rules

1. **That the data collected during my attachment at King Edward Medical University (to be call KEMU here after) for which authorization is being granted by the Institutional Review Board (to be called IRB here after) of KEMU for which I have submitted my synopsis titled_____ _____ shall be used exclusively for the**

purpose of "not for profit" research and will not use for any other purpose what so ever. Any financial gain or patent originating from this research shall be equally shared with KEMU.

2. **The data collected shall be strictly limited to the parameters defined in my synopsis titled _____ _____**
3. **That the identity of patients (cases) shall not be revealed.**
4. **That prior approval for research project (synopsis) has been obtained from the Institutional Review Board/ Ethical Committee of my parent institution.**
5. **That appropriate recognition and acknowledgement shall be given to KEMU in the publication of the paper/papers or any other medium of communication what so ever, if it utilizes the data/ graphs/tables/pictures collected from the aforementioned research, furthermore, in any subsequent publication or any other medium of communication what so ever, if it utilizes the above mentioned data/graphs/tables/pictures with proper acknowledgement (as mentioned below) and with prior intimation and authorization of IRB of KEMU.**
6. **The aforementioned acknowledgement/recognition shall be mutually decided between the principal investigator (myself) and the in charge of the unit concerned at KEMU, under intimation to the IRB of KEMU.**

I have read all the clauses of the above written agreement and hereby agree to be legally bound to this agreement in letter and spirit. I also understand that if I am in breach of this contract; I shall lose the right to the data/publication/graphs/tables collected/published (stored in any form physical/electronic) thereof. In addition, KEMU will reserve the right to initiate proceedings against me at any/all for a deemed appropriate. Research Supervisor (as shown below) shall stand witness and guarantor of this agreement and would be equally liable in case of breech of agreement.

Signature (Principal Investigator)
NIC No._____

Signature of Supervisor
NIC No._____

Proforma for Evaluation of Research Synopsis

Board of Studies

NOTE: (It should be filled in by All Members of BOS individually)

Title:_____

_____

_____

A. Must fulfill all of the following.

Sr.No.	Essential Criterion	No	Yes
1.	According to prescribed format		✓
2.	Principal Investigator and Co investigator mentioned		✓
3.	Consent form given		✓
4.	Proforma for data collection given		✓
5.	Follow up proforma given		✓
6.	Non-compliance with previous research protocol	✓	
7.	Repitition of Study	✓	

B. Kindly evaluate this research proposal and grade the research proposal against each item. Must get at least 1 in all sections to qualify. Please check the appropriate box.

Sr. No.	Criterion	Grading					
1.	Novelty of research idea	0	1	2	3	4	5
2.	Potential for capacity building (Skills)	0	1	2	3	4	5
3.	Multidisciplinary	0	1	2	3	4	5
4.	Contribution of research topic towards public benefit	0	1	2	3	4	5
5.	Contribution of research topic towards medical knowledge	0	1	2	3	4	5

Total Score	**25**	**Score Obtain**	

Name:_____ Signature: _____

List of Required Documents for Approval of

Institutional Review Board

- **Informed Consent Form in English and Urdu**
- **Subject Recruitment Procedure**
  (e.g OPD, Indoor, Advertisement)
- **Investigator's Brochure and Available Safety**
  Information for Patient
  (Please devise patient information in Urdu detailing the complications, if any, and benefits of the device/ devices and comparison with conventional technique)
- **Investigator's Curriculum Vitae detailing qualification**
- **Sanctity of Data form - Affidavit duly filled in and signed**
- **Detailed Visit Forms**
  (Please make Separate Proformas for every visit. Keeping in Mind Inclusion and Exclusion Criteria)
- **Minutes of Board Of Studies / Approval of BOS**
- **Proforma for Evaluation of Research Synopsis filled in individually by members of the Board of Study**
- **Soft Copy of Synopsis along with soft copy of articles of all references submit in Research Center on CD.**